U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

INTERAGENCY AUTISM COORDINATING COMMITTEE

FULL COMMITTEE MEETING

TUESDAY, DECEMBER 18, 2012

The Full Committee met via webinar at 10:00 a.m., Eastern Standard Time, Thomas Insel, Chair, presiding.

PRESENT:

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

SUSAN DANIELS, Ph.D., *Executive Secretary*, Office of Autism Research Coordination, National Institute of Mental Health (NIMH)

IDIL ABDULL, Somali American Autism Foundation

JAMES BALL, Ed.D., BCBA-D, JB Autism Consulting

ANSHU BATRA, M.D., Our Special Kids

JAMES BATTEY, M.D., Ph.D., National Institute on Deafness and Other Communication Disorders (NIDCD)

LINDA BIRNBAUM, Ph.D., National Institute of Environmental Health Sciences (NIEHS)

COLEEN BOYLE, Ph.D., M.S. Hyg., Centers for Disease Control and Prevention (CDC)

PRESENT(continued):

NOAH BRITTON, M.A., Bunker Hill Community College

SALLY BURTON-HOYLE, Ed.D., Eastern Michigan University

MATTHEW CAREY, Ph.D., Left Brain Right Brain

JAN CRANDY, Nevada Commission on Autism Spectrum Disorders

DENISE DOUGHERTY, Ph.D., Agency for Healthcare Research and Quality (AHRQ)

TIFFANY FARCHIONE, M.D., U.S. Food and Drug Administration (FDA)

ALAN GUTTMACHER, M.D., *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD)

LAURA KAVANAGH, M.P.P., Health Resources and Services Administration (HRSA)

DONNA KIMBARK, Ph.D., U.S. Department of Defense (DoD)

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

CINDY LAWLER, Ph.D., National Institute of Environmental Health Sciences (NIEHS) (representing Linda Birnbaum, Ph.D.)

SHARON LEWIS, Administration on Intellectual and Developmental Disabilities, Administration for Community Living (ACL)

DAVID MANDELL, Sc.D., University of Pennsylvania School of Medicine

PRESENT(continued):

JOHN O'BRIEN, M.A., Centers for Medicare & Medicaid Services (CMS)

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

CATHY RICE, Ph.D., Centers for Disease Control and Prevention (CDC) (representing Coleen Boyle, Ph.D., M.S. Hyg.)

SCOTT MICHAEL ROBERTSON, M.H.C.I., The Autistic Self Advocacy Network (ASAN)

JOHN ROBISON, Self Advocate, Parent, and Author

ALISON TEPPER SINGER, M.B.A., Autism Science Foundation (ASF)

LARRY WEXLER, Ed.D., U.S. Department of Education

TABLE OF CONTENTS

In many cases throughout the transcript, two or more speakers began to speak at one time, causing interruptions. When this occurred, it was denoted by dashed lines.

PROCEEDINGS

(10:01 a.m.)

Dr. Insel: Thank you, Amy, and thanks to everyone who's joining us, either as a speaker or in participant mode. This is the second meeting of the full IACC since its re-authorization.

Dr. Birnbaum: Hello?

Dr. Insel: Hello. Can you hear us?

Dr. Birnbaum: Hey, Tom, this is Linda, yes, I can hear you now.

Dr. Insel: Okay. Welcome.

Dr. Birnbaum: Thank you.

Dr. Insel: Let's start by just finding out who's on the line with us. I'm going to ask Susan Daniels, who's here with me in Bethesda, to go through the roster and we'll just see who's joined us at this point.

Dr. Daniels: Hi. Welcome. I will go through the roll call. Tom Insel?

Dr. Insel: Yes.

Dr. Daniels: James Battey?

Dr. Battey: Present.

Dr. Daniels: Linda Birnbaum?

Dr. Birnbaum: Here.

Dr. Daniels: Coleen Boyle?

Dr. Boyle: I'm here and I'm here until noon, and then Cathy Rice is going to represent CDC.

Dr. Daniels: Okay. Denise Dougherty? Tiffany Farchione? Alan Guttmacher?

Dr. Guttmacher: I'm here.

Dr. Daniels: Alan, great. Laura Kavanagh?

Ms. Kavanagh: Here.

Dr. Daniels: Donna Kimbark?

Dr. Kimbark: I'm here.

Dr. Daniels: Walter Koroshetz?

Dr. Koroshetz: I'm here.

Dr. Daniels: Sharon Lewis? John O'Brien? Larry Wexler? Idil Abdull? Jim Ball?

Dr. Ball: Here.

Dr. Daniels: Anshu Batra? Noah Britton?

Mr. Britton: Here I am.

Dr. Daniels: Sally Burton-Hoyle?

Dr. Burton-Hoyle: I'm present.

Dr. Daniels: Matthew Carey?

Dr. Carey: Right here.

Dr. Daniels: Dennis Choi? Dennis said that he might be a little bit late joining us. Jose Cordero? Jan Crandy?

Ms. Crandy: Here.

Dr. Daniels: Geri Dawson? Oh, she's not going to be here today. David Mandell?

Dr. Mandell: I'm here.

Dr. Daniels: Lyn Redwood?

Ms. Redwood: Here.

Dr. Daniels: Scott Robertson?

Mr. Robertson: Here.

Dr. Daniels: John Elder Robison?

Mr. Robison: I'm here.

Dr. Daniels: And Alison Singer?

Ms. Singer: I'm here.

Dr. Daniels: Okay. Great. Thank you.

Dr. Farchione: Hi. This is Tiffany Farchione. I'm here too.

Dr. Daniels: Who is this?

Dr. Farchione: Tiffany Farchione.

Dr. Daniels: Oh, okay. Thanks.

Dr. Choi: And Dennis Choi.

Dr. Daniels: Thank you. Hi.

Dr. Insel: Oh, great. Welcome. Okay. We've got a good turnout and this is a critical meeting to update the strategic plan. As you can see from the agenda, we're planning to go to 4 o'clock, if that's what it takes, although, I suspect the meeting should be able to end much sooner, depending on how much discussion we have on each of the chapters.

The format will begin with some oral public comments as well as some time to

discuss that and I also wanted to point out that we, at this point, plan to take an hour lunch break so that people can have some chance to take a break from what is going to be a very long conference call.

Would have been better, maybe, for us to meet here in Bethesda, but given the timing and given everything else going on, I think this is what we'll have to settle for; is this conference call. There will be some webinar parts to it, so you will be able to see some slides, and we want to make sure that the oral public comment is done on-screen so you'll have a chance to hear directly from anyone who had submitted public comments for presentation at the meeting.

Before we begin, I think it's really impossible not to say something about the tragic events of last Friday in Newtown, Connecticut. There's really not been very many events that have so gripped the nation in both shock and grief, especially something

like this that happens during the holiday season when most of us are thinking more about family celebrations and not about funerals for our children.

I bring it up because this shock and grief was, I think, especially acute for many members of the autism community, mostly because of reports that the perpetrator had a diagnosis of Asperger's syndrome. In fact, we still know very little about the details of his diagnosis or of any treatment, and we actually know almost nothing about his motives, but nonetheless, there have been some who have been quick to link the violence with this label somehow, as if having an autism spectrum disorder which made him appear different also made him dangerous.

I think everybody on this committee knows well that, people on the spectrum are more likely to be the victims of violence and not the perpetrators, especially of anything that is a carefully planned,

highly-organized, mass shooting like this; a rare event in any case.

And looking at comments from many of you, either on Web sites or in emails, I realized that some of you have tried to clarify the message, but I still sense there's a lot of misunderstanding in the press coverage, and even in the community, about a potential connection between autism spectrum disorders and this kind of an event.

So I thought it really behooves us to take a few minutes at the outset, before we get into the agenda, just to recognize where we're at here. I'd be interested in any of your experiences or thoughts about this and, particularly, anything that you feel that you want to do as a committee that may try to convey a different message.

So let me stop there and just open up the floor to anybody who wants to respond or have a suggestion about this. And because we can't see each other, it would be helpful

if you would also just identify yourself as you make comments on the phone.

Ms. Abdull: Hi, everyone. This is Idil Abdull. I wanted to say, if there is a way for our committee, Dr. Insel and everyone, to talk about counseling for children that become wounded, so when they leave high school. And counseling not just for the adults or young adults, but also for parents.

There's not enough times, I don't think. We're so focused on early intervention, early intervention, that we sometimes assume they're going to get rid of the autism diagnosis, whether it's Asperger's or classic autism. And I just would like us to see if we can concentrate heavily on young adults for employment, for housing, all the things we talk about, but also at counseling for parents, and for families, and caretakers, just to sort of know what's happening throughout their life.

You know, I'm not expressing this, but maybe if the mom had help, if she had a psychologist, if she had somebody she could talk to, what was happening in her son's life, maybe somebody could have intervened.

Mr. Robertson: Tom, I had some thoughts. This is Scott Robertson. I think, also, one thing that would be helpful on this is more, just, out there in terms of what you said, in terms of just things on the research base, that backup the fact that autistic people are much more likely to -- autistic adults and youth are heavily victimized.

There's research that shows that, just like people with disabilities broadly, and to, you know, get that out there so people don't misconstrue and believe, because there's already been a lot of stuff out there over the last few decades trying to paint this picture in media circles, especially whenever any incident happens where a person happens to be autistic or things in the media

kind of have statements that suggest they're autistic, people immediately get this correlation, or belief, that there is some kind of relationship between that and violence.

So even just getting out there on the research, showing that the research literature, you know, doesn't backup, you know, such constructions, or such things that are even painted by -- you know, I guess other way as well, to do clinicians on, you know, the television. I mean, that's where some of the public is getting wrong information.

Some of the stuff said on, like, CNN and things like that, it's wrong, because they don't have experts who have background in autism and neurology, kind of, on there at times to understand, you know, development disabilities, so a lot of the stuff they're saying is not right.

Ms. Lewis: Hi. This is Sharon

and I just wanted to also add that, in case everybody hasn't seen this as a good resource, and we can, maybe, Susan, you can help us get this out to everybody, but there is an important fact sheet related to individuals with mental disabilities and violence that specifically talks about things like; studies indicate that people with mental disabilities are more likely to be the victims of violent attacks than the general population; demographic variables, such as age, gender, and socioeconomic status are more reliable predictors of violence; misconceptions can cause discrimination and unfairly hamper, you know, the lives of people with mental disabilities.

So I think that there is some information out there and that the administration has actually had, you know, SAMHSA, in particular, and certainly, we have some basic background information. And if there are ways that the committee feels like

that outreach or that work could be better enhanced by the committee, I think that we would all welcome that.

Mr. Robison: John Robison here. Actually, with respect to some of the earlier comments, I wrote a piece about that incident on Psychology Today that's been pretty widely disseminated, and Cathy Lord addressed some of the questions about studies of Asperger people and violence in the New York Times yesterday, but I would, sort of, second a motion that we, on the IACC, might do well to issue a, sort of, public statement like that on behalf of the IACC.

I think that might be something I would volunteer to draft it, if somebody wants to assist me with research citations, and we might even put this up tomorrow as, sort of, a quick thing.

Dr. Guttmacher: This is Alan Guttmacher and I think something along the lines that everyone's talking about is a

great idea, and I would agree with John's point that, whatever we do, we should do it quickly. It should be thoughtful, but I don't think it would take us a long time to pull together both the research background for this and some well-chosen words, because I think, you know, while there have been other voices there, we will come across as authoritative in this.

And I think it's important to get such a statement out and to do it as quickly as possible to help color the future discussions. And I think, also, as many people have brought up in the call already, to have it be about ASD, but also in the context of a larger world of those who are different, who have other disabilities, et cetera, who also tend to be the focus of violence rather than the perpetrators.

Mr. Robison: Well, as I said, I volunteer to be the writer if somebody can be the research backup and people wanted to send

me comments. I'll offer that now.

Mr. Robertson: This is Scott Robertson. I'd be happy to assist, also, with the writing as well.

Dr. Insel: Other comments or thoughts?

Dr. Ball: Hi. I'm sorry. This is Jim Ball. I think it's an excellent idea for something to come out of the IACC and I think it's actually very timely that we're having this meeting now and discussing the areas that we're discussing, because as we push that out through the research that we're looking at, even today, and the in questions, we can give people the correct information so that they have facts to go by.

Dr. Burton-Hoyle: And this is Sally, and I think this would serve to educate the ignorance in the community, but also to serve as solace to families of individuals on the spectrum who, I am telling you, I spent a lot of this last weekend

helping them, because they all became very alarmed, very frightened, very much feeling like they needed to -- they didn't want to tell anybody.

They had become very comfortable with self-disclosure, and then there was a lot of talk about them, maybe they better just go, kind of, underground and not tell anybody, so this particular paper that you want to put together, please do it. I think that would help so many people.

Dr. Koroshetz: This is Walter Koroshetz, and so I agree. I would also think that this is an important opportunity to stress the need for, you know, interventions that will eliminate, or attenuate, you know, kind of, breakdowns that could lead to violence in people who have mental health disabilities.

I think, you know, the argument that, you know, a certain group is more likely to be the subject of violence than the

perpetrator is a good one, but I think the real focus of the country now is on preventing these very rare events from occurring, and so this one is, you know, certainly, way on the outside of what anyone's seen before.

But, you know, patients' families who have disabled individuals with them are, often times, trying to deal with these tough situations in their homes, or communities, and I think that this is a time to, kind of, push to get those people help, so I would also, kind of, stress that side line to it.

But I think a release would be very appropriate and would serve everybody well.

Dr. Birnbaum: This is Linda Birnbaum. I'd just like to say, I am very supportive of getting something out, but I do think timeliness is essential so that, if we're going to get this out, it needs to get out quite quickly.

Mr. Robison: Do we want to take a vote then on doing it? I made the offer to lead a writing effort, Scott made the offer to participate in the writing effort, and I think I heard somebody else talk about helping with research citations, could we, maybe, take a vote on that proposition and move with it today?

Dr. Insel: So before we do that, this is Tom, is there anyone who's opposed to this idea? It sounds, so far, as if everybody's very positive about it.

Ms. Crandy: Dr. Insel, are you also going to include press release and get this out to some of the major networks or you're just talking about posting it?

Mr. Robison: I would think it would be a press release, absolutely, wouldn't you, Tom?

Dr. Daniels: I can work on that to get it to be a press release.

Dr. Insel: So it's a little

complicated as a press release because that would probably require clearance, which would take some time, and is an issue for the Department right now, which is trying to have a single message, as Sharon mentioned. But we can certainly post a comment or statement from the committee, which may be picked up.

Just following up with a couple of comments from Linda and Alan, the timeliness is going to be important here, so if we're going to do something, realistically, it will probably have to be done by Friday at the latest, since getting into next week, we'll be in the holidays.

So what I would suggest, John, is if you're willing to draft something, perhaps, along the lines of what you did for the Psychology Today piece, that would be a good place to start, but we'll need to have comments from others on the committee very, very quickly to come up with something that is acceptable to the whole membership.

And I'm not sure that we need to vote on whether to do this or not because I'm hearing a consensus and no opposition to the idea of doing it, but what the actual statement is will require everybody to concur, if it's a statement from the IACC, so we'll have to send that around and get approval from a majority of the committee.

Just one comment about what the statement might look like, and that is, I think we need to start with a recognition that there's so much we don't know about this individual case, so I would encourage you not to go into speculation about either the diagnosis or the treatment here, but to talk more generally about the issues that any event like this raises, particularly for a community, as we've just heard, that's so concerned about getting services, about inclusion, and about not being marginalized or stigmatized in some way.

Mr. Robison: Yes, I would agree.

We need to speak to the needs of the community and, really, not the diagnosis or issues of the particular individual in this incident.

Mr. Robertson: Tom, this is Scott Robertson, I had a question, so since, as you said, and that's what I was wondering is, if there was going to be a government restriction in terms of around clearance, et cetera, but in lieu of that, once this got posted on the IACC site, theoretically, you know, folks, privately, could just, you know, blog about it, you know, post links to it, and stuff like that, and, you know, kind of, you know, get it out there from a third-party standpoint in terms of, you know, get people's attention that IACC wrote this, I mean, even though a press release wouldn't be able to be issued, you know, maybe, for weeks or whatever, you know what I mean?

I mean, I think that you could still get this to the media forefront by

letting people know that this has been posted on the site, you know, through, you know blogs and things like that.

Dr. Carey: Tom, this is Matt Carey. I mean the question that pops up in my mind on that is, you know, as members of the IACC, we walk a fine line of, you know, where we speak as individuals and where we speak as members. But, I mean, if we took something like this, incorporated it into, say, a letter to the editor of our local newspapers, we said, this is our statement, here's what the IACC said, you know, are we crossing a boundary there? Could we include that as a statement as long as we make it clear what's our own statement?

I don't know if that's getting around the issue in a way that's not appropriate, but I mean, that was what was in my mind.

Dr. Insel: Matt, this is Tom, there's no problem once the IACC posts a

statement and having anybody cite it or use it, in fact, we'd encourage that. There are a couple of rather complicated issues here, and I'm not sure I even fully understand them, but we're, on the one hand, a FACA committee, on the other hand, we're responsive to the Office of the Secretary.

And so we sit in this interesting gray zone between being federal and non-federal at the same time. And so I'm not sure I have the full answer right now about whether we can actually do a formal press release, I'm also not sure that that would really make very much difference, but there's no limitation to us being able to post something on the IACC Web site which is a statement of the committee, and there's certainly no limitation to encouraging other people to use that in any way that they would like to.

The one thing that we have to ensure is that, if we post something, it does

reflect the committee's wishes, and so the specifics here will matter. We'll have to actually have a document that all of you feel comfortable with, or at least a majority of you feel comfortable with, and we'd like to circulate that as quickly as possible if it's going to be done before Friday.

Ms. Abdull: Hi again. This is Idil. Oh, go ahead.

Mr. Robison: I just was saying that I am ready to start on this today and I can circulate some first draft stuff for the committee this evening, and when we can, maybe, give it a couple go arounds and put it out there this week. I agree with Tom that we need to do it before Friday.

Dr. Birnbaum: I think if you can get some drafts out to start looking out this afternoon -- this evening, that would be terrific, because I really think something short and fairly sweet is what's needed now; a more in-depth analysis can come out later.

Mr. Robison: Yes, that's what I thought too.

Dr. Ball: Hi, this is Jim Ball. The Autism Society is going to be releasing our second statement and in that statement we have citations that you probably could use for your writing.

Mr. Robison: Could you email those to me then, please?

Dr. Ball: If you would email me first, I can send you a whole list.

Dr. Insel: Tom here. Having watched how this committee did the update on the plan and how efficient you were with getting through multiple drafts, I was very skeptical about how this would work, but I actually have a lot of confidence that, in 24 hours, we can probably hammer out something that will be of real value.

So, John, thanks for taking the lead on this and we'll get this circulating today and with a goal of having something up

no later than Friday morning.

Mr. Robison: And may I have the email address to get that Autism Society information?

Dr. Ball: Yes. My email is jbautismconsult@aol.com.

Mr. Robison: Okay.

Ms. Abdull: This is Idil. I just have a question, because sometimes perception is even, sometimes, more important than facts, and everybody that I've seen on T.V. now who's talking about mental health, who's talking about autism, or Asperger's, are not particularly experts, so are you then saying that -- because I was thinking I would circle your name out to people in the media and you would be the face for autism because you are the chair of the IACC and you are also director of NIMH.

So then are you saying it's difficult because there is so much rules, and what have you, in the government to do press

for this issue? Because I think it's so important for the people in this country-at-large to know what everybody has been saying, but then also, it's important for people in the country to know that we recognize, we send our condolences to the families, and we want to work on interventions, as Dr. Guttmacher, or Walter, somebody said.

So I'm just wondering, are we not able to do press releases only, but then also, even for you to go out there and talk on behalf of the autism community in the press.

Dr. Insel: So both of those are quite possible, and we've done those kinds of things in the past. There's no limitation. I think the issue for us within the Department was, there's been a lot of uncertainty about the details, and so we've been wanting to be pretty careful about statements until we have more information.

As you probably know, you know,

the Department has been deeply involved in every stage of this tragedy from, almost, the first couple of hours. We have members of the Department who have been deployed to provide support in Newtown as well as outside, to both the first responders and the families. We've got a whole rack of people from different parts of the Department who have been meeting every day, beginning on Friday, and the Secretary is in those meetings.

In fact, I'll have to step out today for another such meeting. So there's a tremendous amount going on, so I wouldn't want you to think that no one is invested or involved here. There's a lot happening.

I think the IACC, though, has a very special role, and a very specific opportunity, because we represent, not just government, but members of the public and members of the autism community to be able to make a consensus statement that will be

extremely important, so I would encourage you to, as a group, if we can pull something together quickly, this is the time that we can make a statement that might get some recognition and it won't be seen, simply, as the perspective of a single bureaucrat or a single part of the government, but as something much broader.

So I think we're on the right path and let's see if we can all be responsive to what John sends in and try to get comments back as quickly as possible so we can pull together a final draft that we can post quickly. Any other questions about this before we move back to the agenda?

Dr. Carey: This is Matt Carey. If I could just make a comment. You know, if there's any silver lining to this it's been the fact that the autism community moved quickly, and I think, with a very unified voice on this, to both show sympathy and support for the people and to try to correct

the message.

It's been, you know, basically, every side, every angle, you can see, just, everybody was very moved by all this and moved very quickly. So it was, in that respect, from our own community, seeing everybody pull together, was very heartening.

Dr. Insel: That's good to hear. Thanks, Matt. Let's move on to the oral public comments session. I want to introduce this by reminding you that you also have received a multitude of written comments from the public and we'll have a chance to talk about those in a few minutes, but we have one person who has signed up and has come to Bethesda to provide oral public comments.

And let me invite Dawn Loughborough to come to the microphone. I think you'll be able to see her in just a moment and then we'll have some opportunity to discuss both oral and public comments thereafter. Thanks for coming.

Ms. Loughborough: Thank you. Good morning. My name is Dawn Loughborough. I'm the mother of three great children, one with autism, and I'm here today to follow-up on my request earlier this year for a task force looking into environmental causation. I return today to describe some points of interest for IACC regarding the Congressional autism hearing: 1 in 88 Children, A Look into the Federal Response to the Rising Rates of Autism in the Office of Government Reform on November 29th, 2012.

In that hearing, Chairman Issa, in his preview statement, said, "In recognition of this increase and the reality that we don't know enough about ASD, the Congress passed the Combating Autism Act in 2006 to establish the Interagency Autism Coordinating Committee so we could facilitate an exchange of information and coordination in the hopes of raising awareness and understanding of ASD research and services."

"In fiscal year 2012, Congress directed $230 million for ASD-specific research and services." He continued, "Today, we will get a clearer picture on what is being done, what questions still need to be answered, and what needs exist for those children, adults, and families who live with an autism spectrum disorder."

So if nothing changes and we project the current rate of prevalence onto children born today, we can expect autism rates of 1 in 26. And if four million children are born this year in the United States, that equates to 153,000 more children with ASD each year that we don't act to address this national tragedy.

The question that still needs to be answered, I'm here to specifically explore that which I will refer to as regressive autism, which, for the sake of opening new possibilities for our children, I will dare say can be considered a medical set of

concerns presenting with autism behaviors, not the inverted current world view.

An overriding concern of the Congressional committee members and family testimonies at the hearing last month was the verbal evidence stating, one, autism is medical, and two, families are seeing their children regress after vaccines.

From hearings back in 2000 to now, 2012, these testimonies demonstrate a 12-year span of medical atrocity by injection for our nation. Dr. Brian Hooker, Ph.D., PE, a parent and research scientist, over the past eight years has looked into government vaccine causation research.

Dr. Hooker has found significant issues with the safety of thimerosal based on the evaluation of CDC vaccine safety research using discovery from over a 100 Freedom of Information Act requests. The government body of evidence for vaccine safety studies is under question regarding overall research

integrity, including, in particular, with the involvement of DHHS, OIG, most wanted fugitive, Paul Thorsen, as lead investigator.

It is time to reopen and re-examine these concerns. The travesty is that the link between vaccine exposure and autism causation has been downplayed, erroneously researched, discounted, and arrogantly ignored too long, and should be revisited looking at the total number of shots given, shot interactions, and the overall exposure of the ingredients in these products.

On behalf of all families living with seizures, gut disorders, mitochondrial breakdown, chronic pain, myopathy, and neurological impairment, I am requesting a task force to, one, investigate the complex medical interactions of the childhood vaccination schedule, the associated vaccine ingredients, and perform a long-term vaccinated versus voluntary unvaccinated study review of health outcomes.

And two, determine appropriate integrative treatment solutions to help these children. I have names of excellent qualified physicians, parents, and researchers to recommend, upon request, for such a task, which have been presented to IACC in the past. I propose that our health institutions expand to a new paradigm of looking at autism as a complex multi-system medical condition instead of a set of psychological behaviors.

We need medical programs and insurance coding to embrace the current science on autism that recommends an integrative medical outlook to this disorder.

In summary, for the regressive community, autism is brain damage, and immune system damage, and much verbal evidence exists for concern of vaccine causation. Vaccines are known to cause brain damage and death, which is why the National Childhood Vaccine Injury Act was passed in 1986.

Vaccines were a primary concern of the Congressional hearing last month. Somewhere along time, the national vaccine policy became more important than the children it was designed to protect. Looking directly in the face of what is happening to our children's health outcomes in this nation, the CDC reports 1 in 2 U.S. children have chronic illnesses.

We are everywhere and we're not going away. Thank you.

Dr. Insel: Thank you, and thank you, in particular, for coming to provide that testimony, since this is not a meeting in which lots of the committee was able to attend, so we really appreciate you being here. Let me, before we open this up for discussion to the rest of the committee, just point out that you should have received, and let us know if you haven't received, a great deal of written comment.

I think there were a 120-something

pages that were submitted for this meeting suggesting a whole range of areas that the public would like the IACC to attend to. In addition to what you've just heard, there were many comments about everything from albumin, to pre-natal injury, to soy, to the need for better adult services.

There were some specific comments on the strategic plan and some of its specific chapters, and much, much more, so as we take a few minutes to respond to, or to reflect on what we've heard, I want to make sure that you take into account what was sent in as written comment as well as oral comment.

And I'll just open up the floor for the committee to respond. We have about 15 minutes or so before we start on the agenda for updating the Plan.

Dr. Carey: Tom? This is Matt Carey.

Dr. Insel: Yes.

Dr. Carey: One comment, you know, that popped out of my mind from the written comments was the comment by Carol Greenburg which sort of ties into, I guess, the other, sort of, major event in the U.S. in the past few months, which was, you know, the hurricane, and brought in the idea of emergency response and the difficulties that people had, you know, in following the hurricane, and getting services, getting back on track, and everything else.

And I think, you know, services are difficult enough, but I think, you know, emergency response, how to respond in an emergency with, you know, people who have, you know, difficulties to begin with, and also, medical issues, you know, perhaps, special diets, and anything else, is something that, I think, I don't know how we can incorporate that, but it's a topic, I think, is very -- I've seen a lot in discussions over the years online.

Dr. Insel: Yes, for others on the committee, this was a November 2nd email that arrived on what autistics need in emergencies from Carol Greenburg. And I agree, I think this is something that we've heard in the past. I think this came up after Katrina as well, and is one of the places where, within our purview, if our job is to make sure that the Secretary hears about issues emerging with respect to service needs is one of the places we may want to begin to focus.

