U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

INTERAGENCY AUTISM COORDINATING COMMITTEE

FULL COMMITTEE MEETING

TUESDAY, DECEMBER 14, 2010

The Committee met in The Grand Ballroom, Salons A-D, of the Pooks Hill Marriott, 5151 Pooks Hill Road, Bethesda, Maryland at 10:00 a.m., Thomas Insel, Chair, presiding.

PARTICIPANTS:

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

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

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

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

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

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

PARTICIPANTS (continued):

JOSEPHINE BRIGGS, M.D., National Center for Complementary and Alternative Medicine (NCCAM) (representing Francis Collins, M.D., Ph.D.)

HENRY CLAYPOOL, U.S. Department of Health and Human Services (DHHS), Office on Disability (attended by phone)

JUDITH COOPER, Ph.D., National Institute on Deafness and other Communication Disorders (NIDCD)(representing James Battey, M.D., Ph.D.)

GERALDINE DAWSON, Ph.D., Autism Speaks

GERALD FISCHBACH, M.D., Simons Foundation

LEE GROSSMAN, Autism Society (attended by phone)

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

GAIL HOULE, Ph.D., U.S. Department of Education

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 for Children and Families (ACF)

CHRISTINE MCKEE, J.D.

PARTICIPANTS (continued):

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

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

DENISE RESNIK, Southwest Autism Research and Resource Center (SARRC)(attended by phone)

STEPHEN SHORE, Ed.D., Autism Spectrum Consulting (attended by phone)

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

MARJORIE SOLOMON, Ph.D., M.B.A., University of California, Davis and M.I.N.D. Institute

PETER VAN DYCK, M.D., M.P.H., Health Resources and Services Administration (HRSA)

TABLE OF CONTENTS

PROCEEDINGS

10:04 a.m.

Dr. Insel: Do we have our audio link and at this point, webcast link live?

Dr. Shore: I can hear you. I don't know if you can hear me.

Dr. Insel: Who's that? Who is speaking?

Dr. Shore: Oh, this is Stephen Shore.

Dr. Insel: Hello, Stephen. This is Tom.

Dr. Shore: Hi, Tom.

Dr. Insel: Let me just make sure that the web link is also up and running.

Dr. Shore: I can see it on here.

Dr. Insel: Good. All right. Assuming that we are good to go, let me welcome everybody to a meeting of the full Interagency Autism Coordinating Committee. We have several people around the table so we will do a quick around the table and then also take attendance for who is on the phone with us, so those who are listening in will have a full roster to be able to identify.

I'll start. This is Tom Insel. I am chair of the IACC and to my left --

Dr. Hann: I am Della Hann. I am the Acting Executive Secretary for the IACC.

Ms. Singer: I am Alison Singer. I am the President of the Autism Science Foundation and I have a 13-year-old daughter diagnosed with autism and I also serve as the legal guardian for my older brother who is diagnosed with autism.

Dr. Koroshetz: Walter Koroshetz, I am the Deputy Director of the National Institute of Neurological Disorders and Stroke.

Mr. Ne'eman: Ari Ne'eman, President of the Autistic Self-Advocacy Network and an adult on the autism spectrum.

Ms. Blackwell: Ellen Blackwell, Centers for Medicare & Medicaid Services. I also have a 23-year-old adult son with autism.

Dr. Lawler: Cindy Lawler, I am representing National Institute of Environmental Health Sciences for our Director today, Linda Birnbaum, who may be joining us by phone later this afternoon.

Dr. Solomon: I am Marjorie Solomon and I represent the M.I.N.D. Institute.

Dr. Boyle: I am Coleen Boyle, representing the Centers for Disease Control and Prevention.

Ms. McKee: Christine McKee, parent of an 11-year-old girl with autism.

Dr. Battey: Jim Battey, the Director of National Institute on Deafness and Other Communication Disorders.

Ms. Redwood: Hi, Lyn Redwood, Executive Director of the Coalition for SafeMinds, also the mother of a 16-year-old son who has essentially recovered from autism.

Dr. Daniels: Hi, I'm Susan Daniels, Deputy Director of the Office of Autism

Research Coordination at NIMH.

Dr. Insel: And if we could quickly do a round of who is on the phone. We have heard from Stephen Shore. Who else is with us on the phone?

Ms. Resnik: This is Denise Resnik, co-founder of the Southwest Autism Research and Resource Center and mother of a 19-year-old son with autism.