Dr. Koroshetz: I just say, this is Walter, that, yes, I'm pretty sure that there is an office, I think it's in ASPR, that the Assistant Secretary for Preparedness and Response deals with emergencies, and I believe they have a special office that is dedicated to the issue of care of people with disabilities during disasters, so that may be the first place to engage.

Dr. Boyle: Yes, Walter. This is Coleen. That's actually vulnerable

populations.

Ms. Crandy: This is Jan Crandy. I just want to commend the mom that came forward, that just spoke, and I want to, again, say that our group, I personally, had made a motion to have a task force for environmental factors, and I would like to bring that back to the committee at some point.

I think after that autism oversight hearing, I think it was brought up about having a study for vaccinated versus unvaccinated studies, and I think that is a gap that we need to address.

Ms. Redwood: Hi. This is Lyn Redwood and I support what Jan just said, and also would very much support the establishment of an environmental task force. This is something we've been recognizing for years now and this strategic plan dating back to when it was under the Children's Health Act, that environmental factors have not

received as much funding as they should, and that it's an important area, and I think without an established task force, it's going to be difficult for us to set some priorities with regard to research.

You know, back at the second IACC, there was a lot of discussion over vaccines at that time, we did have a joint meeting with NVAC, and if you look at the strategic plan, it says that we should continue to coordinate with NVAC, but to my knowledge, that has not happened, and I do think that it's a very pressing issue that the committee needs to address.

And I would very much support the task force. On one of our previous calls, there was a motion and a second, and actually, a third, but the question was never called to a vote, so I would like to put this to a vote with the committee today.

Dr. Carey: This is Matt Carey. I mean, a couple comments on that, I think one

is, there is a perception, you know, in the public's eye that the IACC has not been supporting environmental research, and if you look at the amount of money that has been called for by the previous IACC, it's actually quite high.

It's somewhere, you know, after the IACC, you know, and it's in areas I don't think we can really address easily in terms of how, you know, the advice gets implemented, but I think there's been very strong support from the IACC itself.

The other thing I would say is, I mean, to me, I have a question in terms of, you know, we are an advisory committee and we're not going to create an entity that has more power than ourselves. We can create something that can advise us, but that's actually been done a few times.

If I recall, there's been, you know, workshops on autism and the environment, and those have been incorporated

into the strategic plan, which has been, then, put into exactly that, that emphasis that I was just talking about, so, you know, we want to move forward and doing the same things over and over again, I don't see that that, you know, will get us somewhere.

Now, if we want to look into how does the advice of the IACC get implemented and how can we, you know, potentially effect, you know, more advice getting accepted and implemented, that would be one thing, but I think there is, already, a lot of information coming in to say, you know, let's look at the environment, both from research from the workshops, from the public, it's been incorporated by the IACC.

It's, sort of, the next level that really would have to be addressed and I'm not sure that that's something that we could -- because again, we're not going to create an entity that has more power than ourselves, so where would we go with that, I guess, would

be the question?

Ms. Redwood: Matt, I think you sort of hit the nail on the head when you said IACC has some focus on environmental factors and it is in our strategic plan, but when you actually review of our funding for 2008, '09, and '10, you can see where the research that we've identified as being high priority and the amount of money that we thought would be necessary to address those issues, is woefully inadequate.

And I think that's where this task force, or subcommittee, could be beneficial in terms of recommending ways that we can move this research forward because it's not getting done.

Dr. Insel: Lyn, this is Tom, just a point of clarification, and I think we'll come back to some of this later in the day, but I'm hearing what I think are two quite different issues. One is, an interest in a group that will increase the focus on

environmental factors and figuring out ways to make sure that more of that science is done and done well.

And then a second is a question about vaccines, per se, which is a very specific question. When this has come up in the past, as you well know, we've talked about this quite a bit at the IACC, and have often concluded that we do not really have the expertise on the committee and we've turned to the National Vaccine Advisory Committee, which is, after all, another federal advisory committee which is put together, specifically, around the vaccine issue.

They, in turn, have asked the Institute of Medicine to conduct a study, which I believe will be available, there should be a report out fairly soon, and we referred to all of that in the 2011 strategic plan update.

So I'm just wondering how much

that issue is a proxy for the environmental issue or is that really a separate issue, irrespective of whatever we do, in terms of increasing the focus on environmental factors.

Ms. Redwood: But, Tom, I think that this is falling under the same rubric of that environmental committee, or environmental task force, and that vaccines would just be one of many environmental concerns. You mentioned previously that, in public comments that we've received, there's also been concerns about soy products and ultrasounds.

So I think that this would be one of many environmental issues that needs to be addressed further and in more detail.

Ms. Crandy: This is Jan Crandy. I do think, though, with the autism oversight hearing that just took place and public perception, that we do have a gap missing with the study of vaccinated versus

unvaccinated, and I think that that needs to be included in this chapter when we say what needs to take place and what hasn't taken place.

Dr. Carey: Tom? This is Matt Carey again. Another question I would have in this, that's been in my mind, is, I mean, how much is the National Children's Study really going to play into just exactly this? I mean, there's a large amount of funding going into tracking a vast number of areas, you know?

But, I mean, obviously, autism is something that could be included, and will be included, and, you know, it's not going to be something that's, right now, perhaps, reflected in the way the plan, or the way we're reporting the funding levels right now, obviously, because, you know, it's a different area and it's also something that's new, or the ramp-up is fairly new, but I mean, there is a large effort going on in

exactly these areas.

I mean, are we asking for something that's actually duplicating our efforts?

Dr. Insel: Alan Guttmacher --

Dr. Guttmacher: Tom, for those who aren't as familiar as Matt appropriately is with the National Children's Study, let me just sort of sketch-out what that is. It's a program, basically, to enroll 100,000 children at or prior to birth.

The way it'll probably work is something like around 40,000 to 50,000 at birth with about another 40,000 or so during pregnancy, and maybe 5,000 or 10,000 even pre-conceptionally. That's all being worked out still. But then to get very rich data and samples about their environmental exposures during pregnancy, during life, so that, for instance, for the prenatal sample, we would have dust samples from the parental home, and other kinds of environmental

samples, but also, biological samples, so that besides having, for instance, the placentas, we'd also have blood samples, urine samples, other kinds of things, from the children, and in fact, many of those from their parents as well, following those kids until age 21.

Following them in terms of growth, health, development, using medical records, various kinds of survey instruments, other kinds of things, so in fact, you know, depending upon what one believes the prevalence of autism will be at the time these kids are enrolled, and I'll get back to that in a moment, there clearly will be one to several thousand kids enrolled in this study, which will, basically, be a nationally representative sample, who will fall someplace on the ASD spectrum.

And lots of information about them, and also, obviously, well-matched kids who do not fall in the ASD spectrum. So that

will give us a lot of information about various environmental influences that may play a role in autism and also be able to cross some of that with genetic factors, because we'll have DNA, for instance, from all these kids, et cetera.

There's been a pilot study, so-called Vanguard Study, which has enrolled close to 5,000 kids. The main study, which will enroll 100,000 kids, the current plan would be for enrollment to begin in 2014.

So clearly, it will be several years from then before we have robust samples, et cetera, but it won't -- you know, one would hope that many of these diagnoses will be made fairly early in the children's lives, et cetera, so certainly, by the end of this decade we'd have rich data about environmental and other influences on kids who do develop ASD.

One of the strengths of the study, of course, is it's a longitudinal study

following kids from birth, and even before, as I said, and then following them regularly after that. And also, that it's not a retrospective study. You don't have to go back and ask people about what happened during pregnancy or go back and say, for some reason, do you still have your placenta lying around, or something, we will have gathered all of that information prospectively, then be able to go back and look at those samples that were gathered just as part of the normal operation of this study.

So that's it in a nutshell. Happy to answer any other questions about it.

Ms. Redwood: Alan, I had discussions with Duane Alexander several years ago about the National Children's Health Study and at that time, they were not collecting vaccine records. They did not have that in the budget to be able to do so, so I see that as a gap that still exists. And while I think it's a wonderful study, it,

as you mentioned, will be years before we have any findings.

And I think there's things that we can do now to help get answers and also address one of the core values of the IACC, which is a sense of urgency.

Dr. Guttmacher: In fact, Lyn, the study design has been changed since those conversations in a number of ways, and one of them is, it will be more tightly tied to electronic health records, for not all, but for many of the children in the study. And in fact, we will have direct access to vaccine records.

Ms. Redwood: Including lot numbers?

Dr. Guttmacher: Depending on the detail that's in the medical record.

Ms. Redwood: Okay. Well, very good.

Dr. Insel: Lyn, if it's helpful, this is Tom, I mean, the other potential

source of information will be the Health Outcome Study, which I think you know a bit about, but that is available more in real time, that 33,000 children with autism, 100,000 family members, also, a control group that's included.

This is, of course, claims data, but this is the Lewin study, which is just now about to report out, so we'll have the results of that over the next few weeks, I believe, and it won't be in time for the 2012 update of the strategic plan, but should inform what happens next year.

And there should be, again, depending on what's in the medical record and how good those electronic records are, what's in the claims base. There may be information that could be relevant to a number of factors connected to the things the committee cares about, and that'll happen in a much shorter time frame.

Dr. Birnbaum: This is Linda

Birnbaum and I just wanted to mention, and I know that the members of the committee are well-aware of the studies that we have ongoing, several longitudinal birth cohorts, relatively small, but looking at families who already have one autistic child and who are having a second child, so that will involve prenatal information as well as genetic information, and exposure information, certainly, during the pregnancy and afterwards.

And some of those studies are in-progress right now.

Dr. Koroshetz: This is Walter. So the NINDS also funds a study in Norway, a large population study, looking at all births over about a ten-year period, and they've identified, I think, up to about 400 to 500 cases of autism, so they have pregnancy records, they have data about the pregnancy, they have vaccination records, and bio samples were taken during the pregnancy and

at the delivery, so that's another potential study that could turn up environmental factors related to the development of autism in this, kind of, interesting society where there's a lot more data on everyone.

Dr. Boyle: And this is Coleen. We also have the SEED study that's completed its first round of data collection, and that's at six academic centers in the U.S., and trying to be population-based, and also has a wealth of environmental-related factors.

Dr. Insel: Other comments about either the oral or written comments? So Jan had made a recommendation about having a task force, and I think we'll probably circle back to that as we get into some of the issues around the update. If not, let's make sure that we do circle back to this towards the end of the discussion today, get a sense of the temperature of the full committee on that particular issue, and at that point, I think

there will be some time for further discussion as needed.

Unless there's any other comment about what's been put in front of us, I think we want to go ahead with the agenda. Let me just check with the committee and see if there's anything else before we embark on the update.

Dr. Koroshetz: I'll just add, I don't know if Jim wants to say anything, that there were a number of comments about the auditory system and abnormalities in auditory system, and certainly, with language being, you know, an incredibly important issue in autism that, certainly, those circuits, you know, do need to be explored.

And there is some work going on in the area, but it is one of the core features of autism, so, you know, I think that we take those oral comments very seriously.

Dr. Battey: I completely agree with Walter's sentiments, and we are

supporting some work in that area, and we will continue to welcome grant applications in both the areas of communication disorders associated with autism and abnormalities in the auditory system associated with autism.

Dr. Insel: That particular comment is based on the observation that the auditory nuclei have the highest rate of metabolism of glucose utilization of anything in the central nervous system of any area, so it makes you wonder. I think it's a really interesting observation that begs for someone to do some more careful exploration, given all of the possibilities that mitochondrial issues are involved as a causal factor in autism.

Dr. Insel: Okay. We're going to move into the next part of the agenda which deals with the actual work of today, the updating of the plan. I want to take five minutes at the outset just to review, especially for the newer members of the

committee, what we're all about here. It's first, updating this plan each year, monitoring federal activities with respect to ASD, and we do that, of course, through the portfolio analysis, which does both federal and non-federal, making recommendations to the Secretary on both research and public participation, and then the role of getting to Congress each year, this update of the strategic plan, which is really what we're about today.

And I know all of you have the most recent version of this, which was done in January 2011. So just a quick review, we advise the Secretary, we coordinate, and we focus and accelerate research progress by the priorities we set in this research strategic plan, and we're also, as we've just heard already this morning, a public forum where we can begin to try to focus on particular issues that may not yet be in either the research or services sector.

Core values are something that we come back to at each meeting and I think that's even more important as time goes on, but I want to just emphasize the sense of urgency, the focus on scientific excellence, and this will come up, I believe, today. We've tried to set a very high bar for what gets into the update, making sure that it's the most rigorous and most well-designed science that we can find.

A spirit of cooperation is something that the committee has made a priority of its own process, keeping a focus on consumer issues and hearing from those, both on and off the committee, who can represent that for us. Thinking about action items that involve partnerships, and we'll hear a bit about that today, particularly with respect to Chapter 7.

And then, important, is this issue around accountability, and although that happens in many places besides the update to

the strategic plan, it's one that we want to make sure, as we think about whatever changes we make, that we are also aware of how they would be measured, and how they would be achieved, and in what time frame we can expect to get realistic results.

So our task for today is to get the update complete so it will be ready to send to Congress later this month. This has to be done by the end of December. We discussed this in July at our first meeting and the decisions were made to keep this as a fairly narrow focus just on the parts of the plan that were on what do we know and what do we need?

In the previous updates that were done in both 2010 and 2009, although they came somewhat later, so the 2010 update was actually published in January 2011, we added objectives. The most recent time, we added 16 objectives, but the IACC, you decided in July, that this was going to be, really, more

about other parts of the plan, the what do we know, what do we need, and really trying to just get us a sense of what areas of science had changed so that it was time to provide some new information for the plan going forward.

We decided we'd do this in two chunks, that there'd be one subcommittee that would go through Chapters 1 through 4, and Chapter 7, and another through Chapters 5 and 6, and that we would utilize scientific experts, and we'd utilize public comment all the way through.

We've already talked a little bit about the public comment. In terms of the scientific expertise, we got a spectacular group for each chapter who helped to advise those of you who volunteered to work on this. We had planned to bring everybody together in, was it, October, I think it was, for a face-to-face meeting, but superstorm Sandy had another plan in mind, and so that

particular meeting was canceled at the last moment.

We were still able to get people together through a series of phone conferences and several rounds of revisions of the text to get us to where we are today. You have, now, in front of you, and you've all received the final draft, and the plan for today will be to go through that draft chapter by chapter and to vote on each to get this into final form.

A couple of things to think about in looking at this, one is that, we endeavored to really keep the update at a very high level, that is, we don't have every paper, we couldn't include every discovery, or every new insight, or every new idea, but we wanted to bring, into the plan, those new findings that really were transformative or changing the way we think about what we need to do going forward.

And to be fair, I think there were

some chapters where there's actually very little of that, but we did our best to try to find what was out there. I'm not sure that we have captured everything, and sometimes in the quest to do this well, you have to remember that the perfect can be the enemy of the good.

We ended up with, I think, a pretty good summary of what's been done in the last two years, but I'm sure that there are findings that we may have overlooked. If there's something you feel is really egregious and really needs to be included because it is a discovery that will completely change the trajectory, or could change the trajectory, of autism research, it will be important to hear about that this morning.

In terms of gaps, this is also an area that is never particularly easy, you want to identify those new opportunities that come about from new discoveries, and I think,

as you'll see, there have been many.

Also, while the focus of the group has been mostly to look at what's been done in autism, we also had to be mindful that, some of the gaps are going to come from biomedical research in other areas, and realizing that there have been discoveries that really are profound in biology and many areas of neuroscience over the last couple of years that have not yet been implemented in the autism community.

And so one of the things the committee can do is to point to those new findings from other areas of science that may be important to include.

And as a final suggestion, we probably don't want to spend a lot of time just repeating what is in the current strategic plan or in the previous updates. We've done that before and I think we're best served, and the community is best served, by keeping a focus on what's truly new and

different.

So I'll finish this introduction simply by reminding you, and reading to you, the original vision statement for the research strategic plan as it was done, and repeated, in the 2011 update that, "This will accelerate and inspire research that will profoundly improve the health and well-being of every person on the autism spectrum across the lifespan."

"The plan will set the standard for public/private coordination and community engagement." So I want to remind you of that very audacious vision, of which we all bought into in the previous versions of this plan, and I think it will be important to connect back to this as we go through the update today.

Any comments or questions before we start on Chapter 1, which is the issues related to diagnosis? Susan?

Dr. Daniels: This is Susan. I

just wanted to remind everyone to please identify yourself prior to speaking so that the transcriptionist can correctly identify you in the transcript. Thanks.

Dr. Insel: Does everybody have the most recent version that was sent out in the last few days from Susan? I think the best way for us to do this, since we've got this broken up into chunks for each chapter, and we had planned to take 30 minutes for each one, it may not actually take that long to do this, but if I can ask the person, or persons, who took the lead on each question to very quickly summarize, and maybe two minutes, or at most, three minutes, the process they went through, what the main issues were, and then we'll open it up to see whether there are concerns about anything that's in this version.

And if there's nothing that requires further editing, we'll put this to a vote and then we can move on to the next

chapter. So if that process sounds workable to the group, let's go ahead, and let me ask, who can take us through Question 1?

Mr. Robison: I'm ready to do it, I guess. John Robison here.

Dr. Insel: Okay. I'm going to turn this over to you and let's take two or three minutes to just summarize the process and what we've got in front of us.

Mr. Robison: Okay. So for Question 1, when should I be concerned? I would say the principal change in Question 1 from the previous strategic plan is that, Question 1's scope has been expanded to include adults with the reasoning that the question of when we should be concerned, really, bears on when you learn about autism, not when you are a child.

So we began by summarizing prevalence findings. We report on the 1 in 88 finding in the United States and we contrast that with the British study that

found a similar prevalence of autism among a previously undiagnosed adult population in the U.K. And we mention the Korean study which found an even higher prevalence, but with slightly different criteria, among children in Asia.

And then we move on to talk briefly about how the diagnostic changes in DSM-5 may impact diagnosed prevalence in the future and we expressed a concern about social communication disorder, and it being a diagnosis that has no service associated with it.

Then we look, quickly, at early screening and we report on some positive results in early screening and detection. We have some positive results to report in early diagnosis. For gaps in when I should be concerned, or when we should be concerned, the first gap we note is that, the age at which autism is diagnosed in children has not changed materially in recent years, even

though we have made major advances in early detection capability.

We also see as a major gap, the lag in reporting systems so that we, today, are considering a fairly old and potentially obsolete data, and we need to reduce that time lag. We mention as a gap, as I said earlier, social communication disorder.

And then, as another gap, and this, I think, is a big change from what we had previously, we cite unrecognized adults with autism as being what is potentially the principal overlooked and unserved population in the autism community. And we mention that we really haven't done anything for the adult population.

And finally, we talk about the gap in discussion of bioethical issues surrounding diagnosis and what one may do with diagnostic information. So that's my quick summary of Question 1.

Dr. Insel: Excellent. Thanks.

Let's open this up to questions or comments.

Mr. Robertson: Tom. This is Scott Robertson, I had a comment on the adult facet of this. While I thought it was really, really important, the inclusion of that study from Britain, and I really like a lot of the coverage on lifespan, et cetera, issues in Question 1.

I have a concern that, particularly, the paragraph on the British study toward the end of the document, Page 4, doesn't go further, and maybe this is because the place was felt for another question, I don't know, but it doesn't go further to suggest that there should be similar, kind of, broad initiatives like there are with the CDC monitoring network for children to be looking at prevalence among adults in the United States and make this a major priority of NIH and CDC to be finding out, you know, to be looking at, broadly, you know, population among autistic adults, and issues,

and things like that, and not relying on, say, for instance, folks in England to be doing, you know, this research for us.

I mean, we're citing a study from somewhere else when we should be taking the trailblazing and looking at undiagnosed autistic adults in the United States, and diagnosed, and looking at what we should be doing for better diagnostic instruments for that.

So I have a concern it doesn't really go far enough in that paragraph for what we should be doing as a major priority area for autistic adults within NIH.

Mr. Robison: John Robison here, again, if I may answer that. I think that your point is a good one, and I think that we should be doing more research to discover adult issues and needs. However, the scope of Question 1 was when should I be concerned, and it was limited to diagnosis.

And I think that the British study

has made clear that there is a large undiagnosed adult population. I don't know that we need a lot of additional studies to further reinforce that finding, although, such studies may come along. I think, really, your point is that we need to now do studies to discover what that unrecognized population needs.

And I believe that that is beyond the scope of Question 1, though I believe it should be within the scope of the IACC's report overall.

Dr. Insel: This is Tom. Can I just interrupt for a second? There is a piece in the gaps on Question 6, which is, what does the future hold, particularly for adults, that says, specifically, additional research is needed to identify direct observation measures that can be used in adult diagnosis and validate diagnostic instruments for adults.

So it may be that in terms of the

question you're raising, we'll want to postpone that and put it into that context, rather than in this first chapter.

Dr. Boyle: I'm sorry. This is Coleen. I was going to say that I might suggest, also, under Question 7, which is also on the gaps under surveillance, last sentence says, "Further surveillance among ethnic minorities and underserved populations will be critically important to understanding risk factors and barriers to services in these groups."

So again, maybe inserting adults within that context might be appropriate.

Dr. Insel: It's a great point, though. I think we'll want to come back to it, if not in Chapter 1, then figure out where we can insert it later.

Mr. Robison: John Robison here again. I absolutely believe that that's a very important point and it should be a very important gap that we describe in the plan as

a whole. I just don't think Question 1 is a place for that.

Mr. Robertson: Yes, and I understand the point. This is Scott Robertson again. I understand the points, and maybe it's a place in the other questions, I just want to ensure, for instance, that adult issues don't become, like it was said, you know, point back to Questions, you know, 5 and 6 around services, but I think that there should be a major priority among autistic adults to make sure that that's embodied across the plan in all the questions.

That's why I just wanted to ensure that, because it just seems to me that, overall, there's still more priority on the looking at population estimates, et cetera, among, you know, children. I mean, we have this active monitoring network with the CDC and that's only focused on children.

And, yes, I agree that we don't

necessarily need to completely duplicate with the British study, and I know this is going to come up more in the later questions, but I do think that, you know, there is a place to be looking, you know, more in-depth on some of this with autistic adults.

So you're right, you know, maybe that belongs in some of the further questions.

Dr. Insel: Scott, this is really important, so let's flag this and make sure that we come back to it when we talk about surveillance and build that in, because I think it was overlooked. This may have been an area that everybody assumed somebody else was going to cover, and if it is not present someplace in the plan, we'll want to make sure, as John says, that the plan, someplace, captures this need.

Other comments on Chapter 1?

Ms. Crandy: This is Jan Crandy. I have a comment on the SCD paragraph, and it

could be addressed again somewhere else, but we might need a longitudinal study of what happens to that population, because with the fear of needing less support, and do they get less support, and what do those supports look like in the future for that group?

Mr. Robison: John Robison here. That's a good idea to, perhaps, just add a sentence that we would like to see a longitudinal study following the SCD group as it evolves.

Dr. Carey: This is Matt Carey. I mean, I think that brings up just the more broad question, are we going to include -- I mean, is SCD going to be part of our purview in the future or are they getting, sort of, cast aside and, you know, are we going to follow them up as the IACC, and are they going to fall under our umbrella?

And I would think, you know, historically, that would be yes, I mean, they should be, but, you know, and such a move

that John just mentioned, I think would help to cement that.

Mr. Robison: Tom, do you have a thought on that?

Dr. Insel: Yes. It's a really interesting question that's never come up before. If this is no longer considered part of autism spectrum disorder, then it is, really, outside the purview of the IACC, as far as I know.

Mr. Robison: Well, you know, Tom, you say it's not considered part of the autism spectrum, but really, that's not true. If we consider the autism spectrum as it's defined elsewhere in the world, ICD still includes all of that. And if we were to say that our charter is more governed by the U.N. definition, it's certainly within the scope of the autism spectrum, it may just have its own category in the U.S.

Ms. Crandy: Right. And this is Jan Crandy. I know some states are doing

legislation to bypass that new DSM-5 and we maintain the old diagnosis in the autism spectrum disorder.

Dr. Carey: Yes, this is Matt Carey. I mean, to throw out some of the experience from California, when the DSM-IV was implemented, you know, and PDD-NOS, and Asperger Syndrome were added categories of PDD, it became a major problem here because the law was written such that, autism was recognized as a qualifying category, and people who got PDD-NOS, and Asperger diagnoses were very often rejected for services.

And so, you know, they were, sort of, neither in nor neither out of autism from that perspective, and I think we should, you know, make sure that that doesn't happen here. I mean, SCD, if you think about it historically, right, right now, the people who are under SCD are being covered by us. They are under, sort of, the umbrella of what

IACC is.

You know, that's what we were chartered to do, you know, who's going to pick them up if we don't? So I think, you know, to me, it is a troublesome question. I haven't put a lot of thought into it up until now, but, you know, these discussions really do make me worry based on what we've seen in the past. If no one's looking at this group and following this population, how will we know what services they need? How will we know what supports they need?

And, you know, if we aren't doing it, who will?

Mr. Robison: John Robison here again. I really do think that we are in a good position to assert that we should follow the SCD group because SCD is, I think, within the diagnostic scope of the definition in ICD. And I think that is still the definition by which we code disorders for statistical purposes in the United States and

it's the defining definition everywhere else in the world.

Dr. Insel: John, this is Tom Insel, just as a point of fact, do we know that the final version of DSM-5 is going to have this in it or how it'll be organized? I know that there was a retrenchment from many of the suggestions before the final draft went to the board of the APA.

Mr. Robison: You know, I thought I got that from Sue Swedo. I could send her an email and ask her. I think she is supposed to be on the ICD autism steering committee with me. I can write her and ask and get back to you.

Dr. Insel: Anybody on the committee know the answer to that question?

Mr. Robison: It certainly appears on the APA Web site. It absolutely appears there, so I would think it is in.

Mr. Robertson: Tom. I had a comment. Assuming it is in, one of the

concerns that I would say that, I guess hasn't been thought about as much is that, and it's mentioned a little bit, I think, already in Question 1, is that, some autistic people who are autistic, but because clinicians don't see it that well, and I've seen, you know, many different experiences where clinicians sometimes, and I think DSM-5 won't change this, come in with their own thoughts about what autism is and say, because this individual, you know, their language, or their social, or whatever, because this individual basically passes as normal, they've learned to adapt, that folks are going to get pigeonholed, in some cases, into the SCD categories.

So, you know, that may become, you know, a problem, you know, in terms of it being used as this, you know, pigeonholing diagnosis.

Dr. Insel: The final sentence, "There's a fear that it will be interpreted

as mild ASD without the need for supports." Does that help with that particular concern?

Mr. Robertson: Yes, it does. I'm just kind of echoing in terms of, you know, out there, in terms of the discussion with, you know, the need for SCD being included among the discussions of autism moving forward, as John and others have mentioned, will be particularly important because of the fact, you know, as laid out in there, that some folks who are actually autistic may actually be lumped into SCD, you know, wrongly and inaccurately.

So therefore, that gives us major reason for IACC to continue to include SCD among discussions, assuming SCD is, you know, in the APA categorization.

Dr. Insel: What I'm hearing from the committee is that, you'd like to see an additional sentence here that deals with the follow-up and the consequences of creating this new diagnosis. And, John, I wonder if

we can just put a sentence in there that says that the IACC continues to be interested in this and its relationship to the ASD diagnostic group and feels it will be important to have longitudinal data about people who receive this particular new diagnosis.

Mr. Robison: Yes, Tom, I think we should add a sentence saying that we, at the IACC, would like to continue to follow this with longitudinal studies, just as you say.

Dr. Insel: Okay. Anything else that needs to be changed or any other questions about Chapter 1? Susan, you want to look and take this to a vote at this point, with that one addition?

Mr. Robison: Well, I guess I'll move then that we vote to accept Chapter 1, as the Chair of that.

Mr. Robertson: Second.

Dr. Daniels: All in favor?

(Multiple Ayes)

Dr. Daniels: Are there any opposed? Any abstentions? Hearing none, then this motion is carried.

Dr. Insel: Good thanks.

Mr. Robison: Very good. Thank you all.

Dr. Insel: All right. Nice job and, John, not only thanking you, but thanking the team that worked on this. I don't have all the names in front of me, but I know it was a group that worked hard to get us to this point. I was really impressed by the way in which you were able to edit by committee.

It's not a skill that you see often, so that's great to know. We're going to move on to Question 2 and Walter Koroshetz will take us through a high level, in a couple minutes, what the main changes are.

Dr. Koroshetz: Okay. Thanks. We had a great committee, Carlos Pardo, an immune expert, David Amaral, Kevin Pelphrey,

Alison Singer, Dennis Choi, and we brought in Beth Malow for some input into sleep disorders.

So we were looking at major advances in our understanding of the biological causes of autism and I think that everybody was pretty convinced that the year was quite productive, that there was some really interesting, what hopefully will turn out to be, major discoveries.

They fall into two general categories. One were studies of brain circuits in persons with autism, or actually, in persons who are at risk for autism, using standard neurophysiological tools, but also, advances in neuroimaging, which will now allow us to look at brain circuits and also to look at the connections between brain areas.

And so, for instance, in the area of language, these are the first two studies to show differences related to language in

autism associated with differences in the, basically, the structure of these pathways connecting language areas in the brain.

In terms of the molecular basis, the general theme is that, the genetic studies in which genes that were identified for disorders, such as fragile X, tuberous sclerosis, or Rett's, so the genes have been discovered, they're now being looked at in animal models, and there are some really interesting clues that may tie a number of different disorders together with respect to the pathways that are disturbed, and even people who are working on potential therapies to reverse the implications of these pathway abnormalities.

The second area is rare genes that have been discovered through GWAS studies are now being looked at for what their function is, and again, they seem to be moving towards pathways involved in synaptic function. One interesting finding, just to point out, was a

paper in Science where they identified a mutation that gives rise to rare cases of autism, also, intellectual disability, and seizures.

It's a receptor kinase that was found to have a known biological function, and in animals at least, they were able to reverse some of these abnormalities with dietary therapy.

The last one I'd mention is a study of gene expression in brains of persons who died with autism. A very interesting study, small number of brains, but they found a number of genes that had their expression altered in autism compared to typically developed, and they fell into two groups.

One was, genes that have already been implicated in autism, so it was kind of confirmatory that the genes from these GWAS studies, when you look and you can actually see in autism how there may be changes in their expression, but the other was, they

found a whole set of genes that were transcribed differently, they have never been thought about before, and they all seem to fall within the immune system category.

So there's been a lot of discussion and some studies from the immune side, especially during pregnancy, that immune challenges and immune deficits may be related to developing autism. And this study actually showed that there may actually be gene expression changes in the immune system in autism as well.

So again, confirmatory to that theory, but new area. It should be noted that there were a couple of major scientific advances that occurred which, you know, people may not think, offhand, they're related to autism, but the committee saw that they have tremendous value in, kind of, moving forward.

One of these, which is in the write-up, is the fact that the immune system,

particularly microglia, have recently been implicated in the pruning of synapses in the brain, so how circuits are formed.

Many synapses are formed, but then, in general, the strong circuits are retained and the weak circuits are pruned, and the microglia, the immune system cells, are inherent to that process. And so, again, putting emphasis into the potential immune system interaction with brain development.

The other areas which opened up were the Connectome, is a major project on the part of NIH, to map out the connections between brain areas. So once it's done, this will give us, really, new opportunities to explore what's different in these pathways in persons with autism versus typically developed.

The other one is the new study of the part of the genome, which is actually more than the majority of the genome that is not transcribed into proteins, that this is

now being looked at, and something that has never been looked at in autism, but these new techniques which allow you to do whole genome sequencing now, offer this whole new area to look at, the DNA that is probably associated with the control in development, but not through gene expression of proteins.

And the last one was the Human Microbiome Project is well underway and could be, potentially, explored, particularly in terms of how the GI system, the immune system, would interact with the gut flora.

So those were, kind of, the major highlights that we looked at. Again, as was mentioned, there were lots of really interesting results that came in over the last year. We couldn't highlight them all, so we had to, kind of, really prune down what we put in because of space.

I think it was a very positive story going forward in terms of all that got accomplished. Thanks.

Dr. Insel: Thank you, Walter. Comments or questions about Chapter 2?

Ms. Redwood: Walter, this is Lyn Redwood. I just want to comment that I think you did an excellent job pulling all of this information together.

Dr. Battey: Yes, this is Jim Battey. I'd like to second that. I think that the committee did a great job on this particular chapter.

Dr. Koroshetz: The committee did a great job, and also Kate Saylor, who now makes sure I finish my job, did a great job.

Dr. Insel: One of the frustrations of this is that there's so much happening, so you guys finished about two weeks ago, I think, and there's, what I think is, a breakthrough paper that came out last week in Science Translational Medicine that shows that the duplication of MecP2, this is the gene that causes Rett's Syndrome, leads to a defect in the immune system.

You don't make CD4 cells if you have the duplication of that, so it's kind of incredible. It actually looks like AIDS in some ways. Who would have ever made that connection between what has been called an autism gene and now looks like it's a really interesting immune gene?

I guess we can put that in for next year. I'm not sure that it needs to go into this one, but it's just emblematic of how difficult it is to keep up. There's so much progress and it's happening so fast that, at some point, you've got to put the curtain down and put this to bed, but my goodness.

Literally, every issue, including, I think, a copy of Cell that is out today, which has a cover story on autism, of a whole new piece of this, so we're just not going to be able to put all that in I think. We have to decide at some point that we've done enough, but this is a great job in capturing

everything up until two weeks ago.

Any other comments or questions. This is just a formatting issue, but, you know, I wondered, in looking through this, whether we need to put in every author of the ENCODE Project, because that's about two pages of text, whether maybe we should just decide that, in terms of formatting, we could do, you know, what many journals do, you put in the first five authors, or something like that.

Dr. Daniels: We have some alternatives.

Dr. Insel: Okay. So we'll be able to fix that. I just don't want to waste the paper. In that case, for some of these, it's just really extensive. Well, unless there are any other issues or comments, Susan, can we take this to a vote?

Dr. Daniels: Okay. Do we have a motion on the floor to accept this chapter?

Dr. Battey: Move to accept

Question 2 as written.

Ms. Redwood: Second.

Dr. Daniels: Okay. Second, did I hear a second?

Ms. Redwood: Yes.

Dr. Daniels: All in favor?

(Multiple Ayes)

Dr. Daniels: Any opposed or any abstentions? The motion carries; unanimously accepted.

Dr. Insel: Okay. Moving on to Question 3, and we are going to try to do this before lunch. Thank you. Lyn, I think you were the leader on Question 3.

Ms. Redwood: Yes. Thanks, Tom. I also want to point out that our external experts that helped us with Question 3 were Matt State, Craig Newschaffer, and Isaac Pessah, and also, Cindy Lawler and Matt Carey from the IACC.

As you know, we had a call several weeks ago with the subcommittee that were

working on the update --

Dr. Insel: Lyn, sorry to interrupt. It's a little hard to hear you. I don't know whether you can get closer to your phone, or your microphone, but it's not coming through strongly enough.

Ms. Redwood: Is this better, Tom?

Dr. Insel: Much better. Thanks.

Ms. Redwood: Okay. I'm sorry. I'll try to talk louder. Did you get the information regarding the external experts and the IACC committee members?

Dr. Insel: Got it.

Ms. Redwood: Okay. Great. When we had a call a few weeks ago reviewing the draft updates, there was some concern about the first paragraph, which primarily focused on genetics, and Dr. Insel, you provided edits to that paragraph and, sort of, summarized several of the genetic studies that have come out over the last year, and you commented that there have been over 900

papers listed in PubMed on genetics.

And in summarizing those, we've reported that there are 1,000 rare changes in DNA structure that may contribute to ASD and these changes are frequently spontaneous or de novo, which are arising from sperm or egg cells prior to conception, and that most of the genetic findings implicated in ASD are non-specific to ASD, and that they include other neurodevelopmental loci, other regions of DNA, that confer this to schizophrenia, epilepsy, ADD, ADHD, and intellectual deficit syndrome.

And then finally, in summary, that this complex picture of multiple non-specific spontaneous arising genetic factors is beginning to converge on a few biological pathways, specifically, we point out signaling pathways and also, some of the metabolic pathways.

So that was, essentially, the rewrite of the first paragraph which dealt,

predominantly, with genetics.

The second paragraph addressed more of the interaction between genetics and environmental issues. And it addressed, primarily, the Hallmayer study that actually came out last year, which was not discussed in our previous update, that sort of emphasizes the role that should be placed on environmental factors.

The third paragraph reviewed over some of the candidate environmental exposures that were identified back in 2010 from a workshop that was supported by NIEHS and Autism Speaks, and that was published in 2012 by Landrigan.

So there's a discussion of the list of, sort of, candidate environmental exposures and how we should go about looking at those, and some of the findings to date. There's also an addition that Geri Dawson recommended about an air pollution study that recently came out related to traffic, and

population density, and ASD.

The next paragraph focused on trying to look specifically at some of these signaling pathways as a possible strategy for identifying these environmental exposures. Also, there was a discussion, and I'm trying to summarize this, between paternal age and de novo mutations.

And again, how a lot of these de novo mutations may be caused by environmental factors, or other mechanisms, which are still unknown, so that's an area that is also a gap.

When we looked, specifically, at the gap areas, there was a discussion, again, about the Landrigan study and how we prioritize environmental research -- excuse me. I lost my focus here. One of the things that I see that is not mentioned in terms of prioritizing the environmental factors is looking at some of the things that actually increased at the same time as the prevalence

of ASD increased.

There is also a recommendation that we use rapid treatment, high-content screening, and that that needs to be, not only developed, but validated and implemented so we can further look at the signaling pathways that are identified in autism and these related disorders, along with synaptic structure and connectivity.

Let's see, there was, also, a recognized need at looking more at family trios in terms of genetic screening and that we also combine genomics data with exposure data to be able to drill down more into some of the environmental exposures.

So that was, essentially, the update. There was, also, a recommendation that we need to determine whether or not some of the documented abnormalities that we see in individuals in ASD, that were mentioned in Chapter 3, if those are actually present at birth and whether or not they're a risk

factor for autism or if it's something that's acquired after birth.

Any questions? Did everyone get an opportunity to read the Chapter 3 update?

Mr. Robertson: This is Scott Robertson. Are you taking comments at this point?

Dr. Insel: Yes, I think so. Lyn, that was a great summary and a great job in putting, really, a diverse, kind of, science together. Not easy to put it all in one chapter. So let's open this up and take a few minutes for questions or comments.

Mr. Robertson: So this is Scott Robertson. I had a couple of comments. One of which is on formatting, and I don't know whether this can be changed, but, like, members of the public, if they're reading this, some of the paragraphs on here, as compared to the other chapters, are really, really, long.

Like, the first one, including the

citations, is, like, 440 words. So that makes it really hard on a readability sense. I just wondered if some of these large paragraphs could be split, like, into, you know, parts, you know, to make the readability a little bit easier, because someone, you know, eyeballing this sees, you know, a whole page that's a single paragraph like that, of text, where it's not broken up into smaller bits, it's a turnoff for some people from a readability standpoint, so I wondered if that could be changed.

Dr. Daniels: Hi, Scott. This is Susan from the Office of Autism Research Coordination. That's a part of the editing process. We were really focusing on getting the content right here, but the OARC will continue to get the editing finalized for publication and that will all be checked through, and looked through, by a professional editor.

Dr. Insel: But maybe what we can

do, Susan, in line with this comment, is turn it into bullets or to break it up, because it's really dense.

Mr. Robertson: Okay.

Dr. Insel: I wrote this; I can take full responsibility to say that it's not good. It needs to be changed.

Mr. Robertson: Okay. The second thing more was a content kind of thing. There's a comment there on etiology saying that autism is, I think it was like, likely distinct etiological -- there's like several different etiologically distinct conditions, or something like that, was mentioned in there.

Do we have enough real justification in the scientific literature to use the word likely versus, you know, maybe, possibly, et cetera? I mean, likely just seemed very strong language when the research base on the etiology of autism is still evolving.

Dr. Insel: If I can respond, this is Tom, I think, at this point, we can say definitively that, with the new diagnostic criteria, you'll have etiologies within autism spectrum disorder that include Rett Syndrome, fragile X, many single gene mutations that are quite different.

So we know already that within that group, which may represent 8 to 10 percent of the whole population, you have distinct etiologies, whether the other 90 percent come from a diverse set of causes is still conjecture, but it seems like enough when you know that about some fraction. And we would say the same thing about hypertension or almost any other major medical problem that's so complex.

Mr. Robertson: Okay. It was mostly in reference to that that seemed to be fitting into a subtyping and it seems like, for instance, diagnostically, we're moving in the other direction, that we moved from these

separate categories on autism to autism spectrum disorder, so that, you know, it's being moved in the opposite direction as autism being thought of as a unified spectrum, you know, diagnosis.

Dr. Koroshetz: It's the opposite, that it's more going towards an umbrella term that includes a lot of heterogeneity within it.

Dr. Insel: Yes, but it's an interesting point, Walter, and I think, again, if you look in other areas of medicine what you see is a tendency, initially, to cluster everything and then, and particularly, you see this now in cancer, where the focus is on what they call precision medicine, or coming up with far more specific diagnostic entities based on many levels of information that come in.

I think autism is, for better or for worse, is at that more primitive stage of saying, we don't know enough to know how to

break this apart. Let's cluster everything based on clinical presentation, but one would hope that that's just a stepping stone to being able to do this in a way that really does get informed by the biology.

However, you know, the little bit of biology we know, even now, though, would say that there are multiple etiologies in those cases where we know about a cause.

Ms. Abdull: Hi. This is Idil. First, I want to say, Lyn, you did an excellent job, not just even telling us, but also, you and your team, and your experts, putting it together, because there are a lot of risk factors for various different ethnicities, and where you live, and I think, if I go back to that oversight hearing in Congress, the Congressman from Utah was saying, why is it so high in Utah and not so much in Alabama?

And so I don't know if that question was addressed, but there are,

obviously, various, maybe genetic predispositions, but then there are also some environmental factors, and I think it's important to note that.

And then I also wanted to ask you, or have a comment, about the traffic. Does that mean, then, urban areas that have high traffic have less people with autism than, say, rural areas? And then my other comment or question would be about the couple of research that came out that said, the age of the father and the weight of the mother, and I don't know if that's just America, but in other countries, mostly third-world countries, men have children up to their 80s, and we haven't seen autism.

And also, maybe it's just America, but other countries, particularly third-world countries, the more meat that one has in her bone, the healthier and the better. And I haven't seen that, so I don't know if the research was done in Hollywood or what, but

that just made me think, that can't be true. That just doesn't jibe with our community and with so many other countries.

And I wanted to see if Lyn or anyone can talk about those risk factors and if there is a way to comment on them. It doesn't necessarily have to be on this report, but it just, sort of, was a red flag in my mind.

Mr. Robertson: This is Scott Robertson, because I just wanted to make a comment in relation to that, is that, I think one of the things, considering autism is being thought of in other countries, is that, culturally, people look at developmental disabilities, disabilities, neurology, things like that, very differently.

So I would take with a grain of salt sometimes, you know, the rates being diagnosed here versus other countries, and I think there's a little bit of research evidence to back this up, is that, in many

other countries there's an underdiagnose because of stigma, because of cultural differences, so autism is not looked at through the same lens that we look at here, in some cases, simply because people look at disabilities broadly, or developmental disabilities broadly, different than they do in the United States.

So I wouldn't necessarily say that, you know, the way people think of, or rates, or causal factors in terms of people understanding in other countries may always be comparable apples to apples in the United States.

Ms. Abdull: You're right, Scott. It's not, but the way autism is hitting those of us that are from the third-world countries. When we come here, you can't miss it. You couldn't miss it. They're non-verbal, they are severe, they have behaviors, so while in those countries, maybe if they had on the Asperger side, or PDD-NOS, they

could, sort of, mix in with the regular population and nobody would notice.

But in Europe and in America, you know, in North America, Canada even, you can't miss it. So for whatever reason, there's got to be some environmental factor. Maybe there's some gene that we're carrying, but there has got to be some other risk factors that, when we come here, it's just blooming.

And I'm just not sure if there's enough research done with that, and I don't want to dismiss it as that, in those countries, they were underdiagnosed, not the kind of autism we're getting here, that couldn't be missed.

Mr. Robertson: And I guess we can agree to disagree because I just don't think there's any evidential justification to say, autism in the United States is different than autism around the country. I mean, I think that the research, you know, shows completely

the opposite.

And if you look at, for instance, some of the anthropology research that's being done by Dr. Brinker and others, you do see a lot of the cultural differences, and things like that, across autism of autistic people of many, many different diversities, including autistic people with very significant challenges, you know, are found around the world.

I mean, you know, people have studied this, you know, and I don't want to belabor the point too much because this is getting outside the scope of the chapter, but I just do think that this is an important point to, you know, understand.

Ms. Abdull: I understand what you're saying, Scott, but I assure you, there are hundreds of families in Minnesota that have children with autism, some of them multiple kids, all of them non-verbal. This didn't exist in Somalia, if we're just, even,

talking one country.

So the notion that autism in America is different than autism in Somalia, I would say 100 percent yes, not maybe all of the spectrum, but the way that autism is hitting, it is silencing an oral society. So I'm completely, respectfully, disagree with you in that it is hitting us severely and there's got to be some environmental risk factors.

I'm not a scientist, but I do want to make the comment that there has to be some risk factors that, perhaps, we have some gene that is interacting with this, but it is not the same, Scott. It's just not the same. I don't remember anyone not talking in Somalia.

Dr. Insel: This is a good discussion, but I'm not sure that it will change anything that's in the current chapter. Let me see if there's any comments about what we have in front of us.

Dr. Carey: Actually, could I

throw one thing in? I mean, I think it points to the first chapter and one thing that comes up is, we make a lot of discussions like this, this is Matt Carey, we don't really have a lot of data. There is very little data on, you know, epidemiological data, on autism in Africa right now, and very little data elsewhere, you know, in many other places.

It's too bad Geri's not here because, I mean, Autism Speaks has a study going on in KwaZulu-Natal. They have a study going on in India, which I think, you know, in, sort of, Southern Africa, I think that will probably be the first study. I think it might be the first study out of India really following this.

We don't really have, really, even epidemiology, we don't have the characteristics, and these are big holes. And I think we need to, you know, have this to understand more of what's going on in

these countries.

Ms. Abdull: Yes. Thank you, Matt. We do need to understand that. I just don't want parents' voices, or views, or comments to be dismissed because we don't have the data. Yes, we don't have the data, therefore, it's a gap. But the idea that these parents are delusional and we're seeing things that are not there, it's simply not true.

Dr. Carey: Yes. I don't think, well, especially nobody on this group, is calling anyone delusional. You know, I think there's room to kind of explore what's going on on both sides. You know, frankly, I think there's a big move to look in more countries and I think if you look, one of our committee members, I think, was co-author on a paper in Nature, discussing, you know, autism outside the U.S. I don't want to say foreign, sorry about that, but outside the U.S., and in cultures where we haven't been looking at it

so closely.

Dr. Insel: Maybe this is something that we want to remember to include in Chapter 7 under infrastructure and be able to include some global surveillance, but in this chapter, I think the relevant point, Idil, that you're bringing up is that, and from my reading of it, Lyn and her group did a great job on this, to really force the increased focus on environmental factors, which, as she says multiple times here, have been in the plan previously, but they're just still not getting the traction that many people think needs to be there. Walter?

Dr. Koroshetz: I was just going to say, the discussion, I mean, I think everybody is right on the phone, the issue is, they're separate questions, I think. There's one that's a global question of autism rates around the world, but I think a very separate question is this incredible natural experiment that is mentioned where

people come from a fairly low incidence rate, and they move to another country, and they see a huge change.

So we've seen biology like that occur, you know, in all sorts of conditions. I mean, multiple sclerosis is the one we study. People move to the Northern hemisphere or stroke, they move from the stroke belt up, and you can see the changes with the move.

So it seems like a really interesting natural experiment to get at the environmental change, but it's a separate issue from the global rates. I think they're both important.

Ms. Abdull: Right.

Ms. Redwood: I'm hearing, Idil, that you want me to add in, under the gaps, that we look at this issue of other populations moving to the U.S. and having higher rates of ASD that aren't (unintelligible) or just --

Ms. Abdull: Yes, I think that's important, and that could be your call, Lyn, but I really like what you did and I think it's important to note that there are many, many, not just even Somalis, but Nigerians, that many people from third-world countries, we're not sure why, whatever environmental factors that that is, we're not sure why, what's in their genes, they carry it, but there are many communities that, when they move here, for some reason, autism is higher, as the previous speaker just said, that for other conditions.

And so I think it's important to note that in the gap. So maybe we can do further studies so we can say research says, rather than now, a parent says, or somebody says. I think it's important to note that in the gap if you would.

Dr. Kimbark: Hi. This is Donna Kimbark. I just wanted to point out that, in Question 7, we do address a little bit of the

Somali children in Minnesota. We talk about the CDC ADDM Network infrastructure is expanded to include six sites evaluating prevalence in younger children, and one of these sites is funded by Autism Speaks, and the NIH will determine the prevalence of ASD with Somali children in Minnesota.

And I don't know how far that goes, we'd have to talk to Geri a little bit about that, but perhaps we could talk, in there, about the global surveillance and comparing that to what the results come out of that study in Minnesota.

Mr. Robertson: Tom, I had just one other comment, like, not related directly on the chapter, but my understanding is that, next year, more can be done with next year's strategic plan in terms of the time and doing a more extensive rewrite on the plan and I wondered if one of the major priorities that could be incorporated, not with this plan, but for next year's, is to put much more of

an emphasis on looking at autism across culturally, across languages, different ethnicities, races, and things like that, you know, as a major thing to be considering and putting, you know, anthropologists that are, you know, at a really major priority for next year's strategic plan, to put that on, you know, just as something to be thinking about when we're looking at this next year.

Dr. Insel: Well, it's a great idea. I think the committee will have to decide how it wants to handle what we do in 2013. So I would say, if it's something that you think is very urgent and needs to be in the plan before then, best bet is to make sure it shows up now.

It really depends on how critical you think it is to have it in here. I guess I'm less concerned about the gaps and more concerned that, what we capture here are the new findings and then what we put into the gaps are those things that are suggested by

some new discovery or some new opportunity.

This one, I think, has been around for a while. I was just looking through the 2011 update to see how we handled it there, but, you know, I'm not sure that what we're talking about is driven by profound new insight or new finding. Maybe I'm wrong and maybe I'm just missing it. I don't see it, though, in the part of Question 3, for instance, that tries to capture what is new.

Dr. Kimbark: I just want to also mention, this is Donna again, that, as far as the international surveillance and epidemiological research, one of the gaps that we talk about in Question 7 is that as well. So some of this will be hit on in later questions.

Dr. Carey: Tom?

Dr. Insel: Yes.

Dr. Carey: This is Matt Carey. There was at least one study, maybe two, this year and if discussion points kind of get

brought up by new studies, then, you know, maybe we want to include it, but there was one, I think it's British Journal of Psychiatry, Migration and Autism Spectrum Disorder: A Population-Based Study. It was out of Stockholm and I believe, just in the past few weeks, there was a similar study out of the Netherlands, also looking at, you know, immigration and autism prevalence within immigrant populations.

So, you know, it is something that has a research base for the year. So, you know, I think there is a hook in that to include it in this year if it's needed.

Dr. Insel: So I guess the question for the committee is, is this something that we want to put into Chapter 3 or do we want to continue with what we have under surveillance and suggest that we use, and we can reference those papers, Chapter 7 to say that, a real gap is understanding more about the prevalence relevant to immigration

and relevant to global rates where the surveillance need, as you just heard from Donna, would be to increase the information that we have from a global perspective.

Dr. Battey: Tom, this is Jim Battey. I think it's a better fit with Chapter 7.

Dr. Carey: I agree. This is Matt Carey.

Ms. Abdull: I have a question, because I think Chapter 7 is more about surveillance, right? So international surveillance, the Somali surveillance in Minnesota, what have you, but Question Number 3 is risk factors, and I think there's someone that just said there's been a couple of studies in different countries, and there is one study in Sweden that says Somalis that come to Sweden are also having higher autism.

So there is a risk factor for people that come from different countries, particularly third-world countries, when they

come to more first-world, or Europe and North America, that there's some sort of a risk. So I really think there must be a way, to at least add in the gaps, that we need to figure out what that risk is, whether it's genetics or whether it's environmental, but there is a risk in these families.

Dr. Insel: Can I just clarify? Idil, if I take your comment, you know, precisely, what you're saying is, we have to define the risk and that means, first, through surveillance, identifying what is the risk. I'm not sure that we know that, either for your own community or for any other population.

We just don't have the population-based studies done in the United States that we may have in other countries. So, you know, I think what you're --

Ms. Abdull: I see what you're saying, we need those data, I just want to speak as a parent, that sometimes government

officials or researchers take the really longer highway, if you will, rather than just a shortcut, and if we just say, let's do the surveillance, let's wait for the surveillance, then we might be missing out researchers who might be reading this and want to do research on those communities, or those ethnicities, that come from third-world countries to these countries and say, well, why is it, even though maybe there is not tons of research, but that's how research gets started; somebody has an idea.

And I just think we need to mention somewhere that, yes, surveillance is there and we need to do more surveillance, and I don't think America can control the surveillance that's done in Africa, or even in Europe, but the risk factors is something that the U.S. researchers can take a look, given that they see it's mentioned somewhere in the IACC report.

And I think Lyn said something,

there was a sentence to include that, and I'm not sure why that would cause a problem if there is a way we can say, and cite some of that research that was done, either Sweden, or Scotland, or other countries, and say there's a -- go ahead, Lyn.

Ms. Redwood: Yes, Tom. I was just going to comment on what you said about not really having the surveillance data. When we look at just the data that comes out of the CDC, they're seeing things like, in Iowa, there's 1 in every 343 children who have ASD, but when you go right next door to Minnesota, it's 1 in 81.

So I think, just things like that, you know, looking at the rate of autism in New Jersey, which we know is probably polluted, and it's some of the highest in the country, and also in Utah, and that was something that was brought up during the recent hearings.

I think there is opportunity there

to go into those communities and sort of dig for what the differences are, and maybe that's something CDC is doing now that Coleen could mention, but I do see that as a gap. And I also wanted to mention that, Chapter 3 is predominantly written by the experts.