Dr. Insel: Welcome. Anyone else on the phone with us at this point?

I think Yvette will be joining us by phone, as will Larke Huang, and I believe that Alan Guttmacher will be arriving about 1:30. Francis Collins will not be here but, as in previous meetings, Josie Briggs will arrive to represent him about one o'clock.

So welcome, everybody. This is really in some ways a business meeting. There's a lot of work that the committee needs to get through. It's part of our obligation each year to complete an update of the

Strategic Plan and we will be doing that for much of the day.

We also have some subcommittees to hear from. So it will be, I think, an active day of getting some of the committee's obligations under way. Before we start that, I wanted to take just a couple of minutes to share with you this enormous amount of science that has taken place just since the last time we met, which was October 22.

You know, we used to do this at every meeting, we would take the first five minutes or so just to do an update on scientific breakthroughs or hot things that are happening in the world of research. We haven't done that for a while because we have been so busy with other tasks and we have also had scientific presentations.

But since we won't be doing that today, let me just take you on a very quick tour of the last eight weeks, or actually only seven weeks in autism research.

First of all, to mention that the Society for Neuroscience meeting this year in San Diego had 32,000 people in attendance, which was, I think, a record. This year there were sort of two emerging, what were called hot topics that people were talking about a lot.

One was optogenetics, which is a technology that allows us to do circuit-breaking in the brain, but perhaps more relevant to this group was that autism really emerged as one of the most exciting areas for science.

There were 337 abstracts at the meeting, which is about a 30 percent increase from where we were last year and probably about a tenfold increase from where we were a decade ago. So this is just an enormous change.

One of the initial events largely, probably one of the largest attended event, which was for the public on the first day of the meeting, is a public symposium that this year was dedicated to autism research and was chaired by Gerry Fischbach, had a number of outstanding scientists in attendance, as well as both a scientific audience as well as members of the public.

It's been just an extraordinary eight weeks if you think about what is actually coming out. Initially, this paper in the *Journal of Neuroscience* which described for the first time what might be called a brain biomarker for autism.

This was looking at structural differences in the cortex using high field strength imaging. It used five different parameters for measuring the structure of the cortex and then it asked in a kind of agnostic way, using a very elegant computational method, which was really a kind of machine-based learning approach, what is the difference between 20 people with autism -- these were adults -- and 20 people without.

And they were able to identify this kind of map here, which may be a little hard to see, but had a 90 percent sensitivity, 80 percent specificity for separating the autism from the control subjects.

So it was the first hint, at least as a proof of concept, we may even be able to do something in the basis of structural differences in cortex that will help to serve as a potential biomarker. That was in adults.

A paper that came out about the same time in the same journal, *Journal of Neuroscience*, was really the first report of ultrastructural differences using electron microscopy in postmortem material and showed something that had been suggested from other studies using imaging, that there may be differences in the wiring.

And specifically, what this really remarkably elegant study showed, for the first time, was at the electron microscopic level, it's a little hard to see here, but differences in the number of fibers that were going long distance, these large-bore axons relative to the, in autism, relative absence of those long-traveling axons and many more short, locally projecting axons, suggesting that there was a kind of a hyperconnectivity locally and a hypoconnectivity, at least in postmortem material, in the cortex.

At the last meeting we heard from Kevin Pelphrey, who described something which was really, again, I think, a bit of a breakthrough for this field. It was again using neuroimaging, but this time using functional studies to look at how the brain is activated in response to seeing biological motion or social images, and comparing not just children with autism to normally-developing children, but also including their unaffected sibs, and showing for the first time that there were differences, which he calls state differences, and this was just published in the past week, show up in red in terms of areas that are activated that only show up in those with autism, some areas which show up in yellow, which were present in both the sibs who were unaffected as well as the kids with autism, but not in the controls, and then interestingly, these areas in green, which he calls the compensatory network, which are actually hyperactive in the sibs who are unaffected, relative to both the controls and those with autism.

So an extraordinary new insight, I think, that could begin to provide a method for thinking about why it is, when many kids have the same genetics or similar genetics, they don't all show the same phenotype.

That same concept was followed a bit here, which was a study that came out in the Proceedings of the National Academy just recently, I'm sorry, in science, translational medicine, just recently, with contactin-associated protein 2, which is one of the candidate genes that has been talked about so much with autism, and showing that the inheritance of this risk allele changed the, basically, the wiring diagram, and that is, again, focusing just on the prefrontal cortex, showing that there were fewer of these sort of long-distance connections to parietal lobe, and more local connections.