And so this is the opportunity for the IACC members to sort of put forth their own personal insights and what they see as gap areas, because the gaps that were identified here were predominantly from the experts.

Ms. Abdull: I agree.

Dr. Koroshetz: So it sounds like there's, maybe, some consensus to put mention in Question 3, under the environmental exposure paragraph, that investigating the changes in environment potentially related to increased risk of immigrant populations as they move to industrialized countries is an area of needed study?

Ms. Redwood: Yes, but I think

also, Walter, they need to look at some of the differences within the CDC data. I think that's really telling.

Dr. Boyle: So, Lyn, this is Coleen. So we are doing some of that, and just a clarification, we don't have a system in Iowa, nor Minnesota, but we do have one, obviously, in Utah. And as you mentioned, there is variability from the location to location.

And so the ADDM investigators are looking at the association between autism prevalence and a number of environmental factors, such as hazardous air pollution, so they're trying to, you know, within the state programs, make the best of those resources and trying to replicate some of the findings that others have alluded to.

Dr. Insel: So what about doing this, to go back to Walter's comment, to include a sentence in the environmental exposure piece of this to note the two papers

that Matt mentioned where there are data that have been published about effects in immigrant populations and to recognize that as an opportunity to begin to ask questions about environmental factors that may be relevant.

As Walter mentioned, this is being done in many, many other disease areas and hasn't really gotten much traction here at all.

Ms. Abdull: I agree.

Dr. Insel: Is there any concern about adding such a sentence into the piece on environmental factors as one of the various approaches that we can now use going forward?

Dr. Boyle: Yes, this is Coleen. I mean, I think it fits both in Question 3 and Question 7.

Dr. Carey: This is Matt. I mean, I think, you know, this is one of those points where, you know, I think it's kind of

a false dichotomy that there's really division between the two. You know, I mean, surveillance is feeding directly into risk factor work and I think the first step really is surveillance on this.

You know, without identifying a population to work from, you know, it's going to be difficult to start. You know, the work may go in parallel, but I think we need to identify a population to work with first before we can move forward.

Dr. Boyle: Yes, and these could be complimentary approaches.

Ms. Abdull: So we can do both of them.

Dr. Insel: You generally want to define the risk before you look at risk factors, but I think, as you said, Matt, there is already some data about this, particular from Sweden, which could be brought to the table. So with that as a new finding, it does open up a new opportunity.

Let me see if there are any other comments on this chapter before we take this to a vote.

Ms. Crandy: This is Jan Crandy. I had a question on the gaps piece, and maybe this is just language, I just want to know if our group, under the prioritization, can be based on expert consensus? Are we saying that we want to say our committee is going to say that we're going to endorse that list of ten priorities because it doesn't feel like we're making a decision there since the word is can.

Ms. Redwood: I think they're saying that it could be based on expert consensus, but also on looking at these other opportunities. If you continue reading the sentence, it goes on to looking at windows of susceptibility in terms of taking those environmental factors and looking at whether or not they could cause the injuries we see in ASD and whether or not those different

chemicals that were identified work on the same signaling pathways and the same susceptibility genes that we see in ASD?

So I think there are several different ways to approach it. Does that answer the question, Jan?

Ms. Crandy: That does. I just wanted to know if your committee was saying, we're going to endorse this list of ten and that's our priority or it should be open to more. And I guess what you just said, that is leaving a window open.

Would this chapter also be where we come back to the study for the vaccinated versus unvaccinated?

Ms. Redwood: I suggested that when we had our call and, Dr. Insel, do you want to respond to that?

Dr. Insel: Well, this is an issue that we brought up in the 2011 strategic plan. I'm not sure there's anything new since then that we'd want to add here other

than what we said then, which was pretty directive at that point, which was the continuing work with the National Vaccine Advisory Committee around, you know, what should be done as well as awaiting the report from the Institute of Medicine, unless somebody thinks that there's new discovery in this arena that demands something different?

Ms. Crandy: I just think that we should have some mention of it in our document going to Congress, since it was brought up in the autism oversight hearing. I don't want them to think that we don't recognize that there isn't a study.

Dr. Insel: Was there something at the committee hearing that would suggest that we should think about this in a different way? Is there a new finding or any new research on this?

Ms. Redwood: One of the new findings, and it doesn't in the medical research literature, it was actually in the

legal literature, but it was from a group that went back and reviewed, and this was several attorneys, the cases that had been compensated in the Vaccine Injury Compensation Program over the years, and then in interviewing this family, they found that, I want to say it was something like, 80 children also had a co-diagnosis of ASD.

Now, whether or not their initial injury that they were compensated for had been seizures or some other injury, something similar to Hannah Poling with mitochondrial abnormalities, I'm not certain that that was actually identified, but the fact that was reported in the paper is that there was an association between vaccine injury and the subsequent development of autism spectrum disorder symptoms.

So I do think that is somewhat of a new finding.

Dr. Insel: How do other people on the committee want to view this? What's the

sense of the committee?

Dr. Carey: This is Matt Carey. I actually did not find that study very compelling at all. For example, one of the cases they cited, the family was actually arguing against autism as a diagnosis for their child in the court, and it was, yet, listed in that.

A second issue, I think, with that one is, I would not want to include it in the plan. You know, as mentioned, there was a survey done. I think there's no demonstration or no comment, in fact, I think they stated clearly that there was no ethical approval sought, or achieved, for that, and I don't think it would be appropriate to include.

Dr. Guttmacher: This is Alan Guttmacher. I would also draw a distinction between the scientific literature and the legal literature. Both have their worth, but this is not something that has had the same

kind of peer review, that is, have others with scientific credentials examine the data, argue about it, et cetera, et cetera, so I think it really has a different level of, sort of, value to it.

And I think that it would be a slippery slope to start including legal pronouncements rather than what we've really done so far. I think the committee, for years, has addressed what we're doing with scientific evidence and that kind of thing.

Dr. Insel: Other thoughts or comments from other people on the committee?

Dr. Battey: This Jim Battey. I agree with Alan on that. We need to stick to peer-reviewed publications, which is the gold standard for developing new information.

Ms. Crandy: Right. And this is Jan Crandy, and I agree with that, to only keep scientific peer-reviewed studies in our report. What I'm wondering is, could we say, it continues to be a gap that there is not a

study of vaccinated versus unvaccinated? Some kind of sentence like that, just to address it, that we recognize that this has been brought forth a number of times publicly and the question is not answered yet.

Dr. Insel: Would that recommend a randomization study? I'm not sure what the consequences or implications of that would be, Jan.

Ms. Redwood: We've discussed this before and I think the consensus was that it was somewhat unethical to select a group of children to not be vaccinated. It would be based on children whose parents had elected not to vaccinate voluntarily.

Dr. Insel: But that wouldn't be a randomized sample then, would it?

Dr. Battey: That would certainly not be a randomized sample.

Dr. Carey: This is Matt Carey. I think there's been a couple abstracts and a couple presentations, I think, in the past

few years on this that have shown, you know, that the biases involved are strong enough that they actually showed that, you know, if you just take the data as they are, you know, the autism risk was actually lower in the vaccinated population because siblings of autistic children tend to be highly represented in the non-vaccinated population and they also have about 20 percent recurrence risk.

So, you know, it's a very difficult study to do, you know, even as a non-fully randomized controlled trial. But that said, you know, as I said earlier, I think that there's work going on, you know, there's going to be datasets being developed in, I think, some of these ongoing projects, you know, that may address some of these questions.

And so, you know, is it really something that's a gap or is it something where the data are actually being produced?

You know, we have the National Children's Study, we have, you know, the Norway cohort, we have other things going on, I mean --

Ms. Redwood: I think one of the problems, Matt, and you bring up the National Children's Health Study to accomplish this is that they would have to actually go out to be able to actively enroll parents who are not vaccinating to have enough power.

Dr. Carey: Which would then introduce exactly the sorts of biases that are possibly out there in that cohort.

Ms. Redwood: Some of the things that I've heard in terms of the biases, though, may be important to look at more closely in terms of whether or not the people are following, let's say, organic diets or purposefully using green cleaning products in their homes, those types of things, that I think would be important to look at too.

Dr. Insel: I know when we've talked about this in the past, and we have at

many previous IACC meetings, one of the concerns that's come up is that, so much of what we're hearing from our experts is that the environmental factors of interest are prenatal and that the additional information, which is in this update in Chapters 1 and 2, is the increasing evidence that there are brain changes in the first year, well before there's any evidence of symptoms, so that autism, whatever it is, in many children has already started long before vaccinations are on the horizon.

So a question comes up about whether raising it at this point is consistent with the scientific evidence that we're putting into the update in the earlier chapters.

Ms. Redwood: Tom, one of the things, though, if you look at the report that Walter mentioned with regard to the group that had regressive autism and the immune system abnormalities, there was a

study that came out that reported the increase in head size was actually more prominent in the regressive group of children with ASD.

So, you know, I don't know that we can say that, you know, those brain changes were all prenatal. I think it would be interesting to try to tease that out more.

Dr. Insel: Well, the changes we have, I mean, and this is what we've cited in Chapters 1 and 2, are between 6 and 12 months. That's where both the EEG and the neuroimaging are pointing to. Now, those are in children at risk, because that's the only group that can be studied, but I'm trying to capture what the update is telling us about the state of the science, and the state of the science is very much changing the way we think about autism to put it into a trajectory that begins very early.

And even though the symptoms may be at a rather late stage. That's a

different way of thinking about this. I bring it up now because what we're talking about is more suggesting that autism is an injury that happens in a child that has nothing wrong until a particular event.

It's a different perspective. It's possible that those two could co-exist, but it's not the message that we've been conveying in most of this document so far.

Dr. Carey: Tom, also, I mean, I think in previous discussions, I think the IACC has sort of taken the policy of not going down to that granular level of, you know, such a very specific, you know, exposure recommendation. But anyway, I think, in general, I don't see it, at this point, as being, for most of the reasons that you've given, you know, I don't really see as being appropriate to include at this time.

Dr. Insel: Well, this might be something we put to a vote. I'd be interested in hearing perspectives from other

people. I think this is one of those areas where there's real disagreement on the committee and what ends up in the plan is a function of what the majority of the committee wants.

Mr. Robertson: Tom, I had another comment on this, is that, I agree with Matt, but I have some concerns about including things in here that, as was raised, could conflict with what the science is saying, and what you're pointing out, that we're seeing, you know, the indication which, you know, seems to make sense, you know, from a plausibility standpoint that, you know, the genetics, and the biology, et cetera, you know, you could see it within children, you know, of young age.

And I'd be hesitant to put stuff into the plan that conflicts with that and doesn't have a really good, you know, backing behind of why we should actually include it in the plan, that there isn't justification

to put that, you know, divergent language in the plan.

Dr. Insel: Other comments or thoughts? Let's do this, not hearing any additional comments, why don't we take a vote on Chapter 3 with the recommendations for changing the formatting, as was suggested, in some of these long paragraphs, including that sentence with the two references around the immigrant populations under the discussion of environmental risk factors.

If we can vote on that, then we'll come back to this third recommendation, which has to do with including a sentence about a remaining gap in the need for a study of vaccinated versus unvaccinated children. So we're going to be talking about the first two modifications and we'll vote separately on the third one, and I'll turn this over to Susan for the voting.

Dr. Daniels: Okay. Do I have a motion on the floor to accept this language

with some additional attention to formatting, which will happen for all of the chapters during the editing process, and some additional language from Walter, Matt, Idil, et cetera, to address risk factors associated with immigration?

Dr. Battey: So moved.

Dr. Daniels: Second?

Male Participant: Second.

Dr. Daniels: All in favor?

(Multiple Ayes)

Dr. Daniels: Any opposed? Are there any abstentions? So the motion carries to accept this chapter with those changes. So second vote. Do we have a motion on the floor, somebody can propose how we would modify this chapter to include concerns about vaccinated, unvaccinated studies?

Ms. Crandy: Lyn, I wish you would make that because you're much more articulate than I am.

Ms. Redwood: Well, I just would

say that it's something we continue to hear from the public over and over and over again, and it's something that should be addressed somewhere in the updates. So I would make a motion that it be added to one of the gap areas and I don't know how the committee feels about putting in any information regarding the recent hearings, because that's where this issue really was heard very loud.

Ms. Abdull: I was wondering if I can say something about that, and I'm no expert in this, but I've seen parents of both sides. I've seen parents who were afraid, who had, like, the first child had autism and said, no, we're not going to vaccinate. We're tired of that. We think it's the vaccinations. And so they didn't vaccinate their third and second, but then those kids also got autism.

So I mean, I want to make sure that, as a public person, I represent everyone possible. I just wonder, I don't

know. I just wanted to throw that out there. There's a lot of Somalis who are not doing it, but then their second and third kids, unfortunately, are still being diagnosed with autism.

Ms. Crandy: This is Jan Crandy. My issue, also, is that, there is going to be a larger population now that is choosing to not vaccinate their children because they feel this question isn't answered and that's going to have an effect on our population too, and what's that impact going to be?

That's why I think that the question does need to be answered so parents feel more secure in making that decision. I know parents that don't have children with autism that are choosing not to have their children vaccinated because they are nervous and they don't want this to be a risk.

So if it is not a risk factor, we need to have that definite answer. If it is a possible trigger for some kids, parents

need to know that too, that it could be a possible trigger.

Dr. Insel: Jan, that's very well said, and I think what the committee is struggling with is, really, a question of the feasibility of doing a scientifically rigorous randomized controlled trial that would answer this question to everybody's satisfaction. I don't think anybody disagrees that it's an important issue, but the question is how to resolve it and whether some of the current efforts underway may be the closest we'll get to being able to do that, not perfect, but could be informative, or whether this still needs to be recognized as a gap and if that gap requires doing an RCT, and what the feasibility of that is still a question.

These are all the issues we dealt with in talking about this a couple of years ago in the IACC, and that was when we brought in the NVAC to get expert opinions about

this. They did provide us with a pretty good picture of what was possible and that was how it ended up in the Institute of Medicine.

So really, I think the remaining issue for the committee is, is there anything new or anything different that needs to be done in the 2012 update beyond what we did in 2011?

Ms. Crandy: Tom, this is Jan again, I think our committee needs to recognize, and continue to recognize, that we value the public's opinion and that we aren't ignoring it, because I think there is public perception that we are ignoring this issue or trying to avoid the answer.

Dr. Insel: So just again, I'll read from the 2011 strategic plan update. It says, "Of note, the committee receives many public comments that reflect concerns about vaccines as a potential environmental factor in autism. Some members of the public are convinced that the current data are

sufficient to demonstrate that vaccines do not play a causal role in autism and argue against using limited autism research funds to do additional vaccine studies when many other scientific avenues remain to be explored."

"At the same time, those who believe that prior studies of the possible role of vaccines in ASD have been insufficient, argue that investigation of a possible vaccine/ASD link should be a high priority for research, such as a large-scale study comparing vaccinated and unvaccinated groups."

"A third view urges shifting focus away from vaccines and on to much needed attention towards the development of effective treatments, services, and supports for those with ASD." So that's in the plan. The only question, I think, in front of us is whether that needs to be restated, or modified, or in some way, put back in yet

again, or whether what we have in there is sufficient.

As I said at the beginning, we don't want to restate what's in the plan.

Mr. Robertson: Tom, this is Scott Robertson. I think that what's in there, you know, already sufficiently conveys a lot of the space on issues. I also worry about any potential, and I think that what was worded previously was worded well, and I worry about the inclusion of any language in there that gives the idea that we have more of a definitive belief that there is a causal link and cause, you know, folks to, you know, not vaccinate their kids in the rate of vaccination not happening in England, and cause consequences of that.

And I also just don't see the need to shift from the previous language. I mean, it seems to state it pretty well.

Dr. Insel: So given the time we've spent on this, and we've been here

many, many times, I think at the end of they day, this is just going to have to be a question that we put to a vote. If people want to put language into this particular update about the need for a study of vaccinated/unvaccinated children, which is what we've had as a motion, we can vote to do it or not to do it, and it really comes down to what the committee wants.

So, Susan, I'm going to, again, turn this over to you and we'll start that process.

Dr. Daniels: Okay. I'd like to do a roll call vote, probably, for this, just because it sounds like it's not going to be unanimous and we want to be clear about the count to make sure that we're accurate. So the motion, as I understand it, would be to add language to the update to describe the need for further research on a study of vaccinated and unvaccinated populations and autism risk.

And the language has not been specified yet, but we could even vote just on whether this type of language needs to be added, so if that sounds accurate to you, we can go ahead.

So all in favor, Thomas Insel?

Dr. Insel: No.

Dr. Daniels: No. Geri Dawson is not here. Denise Dougherty? David Mandell?

Dr. Mandell: No.

Dr. Daniels: Coleen Boyle?

Dr. Rice: This is Cathy Rice standing in for Coleen because she had to leave, no.

Dr. Daniels: Tiffany Farchione?

Dr. Farchione: No.

Dr. Daniels: Alice Kau, or sorry, Alan?

Dr. Guttmacher: No.

Dr. Daniels: Donna Kimbark?

Dr. Kimbark: DoD will abstain.

Dr. Daniels: Abstain? Okay.

Thanks. Walter Koroshetz, is not here. Linda Birnbaum?

Dr. Birnbaum: No.

Dr. Daniels: Laura Kavanagh?

Ms. Kavanagh: Abstain.

Dr. Daniels: Abstain. John O'Brien?

Mr. O'Brien: Abstain.

Dr. Daniels: Abstain. Larry Wexler or Michael Yudin?

Dr. Wexler: No.

Dr. Daniels: No. Idil Abdull?

Ms. Abdull: No.

Dr. Daniels: Jim Ball? I don't think he's here. Anshu Batra?

Dr. Batra: No.

Dr. Daniels: No. Sally Burton-Hoyle?

Dr. Burton-Hoyle: No.

Dr. Daniels: Noah Britton?

Mr. Britton: No.

Dr. Daniels: Matthew Carey?

Dr. Carey: No.

Dr. Daniels: Dennis Choi? Jose Cordero is not able to vote. Lyn Redwood?

Ms. Redwood: Yes.

Dr. Daniels: Scott Michael Robertson?

Mr. Robertson: No.

Dr. Daniels: John Elder Robison? Alison Singer?

Ms. Singer: No.

Dr. Daniels: So I think from this vote it's -- oh, Jan Crandy?

Ms. Crandy: I appreciate the discussion and I understand everybody's views, but I do need to vote yes.

Dr. Daniels: Yes. Okay. Have I missed anyone?

Dr. Battey: This is Jim Battey and I vote no.

Dr. Daniels: Jim Battey. Thank you. Okay. No. So then we, I think, clearly, have an answer on that one that it's

not accepted by the vote of the majority of the committee.

Dr. Insel: But we will go ahead, make a couple of revisions to this chapter and then we'll be able to move on to Question 4. Let's take a break at this point.

Dr. Wexler: Susan? Excuse me, this is Larry Wexler. Could you give us the vote total, please? Is that acceptable?

Dr. Insel: Susan's counting that up. Why don't we plan to, it says on your slide that we'll reconvene at 1:00, but I think it's now, by my watch, 12:35, so let's plan to reconvene at 1:15 as we wait for Susan to give us a final vote.

Dr. Daniels: Okay. So what I have, and staff can also verify, have 14 no, 3 abstentions, and 2 yes's. 15 no, sorry. Okay.

Dr. Wexler: Thank you.

Dr. Insel: And so we'll take a break, reconvene at 1:15, let's try to start

promptly at that time, and we'll start with Chapter 4. Thanks, everybody.

(Whereupon, the above-entitled matter recessed at 12:35 p.m. and resumed at 1:16 p.m.)

Dr. Insel: Hello. It's Tom Insel here. Welcome back, everybody. Let's do a quick roll call and see who's with us before we start on Question 4.

Dr. Daniels: Okay. Thomas Insel is here. Denise Dougherty? David Mandell? Coleen Boyle?

Dr. Rice: Cathy Rice is here for Coleen Boyle.

Dr. Daniels: Oh, Cathy. Hi. Tiffany Farchione? Donna Kimbark?

Dr. Kimbark: Here.

Dr. Daniels: Here. Alan Guttmacher?

Dr. Guttmacher: Here.

Dr. Daniels: Walter Koroshetz is here. Linda Birnbaum?

Dr. Birnbaum: Here.

Dr. Daniels: Laura Kavanagh?

Ms. Kavanagh: Here.

Dr. Daniels: John O'Brien? Larry Wexler? Idil Abdull? James Ball? Anshu Batra?

Dr. Batra: Here.

Dr. Daniels: Thanks. Sally Burton-Hoyle?

Dr. Burton-Hoyle: Here.

Dr. Daniels: Noah Britton?

Mr. Britton: Here.

Dr. Daniels: Matthew Carey?

Dr. Carey: Here.

Dr. Daniels: Dennis Choi? Jose Cordero? Lyn Redwood? Scott Michael Robertson?

Mr. Robertson: Here.

Dr. Daniels: John Robison? Alison Singer?

Ms. Singer: Here.

Dr. Daniels: Jan Crandy?

Ms. Crandy: Here.

Dr. Daniels: Jim Battey?

Dr. Battey: Here.

Dr. Daniels: Okay. So I think we still have a quorum.

Dr. Farchione: Oh, this is Tiffany Farchione. I'm here too.

Dr. Insel: Okay. Welcome back, Tiffany. Okay. We've got a quorum, we're ready to go, and let's start on Question 4. We've got Anshu and Noah were the dynamic duo who worked on this. Maybe the two of you can take us through it very quickly to see what the committee needs to know about and we can discuss whether the committee has any comments or questions.

Dr. Batra: Okay. So Question 4 is, basically, the treatment interventions for ASD. And as Tom mentioned, Noah and I were co, sort of, heading it, and our experts -- oh, and Tiffany, I'm so sorry, Tiffany. Tiffany Farchione, Noah, and I were the

committee, and then our experts were Connie Kasari, Beth Malow, help me out here, Noah --

Mr. Britton: Jeff Wood.

Dr. Batra: Jeff Wood, Lin Sikich, and Matthew Goodwin, who were all just wonderful help. So in terms of what new research has developed regarding treatments for ASD over the last two years, the first paragraph, basically, talks about the more, I guess, sort of, mounting evidence supporting the benefits of early intervention, early behavioral intervention, and several studies were published looking at implementation of interventions on toddlers in community-based interventions, or natural settings, and found to be, again, very effective; positive.

There was an RCT in toddlers with ASD testing the Hanen method that showed some very positive gains in the toddlers with poorer play skills and, really, in another study that Connie Kasari published, identified some key components of joint

attention and play in terms of active ingredients, or targets, to really address, which then showed to help language acquisition, which was actually more long term.

So that was exciting to, again, have research that suggested, earlier the better, and again, targeting certain core areas in the set. Real quickly, another really exciting study that Geri published just last month showed the Early Start Denver Model in toddlers and found that implementation of that model showed some really nice changes in EEG, specifically, the event-related potentials.

And so, really, you know, one of the first papers identifying a biological marker that correlates with a certain intervention. So again, really exciting to see something that we now can, you know, target and see some positive brain changes.

Dr. Insel: Anshu, this is Tom.

Can I just interrupt for a second?

Dr. Batra: Yes.

Dr. Insel: I thought the committee might like to know that work was just cited by Time Magazine, an important scientific resource, as one of the ten medical breakthroughs of the year.

Dr. Batra: Isn't that exciting? So it was wonderful to see that that was, you know, identified and, you know, again, as a parent, and as a pediatrician, my heart was singing because, you know, finally there's something now we, you know, have that's tangible to identify changes and positive changes.

Okay. And then another study that Sally Rogers did and published just a couple months ago, again, looked at the Denver model and compared it to a parent-delivered group versus a control group that just got community-based intervention, and found that both of those groups showed, really, some

nice developmental gains and actually, reduction of some of the core autism symptoms.

And specifically, the group that was younger and that got more hours in the community-based group actually had more developmental gains. And then the second paragraph is looking at treatments, really, for the older set in terms of school-aged children and adults.

And, you know, the first statement in that paragraph, I think, is really important to note, which is that, there's, you know, just a paucity of research on interventions for the adolescents and adults. There's plenty in the young set, but very little in the older individuals and the reviews done by Taylor to support that.

And I think that's important that that be highlighted as the first sentence in that paragraph. And in terms of other interventions over the last couple of years

has been shown to be effective for that set, specifically, were social skills interventions.

One that actually looked at a social skills intervention within the classroom in, sort of, the older age set and found that that was positive in developing more peer interactions; positive peer interactions.

There was another study that showed CBT and social skills training as an effective means of decreasing anxiety in the higher functioning individuals and that it was actually long lasting and not just short term, so that was a new finding.

And also, the social skills training, specifically, had a positive effect on core social symptoms in the ASD population. And then lastly, there was one RCT that addressed depression and anxiety in adults using mindfulness therapy, so that's another, sort of, sudden finding for

treatments in that adolescent and adult population.

The third paragraph is describing medications and what's new in the medication front.

Dr. Insel: Anshu, maybe we can just do this at a summary level, because I think everybody has the document.

Dr. Batra: Okay. So with the medications, I apologize, basically, what's new is that, again, showing some effects of risperidol and parent training was more positive than the medication alone. There was another nice study looking at N-acetylcysteine as a treatment for irritability.

A couple other studies looking at SSRIs and reducing some of the repetitive behaviors in kids and adults. And mixed results there because it was unclear whether it was age-related or it was due to the actual class of the drugs.

And then a real exciting finding in the fragile X population was an RCT of Arbaclofen reducing social avoidance. And then there was a nice study, actually what Tom had mentioned, ten trials looking at oxytocin and improving social interaction.

Oh, and then some studies looking at treating comorbid conditions within the ASD population, and specifically, several studies supporting the use of melatonin, especially extended-release melatonin, for treatment of night awakening and reducing some of the sleep disturbances in the population.

And then there was one study looking at donepezil in reducing REM sleep. And then another study looked at epilepsy associated with ASD and the treatment with lamictal and ensure epileptic discharges and found that it did help that EEG, but unclear in terms of what the relevancies are.

And then a couple other exciting

things that were a little bit outside of the routine behavioral and medication realm. Some really nice studies looking at exercise, and dance, and yoga, and music therapy in improving behavior in the ASD population. And then a study looking at TMS, transcranial magnetic stimulation, and improving some executive functioning indices, so that was very positive. Noah, your turn.

Mr. Britton: Yes. Okay. I'll just go over this really quickly. I covered the gaps and both of us contributed to both sections, but the gaps is more my work. The biggest thing we got from our experts was a need for better outcome measures and more objectivity in measures, and a search for biomarkers so we could phenotypically differentiate populations for whom treatments would work or not, and also, side effects as a result of that.

We started mentioning problems with risperidone and the fact that we do need

to look into the genetics behind who it's going to work on and who it's going to cause side effects for.

I pointed out something I've heard a lot from the community, which is that, comorbid conditions, co-occurring conditions, vary significantly in the autistic population. Certainly, there's a higher incidence and the question is, will treatment for comorbid conditions be as effective on an autistic person as they would be for someone who has anxiety for what may be a different reason?

And not to say that this is definitely true, just that this needs to be looked into, and this would affect intervention and treatment to see if people need to adjust their types of interventions based on whether they're dealing with someone in an autistic population.

Oh, by the way, before I forget, when we start discussing this, my

prosopagnosia extends to both vocal and inflections, so I'm not going to know who any of you are when you're speaking, and for that, I apologize. I will try very hard to remember who's who, but it's going to take a while. So just, please, say your names if it's important.

Several of our experts suggested repetitive transcranial magnetic stimulation needing to be looked into further. There's a sentence here which was added, which I didn't notice in our last edit, it was added in our last edit, and I'm not really okay with it. It's a rewording of something I wrote initially.

It says, "Emphasis on development of behavioral treatments should continue." I would like to change that to say, which, what I initially wrote was that, we need to look into longevity and effectiveness of behavioral interventions, not necessarily that we need to emphasize developing them.

Outcome measures, more objective measures, using fMRI, EEG, et cetera, again, that's sort of a restating of what we said at the beginning. The biggest thing that I wanted to mention, which I put in, which was controversial and was difficult, but we sussed it out within the subcommittee is, the importance of which interventions are going to be effective for different individuals.

And some of these are used in the community with very little evidence to support of negate, and we really need to work on testing stuff like this. Complimentary alternative treatment approaches, initially, I wrote about chelation therapy, but of course, there are tons more that, really, no one knows what they're going to do when they're doing them, and we do need to figure out what's going to be harmful, what's going to be useful, and figuring out exactly why these things are useful.

And finally, biggest point, which

is one the big reasons I'm on this committee, because I wanted to get this across that, we do need to look into global effects of interventions. There are many interventions which report success because they have changed a single behavior or increased socialization, et cetera, but have not looked at the consequences of this in terms of changing the autistic person's life.

You know, is this person truly benefitting from social skills which they are able to report success on in a study in a lab setting, or is this something they're just parroting back, and this is not helping them, and is, in fact, leaving them more confused than before they entered the study?

Also, I did include something that we do need to work on, making sure treatments is done on truly important things and not on harmless behaviors, which, I would say, “stimming” is an example of a harmless behavior, some people may disagree with me,

but I do think that's an example where people trying to address “stimming” specifically, from a behavioral standpoint, are really looking at it the wrong way and are causing a lot of harm to the autistic people in the process, and, you know, is this worth the anxiety and confusion that it will cause?

I wrote a sentence, initially, which was subsequently changed, about the importance of using interventions to direct people's excellent talents and abilities into useful areas. This was reworded a bit to the point where I think it's lost a lot, but I'm okay with this compromise, which is it says, "A worthy goal to any intervention is to help individuals with ASD understand and utilize their strengths."

Whereas, I would say that should be the main goal of any intervention. And of course, we talk about ethical standards, making sure we're taking care of everybody, vulnerable populations, and making sure

benefits and burdens of research are distributed fairly among the entire populations. So that was my section.

Dr. Insel: That's great. Thanks. Noah, before we get into the discussion, can we go back to the middle of Page 4, I think it is, that piece that you said you didn't want to have in there. Actually, in reading it, I'm not sure why it is in there, so could we just -- I think what you were suggesting is that we simply delete one of these sentences.

It's a sentence that says, "Likewise, emphasis on development of behavioral treatments should continue."

Mr. Britton: Right.

Dr. Insel: If we take that sentence out, and we could keep the “likewise,” and go to, "as the effects of behavioral interventions become more apparent, better information regarding the most critical components of treatment are

needed."

And then the next sentence says what you said you wanted, "The effectiveness and longevity of treatment effects in real world settings must also be established."

Mr. Britton: Yes, that's fine by me.

Dr. Insel: Okay.

Mr. Britton: That'd be great.

Dr. Insel: So that would be one edit that I hear you recommending is, we'll just remove that middle sentence.

Mr. Britton: Yes, great.

Ms. Singer: This is Alison. I have a question about that paragraph as well. I'm wondering why the committee chose to call out repetitive transcranial magnetic stimulation as the example of the non-pharmacological treatment that you chose to highlight? What was the thought process there?

Mr. Britton: I guess I can answer

that. So several of our experts pointed out the usefulness that they've identified in papers here. This portion wasn't specifically written for that. It was added in as an example. And certainly, there are many others that are equally valuable.

If you want to add in more example, I wouldn't be opposed to it, although, it would make this even longer.

Ms. Singer: I mean, is it necessary to have that example in there or can we just shorten it up to say, "Alternatives to pharmacological treatments should also continue to be explored."

Mr. Britton: I agree with you. I'm okay with that.

Ms. Singer: But not so much weight on that one.

Mr. Britton: Sure. And that's fine by me. Anyone else?

Dr. Batra: Yes, I’m okay with it.

Ms. Crandy: This is Jan Crandy.

I have a comment on the behavioral interventions. Was there any discussion about comparisons of models of any interventions, because I think those studies are lacking. I know there was a completion of the fourth year of the LEAP model versus TEACCH.

Mr. Britton: Yes.

Ms. Crandy: Was any discussion about it, because we do need a comparison of the different models, for instance --

Mr. Britton: Yes. So that's a great question. Unfortunately, and I can certainly send you this paper, Jan, my first draft said, we really don't know what works as far as those social interventions go. We have a lot of stuff with really weak results. From a scientific standpoint, we can't say anything is effective.

And the stuff that we found tries to argue, oh, look, we found parent reports saying satisfaction with this intervention,

which is really, scientifically, meaningless. So as it is now, we can't point to any model and say this is better than another because, truthfully, the real answer is going to be something we haven't even tried yet, and this is, unfortunately, where the data are.

So I initially wrote something saying that we really can't say anything works, which was edited a bit to be, I guess, more positive, but, yes, we can't compare those models.

Ms. Crandy: Can we not add some language in here, though, to compare some of those models?

Mr. Britton: Well, it's just comparing stuff that doesn't work very well. That's the problem. You know, you can compare things that don't work all day, but it's not very useful.

Ms. Crandy: But you could look at what outcomes there are? I would say behavior. This would say there's some good

studies.

Mr. Britton: There are good studies, but they show very little effects. That's the issue. There are well -- yes, go ahead.

Ms. Abdull: Oh, I'm sorry. This is Idil. I also have a question about the comparing of different methods, whether it's the TEACCH, or the Floor time, or the ABA, so are you guys saying, then, the only thing that we know scientifically is that these two studies that have recently been done, the ESDM and then the other one, is that, it's for younger, younger kids, so for less than three and four?

And then less than about 25 hours or less, and I ask you this because you're always, at least I'm always, hearing that the Lovaas study that was done decades ago that, out of 19 children, 47 percent were recovered, which, in my opinion, I don't agree with, but, you know, it's been cited so

often I don't think you recover, per se, from autism, you get so much better that you are able to function.

And my hope is that my child will be like Scott and others here, but it's been cited so much, at least when legislators in our state and others are trying to get Medicaid, or insurance, to pay for X, Y, Z therapy versus X, Y, Z therapy, and they're always saying, we want 40 hours for a 3-year-old, a 10-year-old, and a 20-year-old, and I'm always thinking, where do they come up with these research?

And I just wonder if you can comment on that now, with the expert, at least in my eyes.

Ms. Crandy: And this is other studies. There's the Gallo study that came after that study that different study, the replicated study of that original study.

Ms. Abdull: So what are we recommending, I guess? What are we saying?

Are we saying these two studies are the only ones that we know and they're for very young children, and for older kids, for non-verbal kids, we're not really sure?

Mr. Britton: Idil, which two studies are you referring to?

Ms. Abdull: You said the Early Start Denver Model, that one.

Mr. Britton: Yes, actually, I have a similar complaint about that. This is something else that was added in the most recent revision, and I missed. In my initial paper, which I submitted, I pointed out the Rogers, et al. paper, which said that the Early Start Denver Model is no more useful than community practice as usual, in that population which they had used.

And I believe Geri personally edited this in the last month to put ESDM very prominently at the beginning of this, and I'm really not okay with that. Obviously, it's a conflict of interest, but

also, I don't think the science is there to backup what she's saying.

I think the evidence is that, Early Start Denver Model may be slightly promising, but compared to other ABA, either intensive or non-intensive, it has not shown anymore use, and I don't really want that section -- I definitely don't want her description in here of that.

And again, it's because it's just not up to par of scientific standards that we need to uphold, just like all of these other interventions. So I agree with you on that point.

Ms. Crandy: This is Jan Crandy. Did you guys look at the 2011 RCT on the LEAP model?

Mr. Britton: Obsolete model?

Ms. Crandy: The LEAP, L-E-A-P.

Mr. Britton: Oh, LEAP, yes. Sorry.

Ms. Crandy: They have another

study that happened in -- it's been around for a little while, but it had another study that came out in 2011.

Mr. Britton: Right. No, I've looked at all of these models and although, personally, I think they're less harmful than ABA, the science doesn't support them being effective, based on having enough evidence. And, you know, I would rather people were doing LEAP than ABA with their children, but we just can't support it with evidence, and that's what we're stuck with.

You know, there's weak, weak evidence in those studies to say, you know, this had mild gains, which were not looked at longitudinally, and were in a very specific setting, and were not terribly useful for improving a child's life.

Ms. Abdull: So is it safe to say --

Ms. Crandy: I don't want to argue -- sorry, Idil. I don't want to argue

studies with you, but there are some studies, ABA studies, that show IQ gains and show difference of -- what part are you not liking in those studies? There are some good studies that show some long-term --

Mr. Britton: I'll try and get you one of the meta-analyses and reviews of all of this stuff that says, we really don't know. One of them is something I co-authored that talks about, we just don't have enough evidence to say any of this stuff really works.

And we could add something in that said there are things that appear promising and we don't have enough to say that they are efficacious. I think that would be fine if you want to add that in.

Ms. Crandy: I don't think that insurance would have allowed for all these mandates, insurance companies, if they did not feel the evidence was adequate for ABA. No insurance company would be covering that

if they did not feel there was some substantial --

Mr. Britton: Right. And ABA is the one that has enough evidence, but the others just don't, and that's what I'm saying.

Dr. Batra: So this is Anshu, and I guess my understanding was that this particular section is to identify what's new, right? And, yes, granted, I think it is kind of heavy in terms of, you know, when Geri edited it, I think it is a little bit heavy on some of her studies, but having said that, I do think that it's something that is new, and it's interesting, and it shows some promise.

So I think we could definitely reword this and say that, yes, you know, these studies have shown some promise and, you know, we'll have to --

Mr. Britton: And I think I agree with Jan and Idil that we could put that in

and include some other stuff that may have shown promise.

Dr. Batra: Right. You know, I think our original draft, I think, you know, didn't shine so much light on this particular model, it basically just, you know, highlighted the fact that, yes, there's more evidence to support early intervention and early behavioral intervention.

Ms. Abdull: This is Idil again. I guess what, at least, I'm trying to say is that, we don't really know. And even though a lot of insurances and a lot of states pay for this through their home and community-based waivers, not necessarily because there's so much research, but a lot of times it's because there's a lot of lobbyists and a lot of big people that influence the legislators who vote for those parents.

So it's sort of, you know, American politics; who's got the big voice, who's got the big lobby? But on the

scientific tests, I agree with you guys that, I think it's important to say, this is what little we know, so most of it we don't know. We don't know what works for what kids, where on the spectrum, and what little has been done within the last couple of years, it only gives us more questions, not more answers.

Mr. Britton: I think that's great. I agree with that. Go ahead.

Dr. Insel: I think this is a committee, so you have comments from your expert group, which I'm now hearing you want to rewrite, or reformat. It seems to me the question, then, you have to address is, what is the evidence base that you would accept and how would you define knowing something, how would you define what gets included and what doesn't?

I think what the expert committee did when they looked at this is to say, it needs to be an RCT. You need to have control group, it needs to be randomized, and you

have to have a significant difference on predetermined outcome measures. And if that was present, then it got included, and this is just my memory of the discussion, so I may have this a little bit wrong, if it wasn't present, it wasn't included.

If you want to redo this at this point, it's really late in the game, but you need to be able to provide the IACC with a different definition of evidence that they want to accept that's different from what your experts gave you. I haven't heard that yet.

Mr. Britton: I don't think anyone's questioning --

Dr. Batra: This is Anshu. I'm not proposing changing the content. I'm just proposing to, maybe, thin out some of the emphasis.

Mr. Britton: I agree with that.

Dr. Batra: Yes.

Dr. Insel: But specifically, what

would you change, because we're going to have to move on if we want to capture the -- you know, we've got three more chapters. So what do you want the IACC to look at and to alter? You know, the concept here was that you guys were going to present the final version that the IACC could comment on.

You're coming to us now saying that you're not happy with the final version, so it puts us in a very uncomfortable position because if this isn't what you want us to vote on, we're not going to have time to have another meeting between now and the end of December to finalize this.

Mr. Britton: Well, I guess -- go ahead. Sorry.

Dr. Mandell: David Mandell. I was going to make a suggestion about the Early Start Denver Model. The original trial is already discussed and wouldn't necessarily be part of this update at all. The part that would be part of this update is the parent-

mediated version, which was the one that was tested and published this year and found not to be more effective than community practice.

And I don't think that speaks to the effectiveness of ESDM, per se, I think what it speaks to is that we don't know how to design and successfully implement parent-mediated intervention, because this is not specific to Early Start Denver Model, it's also the PATH trial in the U.K. and Hanen More Than Words, both of which were rigorous randomized trials with parent-mediated intervention.

And I wonder if you could actually take out the Early Start Denver Model randomized trial completely. I think the association with brain findings is a very interesting new step related to biomarkers for treatment effectiveness, but you could put in a more general statement about the fact that we have a lot of work to do with parent-mediated intervention if we think that

that is an appropriate avenue for intervention.

Ms. Crandy: And I do like the part, though, that talks about, this is Jan Crandy, that the children that received more hours of intervention in the younger children made more developmental gains than the older children. I think that's important to --

Mr. Britton: Unfortunately, in the actual paper, correct me if I'm wrong, David, I believe it was still not a significant gain compared to the community-at-large that neither of them was showing --

Dr. Mandell: No, there was no interaction by program and age, so there was difference in the relative effectiveness of community-based practice and Early Start Denver Model for the parent-mediated version of Early Start Denver Model.

Mr. Britton: And so I, unfortunately, don't think we can include that either because it's not supported by the

evidence. Thank you, David. That's a great point that you were making. I was referring to Jan's point. Sorry. Go ahead, David.

Dr. Mandell: I mean, certainly, I think Jan's point about, in general, the gains observed in younger children were greater than the gains observed in older children, I think, may be an important point to make, but it doesn't relate to the relative efficacy of different intervention models.

Mr. Britton: Okay. Yes, and I think that's been stated before in the strategic plans, but we can certainly say that this continues to be supported. Is everyone okay, then, because I know, Tom, this is late in the game and I'm just saying, if we can vote to agree to change this draft, then we don't have to do another meeting, but is everyone okay with cutting the part on Hanen, cutting the part on ESDM, and saying, in general, something to the effect of, we

are not certain what specific parent-mediated interventions are going to work and how to do those properly?

Dr. Insel: The irony is that, of course, this was the very thing that was recognized as the breakthrough of the year by a general --

Mr. Britton: I realize, but Time is not a reliable source compared to the primary articles.

Dr. Insel: No, that's why it's ironic, but I wonder whether the committee, because one of the things that this provides is the biomarker, which is, you know, the exemplar, which we keep saying we need in the gap section --

Mr. Britton: Yes, I think we can include that. I think that's good to include, so I don't want to cut that. And we can say that's true of the ESDM finding. That's great, but cutting out the ESDM finding on the other aspects; on the

behavioral aspects.

Ms. Crandy: So are you talking about cutting from where it starts, "In a different RTC", cutting from there down?

Mr. Britton: In a different RTC, I don't know which --

Ms. Crandy: That's the --

Mr. Britton: Oh, no. I was talking about cutting much earlier. I do want to cut the Hanen thing because it didn't find significant effects. It found very minor effects and that toddlers with poor play skills benefitted more than the others, but neither one benefitted that much. And also, cutting that sentence entirely and then rewording the ESDM portion.

So I guess, cutting the first sentence of the ESDM section, early intervention, so just say, "ESDM is the first study to demonstrate that behavioral interventions can result in changes." And, you know, that whole sentence is fine. And

then the second sentence indicating that, "The parent-delivered ESDM intervention was not significantly different than typical community interventions."

Dr. Insel: So, Noah, this is Tom, I'm just trying to get to an end game here. Would it be helpful, as the kind of most efficient way to handle this, if we go back to the very first sentence in this section, where it says, "Evidence for the benefits of early behavioral intervention continues to mount, with researchers now focusing on testing interventions for infants and toddlers," da-da-da, and then add in there the proviso that the effects in most of these studies continued to be modest at best, or something like that, leaving the rest of this in play, but simply put in the context that --

Mr. Britton: I don't think that would help, no, because I really don't want this to be emphasizing two studies that

really don't show us very much. You know, you are the one who always says you don't want the gravel, you want the boulders, and this is some pretty weak gravel that's been included.

Dr. Farchione: This is Tiffany. Can I just make a small comment? Because I think that the whole point is that we're supposed to be describing the research that has occurred over the past year, right?

Mr. Britton: Yes.

Dr. Farchione: So this is what has occurred and this is a description of it, then it probably should remain. And if you have that caveat, you know, that the effects are modest and, you know, something to the effect of, you know, we don't know what the, you know, "active ingredients" of any particular therapy are, that, I think, could be reasonable.

The issue is, is that, you know, if we start cutting out descriptions of

various studies, then we're going to lose the -- it won't be a complete document.

Mr. Britton: I think we can include the studies, we just don't need to claim that they found something when they really didn't find anything of significance. That's the issue. If you want to say the Hanen study didn't find significant changes, that's great.

Ms. Singer: This is Alison. One of the reasons I think that the ESDM paragraph feels so long and heavy is because, and I don't know if this is because Geri wrote it or not, but it seems like the second part of that paragraph where she's explaining the RCT on the parent-mediated intervention, it sounds like she's trying to explain away why it didn't show efficacy, okay, and that takes many, many lines.

And I think the way David stated it earlier, if we could just put in the one sentence so that that describes that.

Mr. Britton: I agree.

Ms. Singer: I don't think we need all of that description in there to try to explain away why the parent-mediated intervention didn't show efficacy. So, I mean, I think it's fine to include the Early Start Denver Model. I think it is really important to include the fact that there was brain-based changes; a biomarker for brain-based response to treatment.

I think in addition to the ESDM study there, though, there were other studies that showed that that were published this year, including one on pivotal response training that Kevin Pelphrey did, so if you want to broaden it so that it's not so Early Start Denver Model we could say, Early Start Denver Model, pivotal response training, and other ABA interventions.

But otherwise, you know, I think we do have to recognize that Early Start Denver Model has, sort of --

Dr. Rice: This is Cathy. I would second what Alison's suggestion was, because I think it's very important that we recognize that, this is a movement forward, it's not where we need to be, but it is a movement forward to be, one, addressing treatment in toddlers, to be looking at parent-mediated, to have any effect whatsoever, in a very hard to reach and an area that hasn't had much research.

So although it's not ideal, and we really need to highlight that in the gaps, I definitely agree with the perspective of not cutting it all, but to couch it in a way that sort of moderates the conclusions.

Dr. Insel: This is Tom. I'm going to have to intervene here because time is passing and we're going to have to get this to a vote. I'm afraid we're not going to be able to rewrite this. That should have been done over the last three months and either you're going to make some minor

modifications here that will allow us to vote on it or we'll have to figure out a way to vote on what's in front of us, but this is not going to be workable for us to spend the next half hour trying to rewrite these paragraphs.

Mr. Robertson: Tom, I had a few comments. One, I support adding in that language of, as a compromise on it, if changing it and adjusting it in ways it substantially won't be possible, then putting in that, that only small to moderate effects, as you suggested, I think, would be a good compromise.

I do have concerns about members of the subcommittee whose own research is in here, you know, rewriting things that aren't necessarily taking the wishes of the rest of the committee. I mean, I worry a little bit about objectivity that happened here in this process, but I think that that's for a longer discussion.

But I also have some comments in other parts of this chapter here that we didn't get to yet on the medications and other areas.

Ms. Abdull: I agree with Noah and Scott. If we can not just so much emphasize on the Early Start Denver Model, but also add other studies that David mentioned, and then also say that it was, that's like Dr. Insel said, modest. The efficacy was modest. In fact, if there is a way to not change everything, but to make sure that we know less than we did before, even though we did more in a way.

Mr. Britton: I agree.

Ms. Crandy: This is Jan Crandy. I would support taking out the Hanen though, if that really did have no positive -- you know, the outcome is so minimal. I don't think we should be recognizing it because there's other studies that showed a little bit more. I mean, that RTC LEAP model shows

more than moderate change in the kids. If we're not including that, I don't think we should include the one that has moderate gains.

Mr. Britton: Tom, can I propose a solution to this?

Dr. Insel: Please do.

Mr. Britton: Okay. So everyone who has an opinion on this, can I write you language today and send you something in email, and then we can have everyone vote by email response on whether they accept it?

Dr. Insel: The concern about that is that this could easily drag on and, you know, this is basically what we've been doing for the last couple of months.

Mr. Britton: Right.

Dr. Insel: And what you have in front of you is what I understood you and your experts agreed to.

Mr. Britton: Well, I didn't agree to it because I was so focused on my half,

which, as you know, took, literally, until the last minute, and actually longer, that I couldn't get through all the details that Geri added in, which none of us wrote.

Dr. Burton-Hoyle: This is Sally and what I was more concerned about was the big change between the draft and exactly what Noah is talking about. So that's the part that troubles me the most. If we had a 5 o'clock deadline on voting, or something like that, I would be in support of that.

Dr. Insel: So how about this as a compromise. We've got folks in the room who have been part of this process who can redraft that section and spin it back to you, is it possible that we're going to be able to get something back in this first three paragraphs in the next hour so that, before the end of this meeting, we could come back and vote on this section?

Dr. Burton-Hoyle: That seems reasonable.

Dr. Insel: What I'm hearing is real concern about the way in which the Early Start Denver Model is featured as such a -- when the main findings were actually in the last update that was in 2010 and 2011. And then --

(Simultaneous speaking.)

Dr. Insel: -- as well. So, Elizabeth, if you and Sarah could rework this over the next few minutes and then we'll spin it back to the committee before the end of the meeting, but I don't want to hold up the rest of the document for this piece.

And again, it's very frustrating because all of this should have happened over the last month and not in the meeting itself. Someone, I think it was Scott, had other comments about other --

Mr. Robertson: Yes. I have comments on other parts of this document that are --

Dr. Birnbaum: Just one sec, Tom,

this is Linda Birnbaum. I'm sorry. I'm going to have to leave. I had hoped we would be through by now. I may try to get on again later. Cindy Lawler will be standing in for NIEHS.

Dr. Lawler: Yes, I'm here.

Dr. Insel: Okay. Thank you. And I'll have to step out for a few minutes right at 2 o'clock as well, but Susan will take over chairing.

Mr. Robertson: So a couple of other things that aren't as substantial in terms of my comments and concerns in other parts of the document, one of which is in the medication area. There was a discussion on some of the anti-psychotic, kind of, medications used at times, like risperidone.

And it mentions some of these effects like weight gain, et cetera. My understanding, and forgive me for those who are more, you know, knowledgeable in this literature, is that, not only was there

weight gain, but there's, like, a risk of diabetes from the use of said medication, and I wondered why that's not -- you know, if there's risk for things like that, why is that not mentioned in that section?

Mr. Britton: Yes, that's a fair point. It was type-2 diabetes from excessive weight gain, so it may not be specifically mentioned in there, but --

Dr. Farchione: Can I specifically address that?

Mr. Britton: Sure, please.

Dr. Farchione: Sure. So the issue is that what we were doing was quoting the recent meta-analysis and that was where they found the weight gain. All of those issues, like metabolic syndrome and whatnot, are already part of the label for those medications. So it's not a new finding. And actually, that was one comment I was going to make.

And I realize that it's my own

language that's in there as part of the medication issue, but maybe in order to avoid that kind of confusion, instead of saying that the study concluded, maybe we could say the study confirms that, you know, while they're effective in the treatment of behavioral disabilities, there are side effects?

Mr. Britton: Yes, that's fine by me.

Mr. Robertson: This is Scott Robertson again. One of the other comments I had on the medication section, and maybe this is similar reasons as diabetes not being mentioned, is on the adverse effects of SSRIs. My understanding is there's been some linkages there in the literature a little bit for adolescents broadly, and I thought in the autism adolescents literature on some other kinds of things in terms of some mental health challenges, and possibilities of linkages on suicide, et cetera.

Is it because, again, those already have been previously, so that's why those have been left out because it's not a new update and that's why those things aren't mentioned?

Dr. Farchione: It's not new information.

Mr. Robertson: Okay. And then the last comment was on some language, and I don't know whether this can be adjusted or not, but this came up in discussion when we were discussing Chapters 5 and 6, is it the language that's used in the strategic plan, at times, has been outdated in terms of modern language for community.

So for instance, like, non-speaking or extensive communication challenges is far preferred to non-verbal, for instance, it's an outdated term, and for instance, “needing excessive supports” was the preferred term to be using versus “low-functioning” in Chapters 5 and 6.

So I had a little bit of a concern about the reference to high-functioning in this particular chapter, is that only there because the study, you know, referenced and used that term? I mean, is that the reason why there's reference in there to that?

Dr. Insel: What section is that in, Scott?

Mr. Robertson: The high-functioning?

Mr. Britton: I found it, yes. Sorry. The paragraph right before medications, talking about behavioral therapy and social skills training were useful for decreasing anxiety, and that was because that was the language in the actual paper that we were reading.

Mr. Robertson: And then along that line, and maybe this is also because it's the language on the paper, is that, my understanding is that the goal is to improve functionality, quality of life, et cetera,

and not necessarily be just focused on tinkering at every, you know, autism symptom in terms of repetitive behavior, et cetera, yet, some of the language in this chapter talked about, I think, reducing core autism symptoms, or whatever, which I guess would include, for instance, things like repetitive behavior that may, you know, not be harmful.

Mr. Britton: I think this is a battle we're not going to win, Scott, but I agree with you.

Mr. Robertson: I'm just letting everybody know. I mean, I know this could not necessarily be changed, but I'm just putting out my perspective on that.

Mr. Britton: Thank you, yes.

Dr. Insel: Scott, can we go back to the high-functioning sentence? This is Tom. Is there some reason not to simply change that to say “were useful for decreasing anxiety in some individuals with ASD,” without making a value judgment on

that?

Mr. Robertson: Is that possible for you to do? I mean, is that feasible? If you can do that, that would be preferable.

Mr. Britton: Well, the problem is, it may not be generalizable to people with low communication and the paper tested people with higher communication. And so I can't assume that this would be --

Mr. Robertson: Well, the way to write that, Noah, and this came up in Chapters 5 and 6, is to put specifically, you know, folks with major communication challenges. You know, just add more extensive, more specific language, or if it referred to, you know, high-functioning in the sense of, you know, IQ score, or whatever, you know, specifically say, you know, for instance, folks without, you know what I mean, intellectual --

Mr. Britton: Yes. I mean, it had a lot of specific criteria and it was quite

long, so I didn't want to get into all of that when this shorthand communicated it, but I understand your point and I'm fine with changing it if everyone else is.