That is a little difficult to see in this image, but you may want to take a look at this paper from early November, which suggests that this -- you could use imaging now to even understand the vulnerability that is conferred by these genetic variations.

So it pulls together both the genetics, which we have talked so much about in the last four or five years, with the neuroanatomy for the first time, and along with Pelphrey's work, which we heard about at the last meeting, suggests that we really can now begin to both think of structure, function of the brain, the wiring diagram which is beginning to be explored with all these new technologies, and how it may be one way in which the genetics plays out.

Last week in *JAMA*, this paper emerged which has gotten quite a bit of public attention about changes in mitochondrial function. It's a small study, 10 subjects with autism, 10 controls. But because it was, though small, a rather deep study looking at many, many different markers in mitochondrial function, it's, I think, one that bears close attention that will certainly require replication, but a lot of excitement right now to think about this topic, which we have talked about here.

There was even a special meeting that we had a couple of years ago from the IACC that was held as a satellite of the international mitochondrial meeting, trying to explore how much this could be done.

This is an offshoot of the CHARGE study out of California, and again Isaac Pessah and Irva Hertz-Picciotto who are coauthors have been people who have presented to the IACC in the past. So I would also recommend taking a look at this just as an opportunity for further follow-up, and something that we talk about in the Strategic Plan.

Related large-scale epidemiological study out of Sweden, just out a couple of weeks ago, comparing 1,200 kids with autism to 30,000 controls, so every kid with autism had 25 controls who were matched to ask what is the parental history of autoimmune disorders, and there's about a 1.5 or so odds ratio increase of having a history of autoimmunity in the family.

You can see there are a bunch -- maybe you can't because you are far away, but it includes all sorts of colitis, psoriasis, ITP which is idiopathic thrombocytopenic purpura, SLE, systemic lupus erythematosus, myasthenia gravis, rheumatic fever, all of these show a slight increase in odds ratio but altogether it's about 1.4, 1.5.

So, again, an interesting hint of something that bears further exploration and it again, it feeds off discussions we have had here at the IACC.

One last comment. This is a piece that is out about a month ago in Cell, which is maybe the most remarkable and it uses a technology that we heard about a little bit from Andy Feinberg a couple of meetings ago, the idea that you can create stem cells from human subjects by taking fibroblasts, de-differentiating them and then making them pluripotent, and then you can have these induced pluripotent stem cells that you can grow and culture and differentiate into different kinds of adult or fully differentiated cell types, including neurons.

So this was done for Rett Syndrome, this is a rare but autism-related disorder of an MECP2 mutation and in this case, and that's what you can see, I think, with this diagram is how you go from fibroblasts to differentiated neurons.

What was extraordinary here was that the neurons that were grown in culture reflected many of the abnormalities we already knew about MECP2 mutations in vivo.

So they showed not only alterations in RNA profiling, but also alterations in synaptic formation, reduction in spine density and amazingly, even altered calcium currents. So they look very much like what many of the newspapers who followed this story called "a disease in a dish," and really open up a whole new opportunity for exploring the biology of these kinds of disorders, especially those that have these penetrant, single gene mutations.

What was even more remarkable in this case was that not only could they essentially recreate much of what we know about Rett Syndrome in a dish, but they could use that as a basis for exploring new treatments.

In this case they were able to show that both IGF1, which had already been talked about in mouse studies, but also Gentamycin, which had not been tried but for theoretical reasons might be interesting, an aminoglycoside antibiotic, were powerful in being able to rescue these cells, so they actually restored the abnormal calcium currents to being more normal, they change the spine density, all of these features, by treating these cells in a dish. Interesting opportunity to actually think about how this technology can be developed further, both for understanding the fundamental biology of disorders, where you have a known mutation, as well as creating new therapeutics.

So a quick run-through, maybe most remarkable for the diversity and just the amount that has happened since we last met seven weeks ago, but this is by all means a field that is moving very, very quickly on many fronts and I think as we talk today about updating the IACC Strategic Plan, this is certainly an opportunity to remind ourselves that there really is progress and it's going to be a struggle just to keep up with it in terms of updating the Plan.

So before we go on, any questions or comments about this? I just thought it would be a good tradition to reinstate, to hear a little bit about the fruits of so many people's labor.