Mr. Robertson: Okay. Because there may be a way to summarize that and still have it in a way that it's using respectful language, because the community of autistic people, you know, would prefer not to have the usage of low-functioning and high-functioning.

Mr. Britton: Right.

Dr. Insel: Scott, can you bring us back to that in the next two chapters as well? If you could just flag those issues if they come up.

Ms. Abdull: Yes, we talked about those.

Dr. Insel: We can take care of the language if it shows up. I hadn't seen it before.

Mr. Robertson: Yes, well, I've

taken care of it in Chapters 5 and 6 because I was on that subcommittee and I already had discussion of that, so I don't think functional language is apparent in 5 and 6.

Dr. Insel: Okay.

Ms. Abdull: This is Idil. That is true that, on Chapters 5 and 6, Scott and I were both in there, and we want to, just out of respect for everyone, just because somebody is not verbally speaking doesn't mean that their IQ is low. Instead of high-functioning I think we put high-communication or low-communication skills; if I'm correct.

Mr. Robertson: Yes, which is much more preferable because it's specific, yes.

Dr. Insel: So we'll change that in the next chapters. Is there anything else on Chapter 4 before we go to a vote?

Ms. Crandy: I do have a couple things, and I just wanted to bring up, what about people first language too, instead of saying autistic people?

Mr. Britton: This came up when we were discussing with some of experts, and I'm sure Scott can back me up on this, which is that, people first language is offensive to the autistic community for the reasons that it is implying that autistic people are, in some way, equivalent to people with cancer, and as such, we don't like that language being used on our behalf.

Ms. Lewis: This is Sharon Lewis. Can I make a friendly suggestion as one of the entities that had to navigate this difference of opinion around people first language versus autistic adults?

Mr. Britton: Sure, please.

Ms. Lewis: One of the things that we had started to do in some of our publications, and I could probably have staff dig out the language that we've used, is, we've actually incorporated footnotes or parentheticals that acknowledges these different preferences, and it may be

something that the IACC wants to begin to do at the beginning of their reports, because there are people who have autism who still prefer people first language, and there are people that are autistic adults who prefer to be called an autistic adult.

And I think that we have to acknowledge both sets of preferences and it may make more sense to just address that upfront in the report and go with whichever language. You know, I'm hearing that the subcommittee is recommending, you know, autistic adults approach, but acknowledging that there are other people that prefer people first, that there was no intent to offend anyone with the use of language.

Mr. Robertson: Can I comment on it? Sharon, just a comment, because I don't know if it would go anywhere, but I know that one bridging term that sometimes has been a amenable to both autistic self-advocates who prefer autistic people versus people

preferring people first language is the construction of “on the autism spectrum,” as in, “adults on the autism spectrum,” you know, “youth on the autism spectrum,” which seems to be more amenable and, you know, it's more a neutral kind of phrase.

I didn't know whether there was any possibility of that making its way into the strategic plan, though, in place of people first language, which, the previous chapters, I think, that we've gone through already, almost exclusively have used people first language, I think, throughout. I mean, I could be wrong and maybe it's a mix of language. Maybe there's inconsistencies. I mean, I didn't really check for it that much.

Dr. Daniels: This is Susan. I just wanted to add as a historical note that, in the past, since 2009, the committee had deliberately decided to use people first language and so if this new committee wants to do something differently, we would have to

go through the whole plan, at some point, and change it, but in this particular update, it might make sense to match what's in the previous plan, but we also could take language, like what Sharon had mentioned, and put it someplace in the preface or somewhere else in the document to explain some of these different points of view about how to use this language.

Mr. Britton: I'm cool with using “people on the autism spectrum” or including a footnote somewhere explaining the usefulness of both styles, either one is fine, and I'm glad you brought this up.

Ms. Crandy: This is Jan Crandy. Getting back to the document, then, in the gaps section, are you saying that we couldn't add something about comparison studies are needed or can we address it here, because I know you had a strong feeling that, since there's not other good studies, except for ABA, we can't have ABA comparison studies to

other types of models or treatment.

Mr. Britton: Well, I guess it's not so much that we don't want comparative studies, and there have been decent comparative studies, they've just found very little effects. So we could say, novel interventions need to be developed and tested to improve upon what we already have, and I feel like that would address your point and is actually a really important idea.

Ms. Crandy: Thank you.

Mr. Britton: Is everyone okay with that one? Susan, is someone taking notes on all these changes? I'm sure they are.

Dr. Daniels: We are taking the notes, but we will have to read back to you what we have with our notes when we are finished with the discussion.

Mr. Britton: Sure. Great.

Dr. Daniels: Is there more discussion that needs to take place on this

chapter?

Dr. Carey: This is Matt Carey. There's one thing I'd like to throw out, which is, on another topic, which mentioned oxytocin, and I think since the draft was started there's one study, it's, you know, an animal model study, so I don't know if it's that strong, but goes into long-term effects of oxytocin and suggests that, perhaps, long-term, you know, there may be actual side effects.

And I don't know if we need to temper the oxytocin part of this to, sort of, include that.

Mr. Britton: Well, we're not coming out in support of oxytocin, we're just saying that it's being looked into, and I think that's all we can do at this point.

Dr. Carey: Okay.

Dr. Daniels: Where are you, Matt? What page are you looking at? Is it on Page 2, the fourth paragraph? Is that where you

are?

Dr. Carey: I'm trying to see. Sorry, I think I just killed that window just as you spoke. So, yes, I apologize, I'm not exactly sure. I know it mentions it in there somewhere, but if Noah is saying that it's not really -- yes, it's just saying it's being looked into, then I think that's fine.

Mr. Britton: Yes. That's all we said in there is just one sentence saying it's --

Dr. Carey: Okay, then I don't think we need to reference that.

Mr. Britton: Great.

Ms. Crandy: Noah, this is Jan again. Sorry to be a pest. In the social studies, I had sent a study, it was from McCackin, I think, and LEAP, for social skills, and it was a comparative study of social stories versus directly teaching. Did you guys even look at that one? Do you know what one I'm talking about?

Mr. Britton: Not off the top of my head, but I'm sure I looked at it, yes. And again, I can send you several meta-analyses that say we just don't have enough evidence to be able to support any of these things. You know, we have a little bit, and some things are promising, but not that anything can be said to really work, because I have looked at things and they found stuff, but they're not necessarily consistent.

They haven't been replicated. They haven't found a whole lot in the process.

Ms. Crandy: So was one of your deciding factors is if a study was replicated you weren't taking first studies to consider them in this section, so it had to be a replicated study, because if it's a first study, and the study is good, you're not including them in here or you are?

Mr. Britton: I mean, personally, I think you're right. I haven't been looking

at first studies. I mean, I've looked at them, but I haven't been considering them as being significant enough to say that they're effective without replication. That's true.

Ms. Crandy: Okay. So that was some of your criteria of what made it into this chapter.

Mr. Britton: I would say, yes. I can't speak for the others on the subcommittee, but, yes, that was part of it. Yes.

Ms. Abdull: Hi. This is Idil. I just have to say, you know, as a mom, and as some of you are on the spectrum, this is the most depressing chapter. It just says to me that, after years and decades of research, we still can't help a family who is just diagnosed. We can't say, your child has this disorder and here's which therapy is going to work.

I just think we need so much more to do and that's probably why parents are

just so tired. We want answers.

Mr. Britton: Yes. People need to try new stuff.

Dr. Batra: You know, I want to bring us back to this chapter in terms of, you know, the task at hand, which is, you know, what's new and what do we need? And I absolutely agree with you, Idil, you know, as a parent, yes, you know, there isn't enough. But I think, again, we have to really address the task at hand, which is, identifying, you know, what's new and not saying that what's new is what's right, but this is what's new.

And then, in the gaps section, you know, the re-highlighting the fact that, yes, we need more. There isn't enough.

Mr. Britton: I agree.

Dr. Batra: So I guess, you know, I've been listening to all the comments and I think, you know, yes, it's frustrating, the treatments, and that's one of the reasons I opted to be on the treatment committee,

because, you know, as a parent and as a pediatrician, this is what we want.

And it is, you know, frustrating. There isn't enough out there that we know. There isn't enough we can do, but, you know, again, the task at hand is, you know, over the last two years, what has come up in research? And in the gaps, what do we still need? And I think that's where, you know, our emphasis, we can voice the frustration, or the need, for more research in X, Y, Z.

Ms. Abdull: I agree. Thank you.

Dr. Batra: Tom, are you still on here?

Dr. Daniels: Tom isn't on here. This is Susan.

Dr. Batra: Oh, sorry, Susan.

Dr. Daniels: I'm just stepping in for him while he's away. He had to take a phone call from the department.

Dr. Batra: Yes, no problem. So I just wondered if you can help guide us back

to, sort of, you know, how we can come to closure on this.

Dr. Daniels: Yes, so in the meantime, while you've been discussing, our staff has tried to take some of the comments you've made on that first section. Tom is just stepping back in. So it sounds like we're wrapping up discussion here. Our staff has taken some of the comments that were made about that early behavioral intervention section on Page 1 and have come up with a possible revision which would significantly shorten some of this.

Adding a sentence in the middle of the first paragraph saying, "While gains have been made in this area of research, the effects of these interventions, as measured to date, are modest." Hoping that will help.

Dr. Batra: Perfect.

Dr. Daniels: Leaving the information about the Hanen study there.

Ms. Crandy: No. This is Jan

Crandy.

Dr. Daniels: That is something that the subcommittee had originally had in there. Are you suggesting it needs to be stricken now?

Ms. Crandy: This is Jan Crandy. I would support taking it out because I know what's going to happen in our state, people are going to say that now it has some evidence and we should be paying for it.

Mr. Britton: Yes, I agree. I do want to cut that Hanen section, or say that it's not effective, or has not shown evidence.

Dr. Daniels: So that's, essentially --

Dr. Batra: Again, my understanding was, this is Anshu Batra, that the items that were highlighted at our last conference call, those are the items that we discussed and we revised. And some of these items were originally there.

Mr. Britton: Well, the original version of that language was quite different, and that was why I didn't complain about it at the time, and the edit that was made in the most recent revision is the one that's causing this to be truly misleading and highlight this --

Dr. Batra: And I think everyone agrees to just temper it down by, you know, basically, what Susan and her staff just have come up with, something along the lines of, you know, results are modest. And that way, you know, we're not saying that this is right, we're just saying, this is what's been reported in the last two years.

Ms. Singer: This is Alison. I would also add to that that, I think it really moves us into a dangerous zone when we start to decide which studies to put in here based on their public policy implications or based on concern that, by putting it in here, a parent may or may not choose to use the

intervention.

I mean, you could make that same argument for almost all of the studies in here. You could make it for the risperidone study, you could make it for a large number of them, so I think we have to really be careful about evaluating them based on the science and not on the public policy implications.

Mr. Britton: And the science is weak, and that's why I do want to make sure Hanen is not emphasized as being particularly effective.

Dr. Daniels: What Dr. Insel is suggesting is maybe we should come back to that whole issue after I go through the other points. So we've talked about there being a need, possibly, to make some changes in the early behavioral intervention section. So setting that aside, the other changes that I've noted are, adding a paragraph on people first language versus other types of language

to the beginning of the entire document to set the tone and that Sharon Lewis can help us with that.

Mr. Britton: Yes.

Dr. Daniels: So we could do that, and in some places, if it's easy to do in this, we could, you know, change in that one place to people on the autism spectrum, but I think, at this point, to go back and change every reference in the whole document might be a little bit time consuming, but hopefully the paragraph in the beginning will take care of some of that.

The next one I have is that you'd like to add a sentence on the need for comparative studies of treatments. Is that accurate that the committee feels that they would like to add such a sentence?

Mr. Britton: I don't think that was what was specifically suggested. I think it was that, novel treatments need to be developed and then tested, and that we need

to continue comparing things as we have been, and study more, which I think we said, actually, in the original language.

Dr. Daniels: Okay. So perhaps, then, we don't need --

Dr. Insel: Yes, I think that's in there already, Susan.

Dr. Daniels: Okay. All right.

Mr. Britton: Yes.

Dr. Daniels: And then striking a sentence on Page 4 in the middle that Dr. Insel went through with us, the emphasis on development of behavioral treatments should continue, so that would be stricken?

Mr. Britton: Right.

Dr. Daniels: So then, really, the only changes are the people first language paragraph and striking that sentence.

Mr. Robertson: Susan, what about the possibility on the change on the functional language?

Dr. Insel: Yes, so I was just

about to say that.

Dr. Daniels: That was another one.

Dr. Insel: That language would have to be converted to something that does not use the term high-functioning.

Dr. Daniels: Yes.

Mr. Robertson: Okay. So that is one of the amendments then. Okay.

Dr. Daniels: Yes, it is. Sorry. I didn't have that one on my list.

Mr. Robertson: Okay.

Dr. Daniels: So should we vote, then, on those last three? So within the group, do we have a motion on the floor to accept the rest of the chapter, except the early behavioral intervention section, with the changes I just mentioned?

Dr. Battey: So moved. This is Jim Battey.

Dr. Daniels: Okay.

Dr. Farchione: And seconded.

This is Tiffany.

Dr. Daniels: Okay. All in favor?

(Multiple Ayes)

Dr. Daniels: Any opposed? Any abstaining? Okay. So that motion carries to accept the rest of the chapter with those few mentioned changes.

Ms. Crandy: And I apologize, this is Jan Crandy, and maybe I missed you guys saying it, I thought there was a deletion of a sentence that was about the transcranial magnetic stimulation? It's on Page 4.

Mr. Britton: Thank you, Jan. You're right. It wasn't deleting the sentence, but just deleting the specific example.

Dr. Farchione: The rTMS example and then also the change from concluded to confirmed for the medications.

Mr. Britton: Yes.

Dr. Insel: Right. So --

Female Participant: And there's

so many things.

Dr. Insel: Yes. Are there any concerns in the committee with putting both of those changes in play? So we would take out the specific reference to rTMS and the term confirmed would be used in talking about side effects. Hearing none, we're going to accept those. We'll come back to that early behavioral interventions later in the meeting, as time permits, and we're going to have to move on because we simply can't spend anymore time on this chapter without risking not having enough time for the others.

So I want to move to Question 5, which deals with services, and in this case, is it David and Denise who had the lead on this?

Dr. Mandell: Yes.

Dr. Insel: So you can take us through this very quickly. We're already well-behind schedule.

Dr. Mandell: I will do it while

juggling. All right. So there's actually one change to the document that people have in front of them, the OARC, and I'll mention it as we go through. We tried to divide the services chapter into specific areas. The first is access and payment, noting the issues related to expansion of services through Medicaid, through the Affordable Care Act, and also, the proliferation of autism mandates for private insurance companies.

We also added there that, federal employees and military personnel now have expanded benefits for coverage of ABA services.

The second area that we attempted to cover was the issue of implementation science, or translating research into practice, pointing out that there are issues, both with existing screening instruments and the need to have better screening instruments before we start moving them into practice, and also, the number of studies that

proliferated this past 18 months showing that, interventions in the community do not look like those tests done in research trials, nor are the results as positive in community settings.

We highlighted in this update, even more recent findings about disparities in quality of care for Latino children and for foreign-born children. We also highlighted in this update, the new findings on wandering and elopement, and how much, you know, the magnitude of the concern.

And also, see this as an IACC success in that, this was an issue that came out of the IACC, resulted in a high-profile publication recently, and led to a change in the ICD-9 so now that there's a subclassification code for wandering.

There's new data on seclusion and restraints showing that this is a really substantial issue that has not been studied. And also, new data on mortality, finding that

individuals with autism have shorter life expectancy than their peers without autism.

And the final new finding related to caregiver burden and families of people with autism, and that when the service systems are not providing appropriate care for people with autism, it exacerbates the challenges, not just what the person with autism faces, but their whole family.

With regard to gaps that have emerged, we tried to tie the gaps very tightly to the new findings that have emerged. The first is a need to study these new policy initiatives that are being implemented nationally, with the idea that, by studying the mandates and the expansion of federal employee benefits, or benefits to military personnel, we have the potential to come up with a set of model policies that can be established for states and other payers to make sure we have cost-effective and high-quality care for individuals with autism.

The finding, you know, on the flipside, the lack of positive outcomes in community care suggests two issues. One is, the need for intervention developers to partner more closely with the people who they ultimately hope will use the intervention; to make sure that these interventions are designed in a way that makes them disseminatable.

And the second is to expand the research that we do to understand the best ways to move evidence-based practice into community settings. Then the other gaps are much more specific to what was described above, gaps related to disparities in care, gaps related to the urgent need to develop and test prevention and intervention strategies, to improve safety for people with autism, and also, similarly, issues related to family support and what's the best way to support families as a whole. And I'll stop there.

Mr. Robertson: I had a comment just on the summary, just briefly, is that, the one thing to emphasize, when checking back at the chapter, is that, my understanding from the literature and the message here in the chapter is that the increase in mortality, David didn't mention, it states here, is that, is mostly due to co-occurring conditions, you know, it's not a finding that, you know, autism, necessarily itself, causes you to, you know, more likely to die than other co-occurring conditions.

Dr. Mandell: Right. And, you know, also injury, and not just co-occurring conditions, you're right, it is absolutely co-occurring conditions, not autism itself, but also injury, which I think relates to the wandering and elopement issue as well.

Ms. Abdull: Hi, David. This is Idil. I was wondering if you could -- remember we talked about the access and payment where we said there are 31 states

that have mostly state-regulated private insurance that cover for early intervention, and then I had asked, or John, or somebody had asked, how many have Medicaid, whereby, Medicaid is covering for this?

And I think you said that maybe there was nine and then John said they were working on the data, so do we know how many states cover services and early intervention for autism through Medicaid?

Ms. Crandy: This is Jan Crandy too, and we're not referencing it in this, but we looked at the report on state services that CMS put out in 4 of 2011, I wish that was referenced in here, because we only looked at nine states. We really need to look at other states and how they're addressing the influx of services, and how they're funding treatment. That's a huge gap that we don't know.

Mr. O'Brien: This is John O'Brien, and there is a follow-up report that

is actually going to look at the balance of those states that should be done, hopefully, in the first six months of 2013.

Dr. Mandell: So I think we, certainly, can put in a line about the lack of knowledge of the specifics of how Medicaid is used to cover autism services. Idil, all 50 states use Medicaid to cover early intervention services, only a handful, though, have a specific CPT code for ABA.

Ms. Abdull: Right. That's what I mean. And they do it through their, you know, home and community-based waivers, but that's voluntary. So in other words, the state has to come up with funding and then CMS matches it. And it would just be important, like you said, to put a line there just so we can see the gap, because we're saying a high percentage of people with autism have Medicaid, yet, there is a huge gap. Medicaid is not covering the specific autism services.

Ms. Lewis: This is Sharon Lewis.

Ms. Crandy: We don't even know the exact number of Medicaid recipients that have an ASD diagnosis.

Ms. Lewis: Can I ask, kind of stepping way back for a second, question about this chapter because, we're using this term autism services as opposed to specifically talking about, and even in this conversation I'm hearing some conflating of concepts and services in terms of early intervention versus ABA. You know, ABA may be one intervention under an early intervention approach.

Early intervention may be something that's educational or it may be something that's medical, and I guess my overall question back to the subcommittee that worked on this services question is, is there an opportunity to provide a level of specificity, because frankly, in its current form, it's very difficult to understand

whether you're talking about educational interventions or medical interventions.

So specifically, for example, when you're referencing the seclusion and restraint problem, that is explicitly and specifically in the schools, and while we have also had conversations about seclusion and restraint in other settings, it's a separate issue and the regulations and data are very, very different, and yet, this is kind of conflating seclusion and restraint as a general concept.

And I kind of feel like there are several parts of this chapter that do that and we're not distinguishing between medical interventions as covered by Medicaid or health insurance versus educational interventions that are supported by the school systems, and if part of the intent here is to assist the various federal agencies in better understanding where there are both the opportunities and the gaps, I

think it's important to acknowledge those distinctions.

And I guess I would go back to the members of the service committee to look at it through that lens.

Dr. Mandell: So I hear your concern and I agree with you that there may be different sets of regulations that govern these issues in different settings, and we probably need to be clearer about that. Part of our challenge was keeping the document concise, especially, frankly, given the fact that there's been relatively little new research in this area that has been particularly illuminating, and that most of what's new actually relates to the policy changes rather than new research.

But we can attempt, especially if you want to send me, or send Susan, specific areas where you think that that's an issue. I'd be happy to try and incorporate it into the document.

Dr. Insel: Again, this would have to be done in the next very few minutes because we want to come to closure on this before 4 o'clock. So I don't want to encourage you to rewrite this document, and it doesn't have to be perfect, it has to be accurate in being able to capture what is really new and profoundly important from the last 18 months or so.

Ms. Crandy: Couldn't we just add something to the first paragraph that says, after services, medical and educational?

Ms. Abdull: Hi. This is Idil. And I think a lot of people might get confused when we say 31 states have passed legislation requiring private insurance to cover ASD-related services. And I would be confused if I didn't know that's only for ABA intervention. And those have specific hours and specific numbers, so maybe, David, there is a way, or Denise, to say this, just that, that it's 31 states that have a specific ASD

early intervention, such as ABA.

It's not even Floor time, it's none of them, it's just ABA, and then also put somewhere, it doesn't include, or maybe we don't have to, but other medical, the speech, and the OT, all of them are covered by Medicaid, but it's not here. So I can see where people could be confused if they were not on this committee.

Dr. Insel: Does the next sentence help you with that, Idil?

Ms. Crandy: And, Idil, some states cover more than just ABA. Nevada covers speech and occupational therapy in their bill, so you couldn't just say that insurance legislation is just about ABA, although the majority of them do --

Ms. Abdull: Right. And that's what Tom just said, that it varies, the types of services, but I mean, mostly it's ABA, but you are right, Jan, some of them say speech and OT, but with or without that specific

bill, though, speech and OT, it's usually, most of the time, covered under Medicaid.

But, I mean, David, what are you thinking? Is there a way to specify some of this, break it down, or should we leave it like this?

Dr. Mandell: Well, so the reason I'd want to leave it like this, is that, not all states cover ABA in their mandates, or specifically mention ABA.

Ms. Abdull: Right.

Dr. Mandell: And so the level of specificity, we would have to provide here in order to truly unpack what is in these mandates, I think it sort of outweighs the utility of the point we'd be trying to make. I mean, I hear your pain, Idil, and I agree with you that we have a challenge in terms of the evidence base, but I think that that's really an issue for the previous chapter and not for this one.

That is, I think this chapter is

about what happens after there's a decision about the efficacy and the utility of a particular treatment.

Ms. Abdull: Okay. So can we at least put down whatever states have Medicaid covering early intervention, similar to the 31 states? The nine states that you've mentioned, is there a way to, just so people reading this can see the gap and the level of disparity that can create, because most low-income people have Medicaid. So if you've got nine, ten states that have Medicaid covering for early intervention, whatever that may be, versus 30-plus, and it's actually 37 now, it might make them think, wait a minute now. We need to do something about making sure Medicaid covers autism services, regardless of what they are.

Dr. Burton-Hoyle: This is Sally. Each state has an autism task force, so I think you have to give the federal perspective and not get into the variety of

ways states write their plans.

Ms. Abdull: Right. So we're saying 31 states have passed legislation through -- so we're not talking just in a federal level, we're putting 31 states that have private insurance. I'm just asking, how many states have Medicaid coverage?

Ms. Crandy: Do you want it to be how many states are covering ABA?

Ms. Abdull: Well, how many states are covering early intervention? We can say ABA, but early intervention, mostly is ABA, but sometimes, like you said, Jan, they do have speech and OT, but mostly it is ABA that has been the big push, and Wisconsin is one of them, Ohio is one of them, I think if we're going to put 31 states have private insurance, there ought to be a sentence, what it covers, where it talks about the Medicaid coverage.

Dr. Mandell: So, Idil, all 50 states cover some relevant services through

Medicaid. And so we could put all 50 states. There are nine states with autism-specific waivers. There are, I think, almost 50, maybe 48 states with home and community-based waivers where at least --

Ms. Abdull: Exactly. We can put that. If we can put that, I think I would be okay.

Dr. Insel: So let me weigh-in here again, as your Chair, because I think we're getting into the gravel and away from the boulders, to quote one of you, the question for us is, has anything changed profoundly in the last year and a half that needs to be captured here? And if not, it doesn't need to be here.

Ms. Crandy: I think Pennsylvania's adult waiver for autism. Didn't that happen in the last couple years? That's probably pretty profound because that's the only adult autism waiver.

Dr. Insel: And I want to also

remind you, this is, basically, set up as a research strategic plan. So we may change the way we think about this in 2013, but what we're really talking about here, to the extent that it has to do with services, is going to be more around services research, not changes in policy. We could include something that's a change in policy, but, you know, that's a little bit off the mark for what a research strategic plan is really going to be about.

So we've done that in the past, we could do it again, but I don't want us to spend a huge amount of time debating the intricacies of different states' services provisions, because that's really not what the research plan is going to be about.

Ms. Singer: So this is Alison, and I just want to restate a point I made when we were on the subcommittee call for this, I think that this group has really, sort of, struggled with the idea that we need

to focus on what's changed in the last year with regard to research, and that this, as Tom just said, is a research-focused plan, but there is so much eagerness on the part of the committee members, I think, particularly, some of the parent members, about getting at some of these issues with regard to best practice in terms of access, and best practice in terms of reducing disparities, and best practice with regard to service delivery, and implementation, and what's going on in the various states.

And I think, maybe at the next full IACC meeting, we need to talk about creating another, either a workgroup or a subcommittee of the services committee that makes a parallel plan so that this is a services research plan, but I think we also need to think about having a services delivery plan where we can address some of these issues that keep coming up because they are so important, but address them in a

rigorous way.

Ms. Crandy: And discuss policy changes there.

Dr. Insel: Yes. So this is Tom again. You know, I guess what I'm concerned about is to try to do this in one sentence here is not going to do justice to what everybody seems to want, which is a much deeper dive on issues related to services, both federal and state level.

So I would agree that I think what you're suggesting is that we need to circle back to this when we can do this with the attention it deserves. I'm just not sure we're going to fix this with a single sentence put into the --

Ms. Singer: I agree, but I think what we're seeing is just the frustration with regard to the limitations of this process. I think we need to stick within the confines of the boundaries we've set for this process, but we need to think about creating

a new mechanism whereby we can address some of the issues that have come up as part of the process.

Dr. Insel: Yes, and I think we heard that from the experts who got very invested in this particular item that, there was real frustration that they weren't able to put in all the things that they felt were really going to be important for the IACC to grapple with. So that was, if nothing else, a strong recommendation that a different process is going to be required going forward.

We're not going to be able to do that now, but either at the end of the day today, or at the next meeting, I think we should come back to this suggestion.

Ms. Abdull: Can I just say something, Dr. Insel, and you're right, Alison, I just want to see if there is a way, because I know that this is research-based, but we're saying policy here. We're saying

between 2008 and the present, there are 31 states that have passed, so couldn't we add a sentence that says, and also, there are home and community-based waivers that all 50 states have and nine states have autism-specific waivers?

Dr. Mandell: Tom, would adding that require reworking the document prior to voting?

Dr. Insel: No. I think as head of this group, if you want to include that sentence, let's do it, and we'll move on.

Dr. Mandell: Let's do that.

Dr. Insel: Okay. Let's move on then.

Dr. Rice: This is Cathy. I do have another issue about the translating research into practice, the part about screening instruments and the not meeting criteria for widespread dissemination.

And I just wanted to raise the issue of, although that one review was very

critical, I do think it is important to recognize that there was quite a response in terms of that conclusion going against both the professional and community support for screening, and that we need to recognize that there is support for screening, and that there have been several research-based studies that have shown that, within pediatric practices, autism screening can be effective, but not only when looking at the tool, but when you're looking at a systematic use of that tool in a clinical setting where there is a follow-up and then there is an actual referral source.

So there is no screening tool in and of itself that would meet the criteria, but there is widespread community support and professional support as well as some studies showing that, in the more ideal situations, they can be more effective than in community practice.

And so I think some way to at

least put a sentence to recognize that this is not the whole story. The critique of screening is not ready because we do have some promising movement in that direction and we need to keep it going.

So in that case, what I would suggest is to put, you know, maybe a sentence at the end saying, in contrast to the conclusions of this review, that there is professional community support for autism screening and some promising findings in terms of more ideal implementation in pediatric practices.

However, this is not yet ready to translate to full-scale utilization.

Dr. Mandell: That makes sense, Cathy, and perhaps this paragraph is a little more nihilist than it should be, so I would be happy to add that sentence.

Dr. Insel: Anything else in terms of revisions, comments, questions, anything that's not clear?

Ms. Crandy: This is Jan Crandy. Under disparities, there was quite a bit of discussion about lack of service in rural areas, and I know there's one study mentioned there about the later diagnosis, but I thought there was also about the disparity for those people having access to services.

Dr. Mandell: So based on the literature that I got from the committee, as well as my own literature review of what was published in the last 18 months, there wasn't anything new other than this study. If you recall the previous plan, the full plan talks a lot about disparities, including issues related to geographic disparity.

Ms. Crandy: Okay.

Dr. Mandell: So I wasn't as worried about it because it's not a new finding.

Ms. Crandy: Okay. Thank you.

Dr. Insel: Anything else? So I've heard a couple of comments, at least one

is to add a sentence that includes the information about state-based waivers; more, in the section under translating research into practice, including a sentence that's a little more positive about what screening could offer in the future, is there anything else that we wanted to modify before we take this to a vote? Susan?

Dr. Daniels: Okay. So then I guess we are ready to go ahead and vote on this chapter. I think you just heard the changes from Tom. So do we have a motion on the floor to accept this chapter?

Mr. Robison: I'll move that we accept it. John Robison here.

Dr. Battey: Jim Battey. I second.

Dr. Daniels: Okay. All in favor?

(Multiple Ayes)

Dr. Daniels: Any opposed? Any abstaining? So then this chapter will be accepted with the changes just mentioned.

Dr. Insel: Let's go on to Question 6: What does the future hold, particularly for adults? And who's going to take us through this very quickly? David?

Dr. Dougherty: Thank you, David.

Dr. Mandell: All right. So for new areas, at the beginning, we highlight the recent NICE guidelines that were not able to identify a lot of high-quality evidence, or frankly, any evidence, for how to care for adults with autism, at least in the U.K., and that is a rigorous selection process for evidence, but I think it was very telling.

There are a number of new studies, and this speaks to a point you brought up earlier, Scott, about validated strategies to diagnose adults with autism. The closer they get to being tried in an unselected community sample, the less well they work.

There's also some new epidemiologic evidence suggesting a prevalence of autism in adults close to 1

percent with no difference by respondents in age. And also, finding, perhaps, an over-representation of people with autism in some settings where, traditionally, people with psychiatric disabilities reside.

There was a lot of research on quality of life, a lot, relative to what has been done in quality of life and functional outcomes, suggesting the importance of the transition out of high school and how much support people with autism lose when they leave high school and how that affects outcomes.

There are also findings reiterating previous findings that sheltered workshops are not an appropriate mechanism to increase the probability of employment among adults with autism, but that social skills interventions can be particularly effective in improving outcomes.

There's also one of the first studies of service use among adults with

autism, again, finding that there's a tremendous amount of service disengagement post-high school and that there are significant disparities, racial and ethnic disparities, in this service disengagement, and also, disparities by socioeconomic status, with traditionally underrepresented minorities and people of lower socioeconomic status, much more likely to lose services.

There are not a lot of new gaps. I think there are a lot of old gaps that are mentioned in the plan that have been quantified in a way that they weren't before. The gaps speak to the very poor level of evidence for interventions to improve outcomes for adults with autism.

There's also been increasing interest, and note that we wrote this prior to recent horrible events in Newtown, about the overlap and intersection of autism and the criminal justice system.

There's no studies to date that

find a link between autism and criminal behavior, but it does seem, at least anecdotally that, individuals with autism sometimes end up in the criminal justice system and they require special care.

There's also been no research conducted on the extent to which individuals with autism are victims of crime as opposed to bullying, where there is substantial literature.

There's also been two reviews pointing out that, as little as we know about adults with autism, we know even less about older adults with autism, and that we may need to understand what the care needs of individuals are as they age throughout the whole lifespan.

And then at the end we, again, based on these new studies from this year, highlight the issue of disparities, and service delivery, and outcomes, which need to exist in adults as much as they do in

children.

Dr. Insel: Great job, David. So questions or comments?

Ms. Crandy: This is Jan Crandy. I just wanted to make a comment that I'm really glad that you included the plateau in the late-20s, that study that is a great concern to me, and I think, although more studies need to be done, it really tells us a story that, once those kids move out of school, that we're going to see, if we don't keep them occupied and give them good quality of life, that there's going to be regression or that they will plateau.

Was there no studies on depression?

Dr. Mandell: I did not find any studies. So I did a literature search of all of ISI, searching on adults with autism, and did not see anything related to psychiatric comorbidity in adults.

Ms. Abdull: Hi. This is Idil. I

was just going to say to David and Denise, thank you very much. I think you did an excellent job in both chapters, but especially this chapter.

Dr. Dougherty: Well, most thanks goes to David.

Dr. Mandell: No, I think the thanks goes to the whole committee.

Dr. Dougherty: Well, it does. That's true.

Dr. Mandell: This was a tremendous group effort and --

Dr. Dougherty: Right. And the experts we had. So as Tom said, it was really a challenge to get this down to three to five pages.

Mr. Robertson: Well, David, don't sell yourself short. This is Scott Robertson. You did a lot of great work on the editing on this, but I do have to say, it makes me feel, you know, depressed to think about the fact that there is no literature,

as was mentioned, on psychiatric, you know, comorbidities, that that should be something that, hopefully, changes in the future.

Dr. Mandell: Yes, I agree.

Dr. Insel: I think that's the value of, you know, when you go through this exercise, you begin to uncover where the big gaps are, and that can be very helpful. The other piece which other people have commented on that, I think, maybe as a committee we can continue to shine a light on is, the transition and what happens after high school.

I think you've got major papers in here and the effect sizes are so huge that it's going to be just vital that we make that a priority.

Dr. Carey: Tom. This is Matt Carey. I mean, yes, the thought that came up in my mind is, I think the work that's been done, and you guys brought out Paul Shattuck, you know, to talk and there's been so much

work that's been done great about that transition.

One area I think I'd like to make sure that we keep a focus on is, the transition -- I mean, there's been a lot of work on the transition of kids who are really on the more academic track, and I think, you know, a focus on students that are more on the functional track. You know, I think, you know, getting that population, you know, well-transitioned from high school, or, you know, really, from, like, age 22 to life is an area that, I think, could use a lot of focus.

Ms. Crandy: This is Jan Crandy. One of the things that I found and was mentioned when we were looking at those state of the states is, kids that are that medium, and I don't mean to be saying this incorrectly but the medium function child, adolescent, that can't get on a waiver because he has too much skills, his IQ is too

high to get on a community-based waiver, what is there for that kid?

Mr. Robertson: Can I make a comment on that? This is Scott Robertson, and I have a little bit of experience here at the state level on this. I mean, I know some of this discussion is more for things in the future, not necessarily putting language here in the plan, but it's something that I brought up here in Pennsylvania is that, we do have two adult-specific home and community-based waivers, the adult autism Medicaid waiver and the ACAP system, and --

Dr. Insel: Scott, you dropped out here.

Ms. Abdull: His is only one of two states that have adult waivers, so whoever was listening cut him off maybe.

Mr. Robison: This is John Robison here. I'm going to actually have to drop-off for 3 o'clock, so I think I'm going to miss the last question, but I'm going to get to

work on the statement, so if any of you want to email me thoughts, I'll be sending back responses to any of you who want to do that. I'll try and do that later this evening.

Dr. Insel: That sounds great, John. Thank you.

Mr. Robison: Okay. Talk to you later.

Dr. Insel: Okay. Any further comments on Question 6 while we're waiting for Scott?

Ms. Crandy: Could we include something on the gap that addresses that issue? It was brought up in stuff that we dealt with in the committee that we need to look at more of the functioning level of the person when we're talking about creating some kind of study on those, what happens to that kid that's in the middle that can't make it, but also can't get services.

Mr. Robertson: Hi. This is Scott Robertson. I got booted off by accident on

the call in the middle of speaking. I was trying to say a little bit ago, before I lost the connection on the phone, was that, in Pennsylvania, we have the two adult service systems and it's come up a lot that there's a lot of autistic adults who could use, maybe, say an hour or two of supports and services, but can't get access to that because they don't meet the criteria from, like, ISTF under the Medicaid standards.

And that might be something in the future in terms of the major gap on explore and research in terms of how to provide supports and services to folks who don't fit into our traditional, you know, service system right now, but autistic adults who, otherwise, live their life, you know, with even a little bit more supports and services, you know, could be that much more likely to be employed and living a higher quality of life.

Dr. Insel: That's a little bit of

what Jan was suggesting as well, and she was suggesting that maybe we could add this into the gap section so that it would --

Mr. Robertson: Oh, yes. That'd be great.

Dr. Insel: -- be clear that there's a need to not just focus on the end of the spectrum, but that there's a need across the entire spectrum. Any ideas about how to word that or where to put that? David?

Dr. Mandell: On the top of Page 3 we say, "It is important that interventions be developed and tested that address the needs of individuals with autism across the spectrum, including those who have greater support needs," and that was a particular issue of Idil's, which I thought was important.

But it would seem that that's the sentence we'd either want to tweak or to add a sentence there.

Ms. Crandy: This is Jan Crandy, because I think we're also talking about, though, services or, not just services, assistance, or money to help them to be able to stay in their community.

Mr. Robertson: And one thing, also, to add on that, you know, funding stream supports and services, and I don't know whether it can be added, but to also support individual self-advocacy and self-determination, which also makes that more likely.

I mean, they're still studying that more extensively among autistic people, but among research into actual disabilities and the broader DD community, I mean, it's already been well-established that folks who also are getting better support for self-advocacy and self-determination when they're transitioning to young adulthood, also have much more likelihood to have better outcomes when it comes to things like the employment

and higher quality living.

Ms. Abdull: Hi. This is Idil. So when we say across the spectrum, would that not be enough or are you guys saying that there is --

Ms. Crandy: The reason why I think there, this is Jan, is a concern for this is because, you're going to be able to get into a lot of doors, but if you're that medium-level person, you are not going to be able to get into doors to even get --

Ms. Abdull: So it's across the spectrum then. I know, so then, Jan, it's across the spectrum, so not on either end, but just across -- regardless if you're medium, or this, or that, but I mean, I don't know, unless you have a different sentence, I thought David put it well that it says, "It's important that interventions be developed and tested for individual needs of ASD across the spectrum."

Dr. Insel: And then leave out the

clause, Idil? So then you just drop out, "including those who have the greatest support needs"?

Ms. Abdull: Right. Yes, we can leave that out if you like. And then so it's everybody. We're not leaving anyone out.

Mr. Robertson: Including greatest support needs and add the other language as well. Yes.

Dr. Insel: Can you give us that? What is that other language?

Mr. Robertson: Well, what I'm saying is across the spectrum and then including, you know, the greatest, you know, support needs, making sure that that's also still mentioned in there.

Dr. Insel: So that's in there.

Ms. Abdull: That's already in there, yes.

Dr. Insel: I thought you were recommending a change.

Mr. Robertson: Yes, but what

you're saying is putting in across the spectrum as well.

Dr. Insel: No. That's in there now. So what it says is, "The needs of individuals with ASD across the spectrum." The question is, do we need to say more than that?

Mr. Robertson: Oh, okay. Maybe I was -

Dr. Insel: The top of Page 3.

Ms. Abdull: Page 3 at the top, Scott. I think you and I, and all of us, we sort of fought for this. And I'm okay if you want to leave it or if you want to take it out. I prefer to leave it there because --

Mr. Robertson: Yes. I think it's okay as it is.

Ms. Abdull: Yes, me too.

Ms. Singer: And the reason we put it in there to begin with was because, when we discussed this as a subcommittee, I think there was a feeling that the majority of this

chapter focused on individuals who had different types of support needs or less support needs, so that was put in there to try to make sure that everyone was covered.

Ms. Abdull: Right. So let's leave it the way it is, please.

Dr. Insel: So I just want to make sure I understand what the sense of the committee is, so we'll leave the wording the way it is currently or is there a movement to change it?

Ms. Singer: I think leave it.

Dr. Insel: Okay. All right. Any other changes, edits, questions, comments, clarifications?

Mr. Britton: I had a really brief thing. This is Noah. On Page 1, talking about the ADOS, in the epidemiology of ASD in adults paragraph, you say, "Using rigorous survey methodology (the ADOS)", but that study actually used three different diagnostic scales.

And I just think it's weird to highlight the ADOS here when, in the previous paragraph, you talked about how we aren't totally certain what the best diagnostic instrument is going to be, because again, you're referring to that same paper and it used three different diagnostic scales.

Dr. Mandell: I think that's a good point and I'd be fine taking out the parenthetical piece.

Mr. Britton: Great. Thanks. That's it then.

Dr. Insel: Any other changes? So what I have down is removing the ADOS reference under epidemiology, but everything else remains as is and, Susan, can we go ahead and vote?

Dr. Daniels: Okay. Do we have a motion on the floor to accept this chapter with the one change that was just mentioned?

Male Participant: So moved.

Male Participant: Second.

Dr. Daniels: Second. All in favor?

(Multiple Ayes)

Dr. Daniels: Any opposed? Any abstaining? The motion carries to accept this with the one change mentioned.

Dr. Insel: Okay. And we'll move on to Question 7, which, Donna, are you on to take us through about infrastructure and surveillance?

Dr. Kimbark: Yes, I am.

Dr. Insel: Okay. There's a lot here. You may want to just skim the high level of it and we'll see what needs to be modified or clarified.

Dr. Kimbark: Yes, I'll try to do that. I realize everyone's having phone fatigue by this time. Okay. So for surveillance and infrastructure, there were a couple of topics that we went through, including data sharing, biobanking, genetics, induced pluripotent stem cells, clinical

trials, and surveillance, and some communication dissemination and the research workforce.

So that's an awful lot to talk about, so I'm just going to highlight the top points. For data sharing, we really focused on NDAR. Our expert there was Dan Hall. He worked very diligently on this to show what NDAR has progressed to, which is really becoming an integral part of funding new research.

And there is a hope that all of the awarded human subject grants through the NIH and other funding agencies will participate in NDAR in the future. All data has been harmonized and validated. So that's data sharing and we'll talk about any of the gaps in a minute.

Biobanking, the most important part of biobanking to really highlight is that there was a loss of over 50 brains after a freezer malfunction in June of this year.

So that made all the rest of the initiatives very important because we've really kind of fallen behind in biobanking processes because of this freezer failure.

So all of the rest of the initiatives, including the Autism Tissue Program and what Autism Speaks, and Simon Foundation, and other leaders in the area have done is very important. So the Autism Tissue Program, or ATP, has a donor registry of nearly 6,000 individuals, and to actually register them, donate their brains in the future.

And they are card-carrying, which is really great to know that as well. There are other initiatives, including the Brain Atlas Project as well as the NIH Neurobiobank. The Brain Atlas Project, which began about 13 years ago for a 3-dimensional map of the brain, and the NIH Neurobiobank, that's not 100 percent focused on autism, but part of that is an autism initiative as well.

For genetics, there were several different things here. We used to have a big table. I'm not going to go through all the data because what we did was we consolidated the tables into language, so there's a lot of data here that is just saying where the genetic and the DNA samples are and how much has been accumulated at this point and what needs to be done, including work from NDAR as well as several other projects, including Autism Speaks, Autism Treatment Network, a biorepository, early autism risk longitudinal investigations, as well as an infant brain imaging study.

These are all different cohorts with different DNA samples for study and they continue to accumulate samples, which is a hope that these will continue to accumulate samples through the next couple of years. They all have goals to accumulate more samples along the way so that genetic studies may be done.

Additionally, AGRE expanded its multiplex family collection by more than 28 percent by making DNA available from an additional 363 families. I'm not going to go through all of this, it's about probands or individuals with ASD, so a lot of this is a bit of jargon, and I'm a little bit worried about how easy it is to read, but it does, essentially, put together the data of what we actually have at this point, which will, in turn, be important when we talk about gaps.

Inducible pluripotent stem cells, this is an emerging gap, and I thought that we had actually taken this out of this section, but it has reappeared, so inducible pluripotent stem cells are important because it's an idea of using fibroblast stem cells from syndromic forms of autism to actually be able to induce nerves within an in vitro system so that we could do studies in the laboratory.

As far as clinical trials, there

have been several different initiatives there, including Network for Excellence in neuroscience clinical trials, or NeuroNEXT, was created to conduct treatment studies, and of course, part of this is within autism.

We also have the Fast Fail Trials in autism spectrum disorder. This is important because what it's actually doing is trying to get experimental medicines quicker into testing and more rapidly pushing them to actually being usable for individuals with autism, which is also an important initiative.

This is something that was done to NIH, but if you'll recall, years ago, this was something that the FDA actually, kind of, pushed for other types of diseases or conditions, so it's important that we're actually looking at that in autism now as well.

Autism Speaks also convened two workgroups to actually look at clinical

trials in order to develop support mechanisms to push medicines into clinical trials, specifically, to improve social communication, repetitive behaviors, and anxiety associated with autism.

These working groups are actually working with the FDA to help put together appropriate outcome measures for autism clinical trials, which is always an effort and a difficulty.

Now, surveillance, one of the people that we talked to with surveillance was Cathy Rice, and she's on the phone call right now, and there's a couple of changes that we will need to make in surveillance, just changes in some of the wording, and we've already sent them to Susan Daniels. It's just a small change as far as these are using diagnosed as opposed to identified; 1 in 88 children in the United States are identified with ASD, not diagnosed with ASD.

And also, as I said before when we

were talking before, the ADDM Network from the CDC is actually working on a project, on an ongoing project, to look at the surveillance of Somali children in Minnesota, or actually, that is a project that is underway and it's not just providing the foundation for methods used in the project co-funded, so that's going to be changed to a project underway. So that's just a little bit of a difference there.

So I'm not going to go into anymore there because we can all read that and what the surveillance says. I think we've all talked a little bit about surveillance already, so I don't have to go into in-depth there much. Communication and dissemination, this is an important part because it also ties into a lot of what families understand about research, and what's being done with research, and using plain language, as well as how many adults are able to actually participate in clinical

research, or clinical trials.

So right now, only about 15 percent of adults that were surveyed that have a diagnosis of autism, or identified with autism, have been able to participate in clinical research, so that's a problem because it does cause an issue with the clinical trials and being able to have successful clinical trials.

When Alison Singer actually worked on this section, and she did a great job, we need a reference from some of the data that she talked about here. So maybe, Alison, if you're still on the call, you can provide that reference that you have.

Dr. Daniels: Donna, we have it. Alison sent it over the weekend.

Dr. Kimbark: Okay. Great. And so the other section was a research workforce development and support. This is all about the future and making sure that autism spectrum disorders research is fully

supported in the out years because, yes, we're having research now, we're having a logarithmic growth in publications and so forth, but the real question is, and this comes back to communication and dissemination is, what have you done for me lately?

It's not only about publications, it's more about treatments and interventions, which we've talked about today, but the research workforce has to continue to be developed and supported. And one of the things that's been kind of a little bit on the worrisome side is that the American Recovery and Reinvestment Act really pushed a lot of money into the autism research area, but there's not going to be a lot of support to keep those labs open, and publishing, and researching, as well as supporting post-docs and pre-docs, so that we have a research workforce in the future.

So the gaps that have emerged over the past two years, I talked a little bit

about NDAR as far as data sharing. Their real issues have been timeliness, getting researchers to participate, and put their data in the database at the right time. There's always some delay.

And data quality, have to make sure that the data is actually the right type of data and the people that are actually putting the data into NDAR are fully qualified to do that. There's also a culture of getting people to actually --

Dr. Insel: Donna, we're going to run out of time here.

Dr. Kimbark: -- use data that's now in NDAR. NDAR is a great resource, but it's not --

Dr. Insel: Can I get you just to summarize because we've got a lot more to get through.

Dr. Kimbark: Okay. And so if we go back to brain and tissue bank, I think I talked a little bit about this already, with

the freezer failure, there's more initiatives that have to be pushed in order to get parents, and people living with autism, to participate. Genetics and infrastructure support redundancies, overall, we're really talking about being able to support all of the data that is being accumulated and the integrity of that data, both physically and virtually.

Those are two systems that really have to be thought about in order to support and continue to keep the integrity of all the samples and the longevity of the samples.

Okay. Pluripotent stem cells, I already talked about that, so I won't go into that. The clinical trials, I already talked about what's needed there. We need a lot more recruitment and a lot more methodology and support there. We talked, already, about surveillance. We talked about getting surveillance, both globally and what surveillance means to identifying risk

factors.

We could add a sentence in here about surveillance and linking it to risk factors. So people wanting to do that, we do have a sentence at the end that talks about ethnic minorities in underserved populations and risk factors, but we could add a sentence about adults in here as well if people would like that.

And I've already talked about issues with communication and the workforce, and that's about it.

Dr. Insel: Great. So what I hear is the draft document will be what you have in front of you, plus two additions around the surveillance in the global context, so looking at what the rates, prevalence, or incidents rates might be in other countries as well as having something in here around surveillance for adults, which is what we talked about much earlier in the day.

So those would go in in addition

to what you see. Comments, question, or anything that needs to be clarified?

Dr. Daniels: This is Susan. I have one other addition. Cathy Rice supplied a couple of corrections for Page 3. They're pretty simple. Errors of fact that just need to be corrected.

Dr. Rice: Those were the ones that Donna reviewed earlier.

Dr. Insel: Okay. The rest of the committee, questions --

Ms. Singer: This is Alison. I have a concern about the first section on biobanking. I think that, just as new language appeared with regard to Early Start Denver Model, now additional language seems to have appeared here with regard to biobanking that I feel mitigates and dilutes the tragedy of a loss of the 50 brains.

That has set research back tremendously. Studies that have IRB approval and are ready to go are now stymied because

of the lack of that tissue. I think that the comments here about the Autism Tissue Program establishing a donor registry appears as if it was in response to the freezer malfunction when, in fact, that registry was established in 1999.

And I think it's absolutely not something that is new this year and I think it mitigates the extent of the loss and I think we need to take that out and really end this section where it says, "Have started to move forward with brain banking efforts."

Dr. Kimbark: Alison, do you think that it would be, and I'm just kind of thinking on my feet here, so give me a bit, a good idea to take either one of two things, we could put the loss of 50 brains at the end of the section and then just talk about, you know, establishing, in 1999, the autism tissue bank and, you know, go into all of the data that we have, and then also, at the very end of that section, talk about the loss of

those 50 brains, or do you think it would be --

Ms. Singer: No, because it's not new. That's not new. I mean, this whole call, all day, we've been talking about making sure that we concentrate in these sections only on what is new, and the establishment of the Autism Tissue Program is not new. What is new was the freezer malfunction and the loss of that significant resource, the bulk of which actually came from the ATP.

So, to me, the way this is written it looks as if this was a response and it is not a response. A response is being developed, but no response has been put in place yet. So I think this is very misleading and I think it really goes against the parameters that we've set up for these sections in terms of making sure that we focus only on what is new in the last year.

Dr. Insel: Alison, this is Tom,

just a point of clarification, so the Autism Tissue Program has been around for a long time, is the figure, 5,976 individuals, is that new? I mean, because I thought the idea here for this infrastructure chapter was to, kind of, put a marker in the ground for where we are at the end of 2012 on all of these different efforts so that we'd know whether we were doing better or doing worse by 2013.

And I agree, I certainly don't want anybody to think that the Autism Tissue Program just started and that was a response to the loss of the brains. So we can change the wording if it reflects that, but the central question is whether it's worth putting in something about the ATP if there is a number that they now have which is a marker of where they are at this point.

Ms. Singer: I think the thing to stress is that, in one day we lost 50 brains, and it takes about two years to get 15, so to me, it doesn't adequately describe the extent

of the loss. This is the one area in autism research where, not only have we not moved forward, we have regressed.

Dr. Insel: If we took out, in the second sentence, the first word, “while,” and just say, "This loss will lead to delays in research due to reduced access to samples.", full stop. Would that help?

Dr. Kimbark: Then we'd have to take out the rest of the phrase, "Other programs have started to move forward.", because it makes it sound as if those other programs are initiated after the freezer failure, and that's not so. So if we take out, "Other programs have started to move forward with biobanking efforts", and we leave, "This loss will lead to delays in research due to reduced access to samples.", and then make a period there, then, essentially, we would have to go into a new paragraph and go into the status of where we are with other efforts.

And some of this stuff, this paragraph was written Roger Little, and I'm sorry I didn't credit him earlier, but he put together all of this data, these numbers, and I think some of these numbers are important to put out there because I don't know that we had published them previously.

Ms. Singer: Well, maybe if we put in the Autism Tissue Program has 5,976 individuals registered since, and then the start date, so that it doesn't -

Dr. Kimbark: Well, I was thinking about, we could do that, we could put since the start date, or I was just going to start the sentence with established in 1999. It's 1999, right?

Ms. Singer: You should check that. That's my vague recollection of when - -

Dr. Insel: But again, Alison, the next sentence does say what's new, which is, in the last two years, they've received 15

brains and two of them --

Ms. Singer: And that's fine. That part's fine. I just think what is misleading to me is the way it reads. It looks as if the Autism Tissue Program was established in response.

Dr. Kimbark: Yes, I think it's that one sentence that's making that happen.

Dr. Insel: So we can change that and make this a new paragraph. So that ATP is a separate paragraph and it gets described just the way the subsequent paragraph does on the Brain Atlas Project.

Ms. Singer: Right.

Dr. Insel: Okay. Other comments, or changes, or questions?

Mr. Robertson: Yes, Tom. This is Scott Robertson, just one quick comment on, when the language is added in, specifically around adults, is there any way, in this section also, to include something about, you know, part of that, like, doing more

extensive needs assessments for adults and, you know, having monitoring around those needs assessments?

Dr. Insel: So this has to do with the surveillance of adults?

Mr. Robertson: Yes, because I think that would be very appropriate for looking at that around autistic adults is, is it specifically a needs assessment in the surveillance?

Dr. Insel: Yes. Someone from CDC, like Cathy, want to respond to that question?

Dr. Rice: Could you repeat it? Sorry about that.