Okay. I am going to change directions here and we will go get on with the business of the day.

All right. So before we get started on the actual business, we have two things we need to do. One is to take a look at the minutes from October 22 and let us know whether there are any corrections, changes, additions, deletions. So let's take a minute or so to go through that.

Dr. Shore: Hello?

Dr. Hann: Hello?

Dr. Shore: Hello.

Dr. Hann: Is that you, Stephen?

Dr. Shore: Yes, I got disconnected and I heard this lovely music and it was hard getting back.

Dr. Hann: Okay. Yes, the telephone line went down momentarily. I'm glad you're back. Thank you.

Dr. Shore: All right.

Ms. Resnik: Hi, Stephen, this is Denise, it went down for all of us I think.

Dr. Shore: Oh, okay. Are we going to be reconnected?

Dr. Hann: You are connected now.

Dr. Insel: So in the absence of that music, are there any comments about the minutes? Hearing none, do I have a motion to approve?

Dr. Koroshetz: So moved.

Dr. Insel: All in favor?

(Chorus of ayes.)

Dr. Insel: Anyone opposed?

(No response.)

Dr. Insel: Minutes are accepted.

Dr. Fischbach: Hi, Tom, it's Gerry. I'm on.

Dr. Insel: Oh, Gerry, thanks for joining us. We just took note of your public symposium at SFN, which maybe you will have a chance to tell us about later in the day.

Dr. Fischbach: Thanks very much.

Dr. Insel: I wanted to also take a moment to recognize a change that we will have in the committee membership. Dr. Della Hann, who has been our Exec Sec [Executive Secretary] for all these many years, has accepted a new position in the Office of Extramural Research, where she will be the Deputy Director of the office for all of NIH, which means that she is not going to have time for us anymore. She is going to be very, very busy with her new responsibilities.

We struck a deal with her new boss

that we can continue to have her serve until the Strategic Plan is submitted, the update of the Strategic Plan. I am going to suggest that we push that off for as many months as possible, but by law that has to be done by the end of January, so I wanted to take a moment to express appreciation for just extraordinary leadership and so much help that Della has provided often late at night, weekends, sometimes from vacations, but always with great clarity and expertise.

And I thought we could take a moment to give her at the very least a round of applause for all she has done.

So we are fortunate to have Susan Daniels, who is experienced and knows all of you well, to be taking over as Acting Exec Sec for the next period of time while we do a search, and as I said, Della will remain with us, though, to the end of January.

Okay, let's go ahead and get started with the business of the day, which is the introduction for the Strategic Plan update. We will take quite a while to go through this. I thought the first thing to do would be just to go back and review what we're about here.

So the Strategic Plan, remember, is the research strategic plan. It's required by the Combating Autism Act and it's required to be updated annually.

In our case, annually means, I think it's January 23rd or 22nd that it needs to be submitted, because that was the date on which it was submitted in 2009 and 2010.

So what we did, just to remind you of the process, is we went back and we did our portfolio analysis. First we formed a subcommittee to look at this, right, because the whole committee felt that they couldn't do this efficiently.

So a group has been working hard on this process using the Portfolio Analysis to identify gaps, using the Summary of Advances that you have all seen, to get a sense of what the opportunities are, like we just talked about with iPS cells and many other things going on, taking public comment into account, both from what we received in RFIs and what we have received on the internet as well as what we hear at the meetings, and then also doing a scan of anything that has changing in policy, and this year there has been a lot, which could also speak to particular opportunities or needs that might be out there.

So what the subcommittee was told to do by you, the full IACC, was to review all of that, and to determine whether there was a need to update the Plan at all, and there was some discussion about whether that should even be done, and then there was a discussion -- there was an agreement that at least the subcommittee could look at that.

What the subcommittee ended up doing was creating essentially a template. They decided not to rewrite the whole plan, but they wanted to look at each part of it, both the introduction and each chapter, and respond to really these three questions: what is new in the past year; are there gap areas that have emerged in this past year and do we need to put any new objectives into play; are there objectives we should remove based on new information?

And so they went through this very carefully in a series of actually six meetings, beginning in April and ending last week, doing a lot of the heavy lifting and at the end really going kind of line by line to figure out what could be added or what could be taken away.

There were, I must say, this was not an easy process and from the very beginning, one of the issues we dealt with was how much of an update needs to be done, and you are going to hear that, I think, again today. There was real disagreement about whether this should be a tweak and a very,

very high bar set for putting anything new into the Plan.