Mr. Robertson: Yes, I was wondering if, when the language is added for autistic adults in this chapter, could there be, specifically, a mention of doing more extensive needs assessments and keeping them updated, because there's a very lack of needs assessments from NIH and CDC when it comes to

autistic adults.

In fact, that's one of the reasons, like, here in Pennsylvania, we did a state needs assessment to look at really specific issues, because we didn't really have good needs assessment data extensively as much from, you know, at the federal level for autistic adults.

Dr. Rice: So in that case, do you mean service needs assessments and is that something --

Mr. Robertson: Well, services, you know, quality of life, how things currently stand, I mean, you know, if you look at how the Pennsylvania needs assessment was done, they looked, kind of, across the board in terms of how things stand and what are the gaps in terms of addressing the problems that autistic people are facing, including autistic adults, with the gap areas.

And that includes services, and

that includes, you know, what are the problem areas as far as challenges in quality of life that autistic adults are facing right now?

Dr. Kimbark: I think that if we go back to the surveillance section under gaps, I think we could address it there, because if you look at the very last sentence there, and I think you might have brought up this before, it says, "Surveillance among ethnic minorities and underserved populations will be critically important in understanding risk factors and barriers to services in these groups."

So if we talk about surveillance among adults and needs assessments, I think that we could also talk about how this might contribute to barriers to services in this group as well.

Dr. Rice: Yes, I think adding adults here is something we talked about earlier this morning, to that last sentence about surveillance among adults as well.

Dr. Kimbark: So I just think we could add another sentence, so we could talk about needs assessments in adults and then tie it all into this one idea of understanding barriers in services in all of these groups.

Mr. Robertson: And I think that's a good fit to put it right near the area of underserved ethnic populations, and I'm not looking at the specific section -- I mean, I'm trying to look at it right now, if it mentions, also, like, you know, rural versus urban, et cetera, to put it right in that kind of an area.

Dr. Kimbark: I don't think it does, but we could talk about demographics as well.

Dr. Rice: Yes, that makes sense.

Mr. Robertson: Okay. You know, and specifically, I just wanted to make, specifically, the term needs assessment makes it into there because I think it would be a

little bit of a travesty if there's data gathered in autistic adults and the only thing that's gathered is race and not, you know, actual issue areas that can help with changes in system infrastructure.

Dr. Kimbark: Okay. I think we can work something out for there.

Dr. Insel: Just to underscore that, I think that's a little bit different than barriers to services, right? It's actually incorporating into the surveillance, trying to get information about what the service needs would be, so that's an important addition and can be worked into that section under gaps. What else do we need or what else do we want to include in the infrastructure?

Ms. Abdull: Hi. This is Idil. I have a question for you, Donna. On Page 4 of 7, I like that sentence that you said, what have you done for me lately? I think I'm going to use that a lot today. But on this

one where there is about 27 individual post-doctoral trainees, and there's 15, or there's 16 new trainees at various organizations, including NIH, do we know how many of those were from diverse communities, and if so, great, and if not, even if so, is there a way to say, on Page 6 of 7, under the gap, research workforce and development, and support, continued focus on developing the research workforce through investment in diverse young investigators?

Is there a way to add the word diverse just so we are making sure that we are precluding researchers that select the communities that they serve and that they are researching?

Dr. Kimbark: Well, that's actually interesting. I mean, from the data that we got from the NIH, I don't think we have any type of ethnic or demographic information regarding the pre-docs or post-docs. I don't know if NIH actually collects

that data.

Dr. Insel: So this is Tom. We do have all that information, but I think what Idil is suggesting is a great addition under, this is on Page 6 of 7, a continued focus on developing a diverse research workforce would really be helpful. And anybody who's interested in this issue further, the New York Times, this morning, has a long piece on the NIH efforts to increase diversity in its biomedical research workforce, so it's very timely.

It's something that we're doing anyway, but why not put it in here as well?

Dr. Kimbark: Yes. I think that would be great idea. I like that idea a lot.

Ms. Abdull: Thank you.

Dr. Insel: Other comments or additions?

Dr. Mandell: Can I raise a question related to that? Given that NIMH funded this large health outcomes contract

with the Lewin Group, it seems like those types of data, and Denise and I have been talking about this, that are collected, usually for billing purposes, can serve a very important research function, and may have a lot of potential of research infrastructure to assess service use and needs of large groups of people with autism.

And I wonder if the group working on Chapter 7 had given any thought to whether that resource should be made available, and I know that there was some conversation with the Lewin Group about how, even, to think about making those data available to NDAR, but was this an area of conversation?

Dr. Kimbark: I'm not sure if we actually touched on that point at all. I don't recall it at all.

Dr. Rice: I don't think we did on this update because the general issue of linking databases and making service databases available for research was

addressed in the earlier version of the research plan, but that would be an important, I think, useful update where there's a very specific resource that is, potentially, newly available to note.

Dr. Mandell: Okay. Great. I should have looked at the old plan first, but as long as it's in there in one form or another, I think it will be an important area to move forward.

Dr. Rice: Yes, just thinking of, I don't know if it's, we should put that somewhere in here and note that in particular. Just trying to look where, because I think -- I don't know if that came under data sharing before. I'm not remembering, but the objective was about linking existing databases, so whichever section that was in.

Dr. Insel: Yes, so this is Tom. It's a little bit tricky because, as far as I know, there isn't anything published. We

have reports that are just getting finalized, so it wouldn't be a new finding. It would have to be worked into the gaps someplace.

Well, let's see, it could, potentially, be part of the surveillance effort. There are a couple of efforts like this besides the Lewin Group. There's something called the Mental Health Research Network, which has 11 million patients in it through several large HMOs, which we use as a, kind of, dashboard to look at changes in everything from medical issues that come up to service issues that you can capture within one of these large datasets.

You know, David, you bring up a good point. I mean, that is a new opportunity to do a certain kind of science, and I'm not sure we've tapped into that yet. I'm just looking to see if there's a place where we --

Ms. Singer: I see a place.

Dr. Insel: Where?

Ms. Singer: What if we put it in as an example under the gaps NDAR sentence number 3, where it says, "Offering funding opportunities for secondary use of existing data to demonstrate and improve the utility of the investment made in data sharing." Well, it wouldn't be to improve the data sharing, so it would be to make additional use of existing datasets, so right in there.

Dr. Insel: Although, I'm not sure how much of this will go into NDAR. It's because some of the claims data, I don't think, will be part of that.

Dr. Rice: Yes, but I think the updates are data sharing more broadly, but then the gaps were specific to NDAR, so maybe if that heading is just changed to data sharing and then we --

Ms. Singer: Yes.

Dr. Insel: God, what a great group. That's a superb idea. So we could just change that heading and then add an

additional sentence or two in a separate paragraph to mention some of the new opportunities that will be emerging in 2013 that could allow for large datasets to be used to answer questions related to autism.

And the two that I know about, there may be others, would be the Mental Health Research Network and then the Lewin Group dataset. Are there others, David, or anybody else, that should go in there?

Dr. Mandell: So another related one, and of course, there's some self-interest in this for me, is, even within the DHHS sister agencies, so for instance, Center for Medicaid Services, if one gets an NIH grant to conduct this kind of research, one has to then buy the data from CMS, so it seems like, potentially, a waste of resources in that, universities are just taking out their indirects, but it's going straight back to DHHS.

And I wonder if the idea of data

sharing could be broadened to think about partnering, even with sister agencies, within DHHS to make data available for research.

Dr. Insel: Right. So what if we call it data sharing and databases as the heading and then we add that as an opportunity to have CMS data worked into this as well? So those would be three new opportunities in 2013 to think about.

Dr. Rice: And I don't know if we want to go as far as, you know, many of the national surveys that exist, and we could just mention it very broadly, but to take better advantage of the national surveys, including, for example, the work of Paul Shattuck, of looking at the education longitudinal database that already exists, it wasn't new data collection, and he's really getting a lot of information out of that, but really emphasizing the analyses of existing data systems.

Dr. Insel: Right. So it's really

about trying to access some of the large datasets, and this is really the era of big data for so much of what's going on in medicine, and we've got a couple of great examples for autism. So we'll try to capture that in an additional sentence or two under gaps, and we'll change it from NDAR to being data sharing and databases, if that's okay with people, and then provide the community with some of these new resources that should become available in the next few months.

Ms. Redwood: Hey, Tom, could we also include in their linking, say, through the surveillance data, with the toxic release inventory data?

Dr. Insel: I don't know what that is, Lyn. What's the toxic release?

Ms. Redwood: Well, if you're, what do I want to say, some type of business where you're actually releasing environmental toxicants, either into the air or the water, you have to get state permits to be able to

do that, and you have to report, I'm not certain if it's quarterly or annually, like, how many pounds you've released into the environment.

So you could use that toxic release inventory data to look at, you know, the different surveillance data that CDC is collecting. There was something recently done, that just came out last week, that looked at fish advisories and found a correlation between fish advisories for mercury and ASD prevalence.

So that's why I'm thinking that we could use some of the EPA datasets and some of the toxic release inventory data to also correlate with some of our surveillance data.

Dr. Rice: Yes, and that may be more broadly about looking for opportunities for linking existing datasets. For instance, I don't know if it's the same one that you were talking about, but we have linked to the hazardous air pollutants dataset through EPA,

national air toxic, is that what you're referring to?

Ms. Redwood: Yes, but there's also water releases too, and other releases besides just air, so that would bring two.

Dr. Insel: These are great ideas. So, Cindy, Lyn, if you just send us, we'll incorporate that into an additional sentence here under databases.

Dr. Kimbark: Wouldn't that be under surveillance?

Dr. Insel: No. This is really trying to link databases that currently exist, so it's secondary analysis rather than creating a new one. Any other questions or comments about what we're --

Dr. Kimbark: Now, I have a comment. This is Donna. The information regarding the data sharing and database that we're going to add, all of that, I didn't get all of that information. I tried to scribble down some of it, but I'm going to need

someone to send me the information.

Ms. Redwood: Tom, this is Lyn. I also had a couple of other, sort of, comments and questions. When we had our call, previously, discussing this, I had asked about whether or not we had included data from the University of Maryland and the NICHD brain and tissue bank, with regard to the number of brains that we had available and whether or not they had increased any of their collections over the last year. I don't know if that got --

Dr. Kimbark: I actually looked for that, Lyn, I couldn't get any information.

Ms. Redwood: I can either contact Ron Zielke, or actually, he should be able to give you that information. I can give you his contact. And also, with regard to the gaps with the brain and tissue bank, you have a recommendation here about enlisting parent advisors to be able to, I guess, reach out

and support getting more brains, but I think another thing that we could do that would really help is if we reach out to some of the large cities and go to the state medical examiners and specifically ask them if they would help us with collections.

I did that here in Atlanta and they were very receptive. We also need to provide freezers so that when they do procure, you know, tissue, that they can freeze it right there on site. That's been one of the gaps in terms of a lot of the cities wanting to participate.

And also, working with the coroners to be able to change their intake questionnaires to specifically ask, especially, either with a child or an adult, if the person had a diagnosis of ASD. And also, to try to increase control brains, because that's another thing that's definitely in need too.

So I would recommend maybe adding

some of those other initiatives to be able to get more tissue.

Dr. Insel: Thanks, Lyn. These are great ideas. I think, maybe this wasn't clear, it's at the top of Page 2, it says, "The NIH has created the NIH Neurobiobank.", and what this means is that, NIMH, NICHD, NINDS, have now joined together their efforts. They've, essentially, canceled out everything they were doing as grants, turned everything into contracts, this includes the University of Maryland, and the numbers that you see there include everything in any of the currently supported biobanks, but it's now given a new name because it's a national federated system.

So part of that process is also creating a network of projects that are both community collections as well as working through medical examiners across the country. You know, we didn't spell all of this out because a lot of it's in process, but that's

all in the works currently and it's not specific to autism, but it's specific to brain disorders.

And I think you'll see, over the next few weeks, a lot more activity in this area, partly brought about by the freezer meltdown that Alison mentioned. So I'm not sure how much of that you want us to spell out, but --

Ms. Redwood: Well, if it's already happening, Tom, then great. I was not aware of that, so that's wonderful to hear.

Dr. Insel: Yes. And it's interesting, just historically, this actually has a lot to do with the IACC because it was from members of the IACC, particularly Simons Foundation, and Autism Speaks, and Autism Science Foundation that we heard the need to ramp this way up two years ago. And it was partly their lobbying along with the needs of some of the investigators that has really

gotten this off to a different start.

So this is all happening. I'm just not sure we've spelled it out, maybe, as much we should have, or could have, here, but there's a little reluctance to do that because some of it is just in process and the awards haven't been made.

Dr. Koroshetz: I was just going to say, we met with a lot of the brain banking groups last week and all the things you said, Lyn, were on the table and that's what everybody is trying to do, so I think everybody's on the same page.

Ms. Redwood: Well, very good. I'm excited to hear that.

Dr. Insel: Huge issue, and as Alison said before, when you look at this entire update, it's the one area where we've gone backwards instead of forwards, and that's just unacceptable.

Ms. Redwood: Right.

Dr. Insel: Okay. Anything else

that people want to change or suggest for Question 7, and then we're going to go back to Question 4 from that point. Susan, can we go ahead and take a vote on 7? And let me just quickly summarize what I think we have, which is, under biobanking, we're going to change the wording such that there's one paragraph that will describe the freezer malfunction and brain loss and what it means in terms of a delay in research, a new paragraph that describes the ATP and where that's at currently, and then under surveillance, within the gaps section, we will focus on the need for both the global effort, surveillance for adults, and that surveillance will include a needs assessment as well as a more typical prevalence kind of effort.

Also, under gaps, we're going to change the part on NDAR to include data sharing and databases, and we'll have a short paragraph that describes the current

databases that could be available for secondary analysis, and the opportunity to link databases, including the ones that Lyn and Cindy will send us related to environmental toxins.

Dr. Daniels: And I have one more on research workforce and development to change it to developing a diverse research workforce. All right. So didn't miss anything, that was everything?

Ms. Redwood: Could I add one more thing? This is Lyn. Just real quick, would it be possible with the surveillance to also include exposure questionnaires?

Dr. Insel: Cindy, you're our expert on surveillance.

Dr. Rice: I'm sorry. Can you repeat that question?

Ms. Redwood: I think this is more a CDC question. If it would be possible, as part of their surveillance when they identify a child with ASD, to also include some

exposure questionnaires; exposure history questionnaires? Is anyone doing that?

Dr. Rice: I think it depends on if you're calling it surveillance or not. Some of the national surveys include some of that information and also ask about diagnosis of autism. And our case control study has specific questionnaires related to various exposures.

Surveillance itself, the ADDM surveillance, is based on existing records, so we're not asking new questions in that case, but linking to other datasets would be possible, and certainly, maybe emphasizing within research that is prospectively collecting data to include that, certainly, could be noted.

Dr. Insel: Is there any reason when we say, understanding risk factors, this is under surveillance, the last sentence, under gaps, we couldn't put in parenthetically, including environmental

exposures?

Dr. Rice: Sure.

Dr. Insel: Just so that isn't overlooked. Lyn, would that --

Ms. Redwood: That would help. Thank you.

Dr. Insel: Okay.

Dr. Lawler: And this is Cindy, there is some online resources that are being developed under, it's called, CNExT. It's a collection of tools that are primarily questionnaire-based under different domains, and there is, sort of, a number of, sort of, consensus questionnaires that have been developed that can be used for individuals who wish to add an environmental exposure component to existing studies.

I mean, these were developed primarily in the context of individuals doing GWAS studies, but that could be, you know, used in other settings as well.

Dr. Insel: So the tools are

there.

Dr. Lawler: Yes.

Dr. Insel: Great. Okay. Let's take this to a vote. Susan, we've summarized the changes. Go ahead.

Dr. Daniels: Okay. Do we have a motion on the floor to accept Chapter 7 with the changes that were listed by Dr. Insel and myself?

Male Participant: So moved.

Male Participant: Second.

Dr. Daniels: All in favor?

(Multiple Ayes)

Dr. Daniels: Any opposed? Any abstaining? The motion carries to accept the chapter with the mentioned changes.

Dr. Insel: Okay. We've got about 15 minutes left and we've got two things we need to finish. One is the -- hold on, one is going to be the introduction and conclusion where we've drafted some language to just try to cover the process, what we've

been through, and to give any reader of this document the context that this is part of a set of publications that come from the IACC, so not everything is going to be here, but it is meant to summarize research progress.

The conclusion is meant to give you a sense of who worked on this, so that we'll list the many experts who were involved, and explain that, again, we've gone through a process in which this is a result of lots of discussion, and that this is a step in time, that we'll be looking at this again in 2013, and that, even though we realized we couldn't get everything we might have wanted, or anybody might have wanted, into this, this was an attempt to at least capture some of the most important advances of 2011 and 2012.

Any comments, concerns, suggestions about the intro and conclusion?

Mr. Britton: Looks good to me.

Dr. Carey: Looks good to me.

Dr. Insel: Can we go ahead and take this to a vote, then, Susan, unless there's comments?

Dr. Daniels: Do we have a motion on the floor to accept the introduction and conclusion as written here?

Several simultaneous speakers: So moved.

Several simultaneous speakers: Second.

Dr. Daniels: All in favor?

(Multiple Ayes)

Dr. Daniels: Any opposed? Any abstaining? The motion carries to accept the introduction and conclusion as written.

Dr. Insel: Okay. I want to revisit, then, Question 4, which we have struggled with a bit. We've tried to put this up as -- how many slides do we have here? Four slides, that will take you through the new language and see if this captures what it is that the committee

wanted. Are you able to see this in front of you? Is there anybody who can't see it? I'll read it if you can't see it.

Dr. Dougherty: I can’t see it right now.

Mr. Britton: I’ll look for it.

Mr. Robertson: On the webinar it just says “Conference call and webinar” right now and I can’t see it.

Ms. Singer: There’s nothing up now.

Dr. Insel: All right. Then let me read it to you then, and in the meantime, we'll see what we can do to get it visible. Can I assume that only the underlined parts are the parts that have changed? Okay. So what it said before and what it still says is, "Evidence for the benefits of early -- now I can't see it.

Ms. Singer: Now it’s up.

Mr. Robertson: Now I see it.

Dr. Insel: Okay. And I think we

want to go back one, is that right? Okay. So only the underlined parts are changed, so we're not going to spend a lot of time on the original language. It goes down to, "While gains have been made in this area of research, the effects of these interventions as measured to date are modest." The rest of it is unchanged.

The next paragraph says, "An RCT in toddlers with ASD tested a parent-implemented intervention without any comment about whether it was particularly successful or not. Furthermore," and the rest of this remains the same.

The next paragraph says, "Early intensive intervention using the ESDM", and I think we've cut out a bunch, okay, "with toddlers as described in the 2011 strategic plan", so there's no reason to go back to talk about those results, "was found to result in changes in electrophysiological brain activity and this biological marker

correlated with positive changes in behavior."

And I think what we heard from the committee, that was the part you were most excited about from 2012, the idea of having a biomarker that went with the behavioral improvement, not so much going back to describe the original behavioral findings, which actually preceded, and those were covered in the previous update.

And then finally, I think this is the last change, "In a different RCT, children who received a 12-week parent-delivered ESDM intervention were compared to a control group of children receiving typical community interventions." We've taken out the next couple of lines. And then it says, "Both groups of children showed developmental gains and reduced core autism symptoms", and added this, "although there was no clear advantage of one intervention over the other. However, the degree of improvement across

both community and ESDM groups was higher in children, that received more hours of intervention."

And that was in there originally and what the subgroup agreed to.

Ms. Singer: Can we go back to Slide 2?

Dr. Insel: We sure can. We just did. Okay. This one?

Ms. Singer: So it seems odd to me to just have a short sentence that says a clinical trial took place without giving any results. So I think either we should include the results or we should take it out completely.

Mr. Britton: I vote to take it out as well.

Ms. Singer: Or say something in general. I mean, maybe we could make a general statement about the need for more parent-mediated interventions and the lack of efficacy in the studies that have been done

to date, or something about the issue of parent-mediated intervention.

Mr. Britton: A parent-mediated intervention was done and evidence suggests that parent-mediated interventions are not currently supported by research and need to be modified to be effective?

Ms. Singer: Well, I don't know if that's exactly correct.

Dr. Insel: Well, but I don't know if we know enough to say that. So, Alison, I think what you were just suggesting is something that focuses on that, during this past year, we've seen the first RCTs on parent-implemented intervention, although, I think as everybody is saying, we've got a long way to go.

Ms. Singer: Right.

Dr. Insel: And simply include the reference, but word this in a way that the advance here is methodological, it's not in terms of having an enormous boost in

efficacy. And I don't actually know this paper, so I'm just trying to gather what I'm hearing from the conversation of the committee. There was no difference in the two groups?

So how could we have said that? Okay.

Ms. Singer: Is David still on the phone?

Dr. Daniels: No, he had to leave.

Ms. Singer: Oh, because he said it very nicely, something about, that the movement forward was in starting to conduct the trials looking at parent-mediated intervention.

Dr. Insel: Right.

Ms. Singer: And that, although they have not yet proven to be efficacious, you know, there's still a need to continue to test parent-mediated interventions because of their -- I'm not sure.

Dr. Insel: So how about some

language just like that, saying that, over the past period, the past 18 months, which is the term we used throughout the plan, there have been reports of randomized clinical trials, there's been at least one report of a randomized clinical trial, in toddlers using a parent-implemented intervention; although, more work is needed to be able to establish the efficacy of this approach.

Ms. Singer: I'm good with that.

Dr. Insel: Okay.

Ms. Abdull: Can I ask a question about the hours of intervention? Were those 25, or, like, do we know or do we just say, when they received more hours of intervention, because some people could interpret that as 40 or 50 hours.

Mr. Britton: Off the top of my head, I recall it was intensive versus less intensive. I don't remember the numbers specifically. It was Geri's paper and I can try to pull it up, but it was something like

25 --

Ms. Abdull: I think it was 25.

Dr. Insel: ESDM was 25 hours, I believe; 25 hours over 18 months.

Ms. Abdull: I wonder if it's possible to say that just to be accurate and that --

Dr. Batra: This is Anshu. I just pulled up the paper. It's 15 to 25 hours.

Ms. Abdull: Okay. Is it possible to mention that in the --

Dr. Insel: I'm sorry. I missed the thread of that, Idil. Where would the change be?

Ms. Abdull: The degree of improvement -- let's see. I don't have the computer. I'm driving. I'm, sort of, waiting for my son to end therapy, but it says that, ESDM groups was higher in children that received more hours of intervention, and so instead of more hours, if we can put what Anshu just said, which is, 15 to 25 hours of

intervention.

Dr. Insel: I like that, because I think it's more informative, but we'll have to go back and actually check what the results were.

Ms. Abdull: I think that's what they said, what Noah said, that he checked and that was the hours. I mean, you can double-check with him.

Dr. Insel: Yes. So we'll double-check, but let's --

Mr. Britton: It wasn't me that double-checked it, but yes.

Dr. Insel: Okay. So that term more will be turned into something that is more specific.

Ms. Abdull: Right.

Dr. Insel: Anything else from this language? Noah, I just saw that you sent in your own language, which unfortunately, I haven't gotten to, but does this work for what you were trying to --

Mr. Britton: This will do, yes.

Dr. Insel: Okay. Other comments or thoughts about this? Let's go ahead and vote, Susan, so we can add this one to the changes.

Dr. Daniels: Okay. So do we have a motion on the floor to accept this language with the edits just discussed, so the language that's up on the screen, plus the items that were just discussed?

Several Participants: So moved.

Male Participant: Second.

Dr. Daniels: Second. All in favor?

(Multiple Ayes)

Dr. Daniels: Any opposed? Are there any abstaining? The motion carries to accept this section with these changes and add it into the rest of Chapter 4.

Dr. Insel: Okay. Great job, everybody. This has been a marathon conference call, lots to go through, and lots

of changes, but I want to thank all of you for sticking with it throughout the whole day.

We have a little bit of work to still do to get this cleaned up and to get it into final form, and you will see the final form pretty soon. In the meantime, John is going to send around a version of something that he'd like to see us post relevant to the shooting in Newtown, Connecticut, and so we'll have a chance to get that, I think, later today.

I'd ask that if you have comments about that you get them back to us as quickly as possible because we'd really like to be able to put that up by Friday at the very latest.

Are there any final comments or questions? Susan, anything else that the committee needs to consider?

Dr. Daniels: No, just reminding you to please CC me on any emails regarding

the final touches on this update and to send me any information that we need to make the changes. And I will be getting instructions about any procedures that might be needed for this statement.

And if you, as a committee member, are willing to be contacted by the press about the statements, please send me a separate email to let me know that, so that if we do alert the media, that they know where they can go for information, so that would be helpful if you could do all of those things.

And for Friday's statement, it would be helpful if we could get everything finished by Thursday so that we have time to be able to put things up on Friday. So by, I would say a good deadline would be, noon on Thursday.

Dr. Insel: Susan, just tell us about our next meeting.

Dr. Daniels: So your next meeting

is coming up on January 29th. It'll be a full day, full committee meeting in-person.

Dr. Insel: In-person.

Dr. Daniels: In-person, so you haven't seen each other since July. We'll all be meeting together here at NIH, I believe it's in the Natcher Center, that we have a room reserved for this meeting, and we will be having all of our normal procedures, and starting to go over what the plans are for the coming year, and what the committee wants to accomplish, as well as doing all of our annual activities that we're required to do under the Combating Autism Act.

Dr. Insel: And when we meet, then, in January, Alison, I think, has put something on the agenda already today about thinking about how we respond on the services agenda. So that is something that we'll need to be sure to talk about then. Let's all hope that there isn't another major storm on the 28th, if not, the 29th, that would

preclude being able to get together in Washington.

Any other final thoughts before adjourn?

Mr. Britton: You guys want to just hangout and chat for a few hours?

(Laughter)

Mr. Britton: How was your day?

Mr. Robertson: Tom, I just wanted to say that, good work and also keeping us so much in time that we're actually adjourning a couple minutes early.

Dr. Insel: Well, we haven't adjourned yet.

Mr. Robertson: We're, basically, on adjournment right now. We're unofficially adjourned, you just haven't said the words yet, that's all.

Dr. Insel: Okay.

Ms. Abdull: Hi. This is Idil. I know you always hear this, but I just wanted to thank you, Dr. Insel, and Dr. Daniels, and

all the chairs for keeping us on task, on time, and making sure that everything gets done, even on long phone calls, it's very interesting because we are all invested in this, either professionally or personally, and I really appreciate everybody's view.

Dr. Insel: Well, thank you. I appreciate that comment. You know, this is kind of messy, obviously, it's not easy to do this by committee, but if it's any solace to all of you who have stayed through the whole day, I think what we ended up with is better than where we started, and it just speaks to the value of doing this as tedious as it may seem at some times.

You just have to get down and do it. And I really admire your willingness to engage in this, stay with the process, even when it's a little bit messy. So thanks to everybody on the committee. Thanks to those who also listened in for the whole day and didn't have a chance to participate. We did

have some people who came for oral comments and some who wrote in written comments, which we always appreciate as well.

We will see everybody at the end of January, and in the meantime, I want to wish everybody on the committee and everybody who's involved with us, a happy holidays, and let's stay safe I'll be seeing everybody in about six weeks. Take care.

(Whereupon, the above-entitled matter was concluded at 4:13 p.m.)