Of course in this case we had a number of people who joined the IACC and also joined the subcommittee who weren't here for the 2009-2010 rendition, and so we had new perspectives at the table and for that reason, also new interest in being able to make sure that other language or other ideas were put into this update.

It's been a year where there have been lots of changing. This was the year of the Affordable Care Act -- that's the healthcare reform bill, which became law at the end of March, March 24 of this year, and also the Mental Health Parity Act, which was implemented in January of 2010.

So many things were happening in the policy sector, which raised questions about whether there were needs for research to inform how those policies would be implemented, or whether -- needs for research to look at the implementation and to identify unintended consequences or identify what the impact of some of these policies would be.

I thought I would try to capture some of the conversations and you will get much more of this as we get into the weeds here about the actual changes that are in front of you.

But I must say I think that we struggled and in some cases we simply couldn't agree on what to bring back to the full committee. We recognized that the subcommittee's role was simply to serve up to you a document of what the subcommittee felt should be considered part of the update and it's ultimately your decision as the full committee.

We also recognized that in places where we couldn't decide, where there was sufficient disagreement, that we wanted to bring this to you really, essentially for a vote, and the hope today is that we are not going to rehash the debates that we have had in the subcommittee.

We would like to do this very efficiently by giving you a sense, when there were two points of view, of what those points of view sounded like, but rather than having a full explication of each of them, we are going to show you language that provides some options and then we will ask your opinion about this and the majority will carry the day and that is what we will go ahead with for the update, to the extent that we decide to do an update today.

The kinds of things that we struggled with were around the extent to which we view ASD as disorder versus a disability, how much of the research strategic plan should be around the disorder-based biomedical science versus more services research.

And that was something that you will see in the language and there were really two points of view, both of great merit, and we heard great discussions about both in the course of these six meetings.

Lots of discussion about co-occurring conditions and we will also share with you some language there, and we struggled because we couldn't figure out to what extent some of these things were actually co-occurring and to what extent they were inherent to subtypes of ASD.

And we really felt that there wasn't enough information to really tease that apart. We will provide you some of the language that we ended up coming up with and you can see whether that works for you.

But there was enough feeling from everybody in the subcommittee that this was an important enough issue to actually add it to the introduction and to make sure that we had this as a crosscutting theme.

And the third and fourth issues that are up here, community-based participatory research and comparative effectiveness research, were both things that were emerging from some of the policy changes, from language in the healthcare reform bill which called specifically for comparative effectiveness research and sets up a new 501(c)(3) to oversee that at the Federal government level, the community-based participatory research coming out increasingly as a priority for the NIH and so you will see language that was not there in 2009 in the original plan, which shows up now, not so much because of a specific discovery that has been made or any scientific breakthrough, but because of, really, changes in expectations and some of the changes in policy.

So before we start I just thought, maybe, once again, especially for those listening in who haven't been part of the IACC process all along, it's worth just reminding you of what we are dealing with here.

Again, this is a research strategic plan, so it's about the science and we had an agreement at the very beginning, when we established this, that scientific excellence was going to be one of the bywords of this process and to make sure that we kept a very high bar for quality and for clarity and for accountability in the document.

So, this scientific Strategic Plan is really advisory and the hope is that it will provide some guidance for the many different funding groups, both public and private, but it is not by itself in any sense mandatory. It has no -- nothing more than at best kind of intellectual heft.

It doesn't have -- there's no money behind it, there's no IACC budget for research at all, so we don't fund research out of this process, we only hope to influence research by suggesting where the best opportunities and most important gaps might be.

Having said that, this was, I think, a very powerful document in 2009 when the Recovery Act emerged about a week or a month after the original version of the Plan, and it was one of the ways in which we argued for a large RFA in the Recovery Act and it was one of the things the president embraced when he talked about the Recovery Act and its impact on biomedical research and he cited autism as one of the three areas that he wanted to feature.

That happened, I think, because we had a plan and that we could go forward with something that was vetted by a large number of people to say these are the most important things for us to pursue.

We are in an entirely different funding climate right now. We actually don't know what the funding climate is, except we know it's uncertain. We do not have a budget for fiscal year `11 at NIH or CDC or actually any part of the Federal government, though the fiscal year started October 1.

So we are almost a fourth of the way through the fiscal year without knowing whether our budget is going up, staying the same as in FY 2010 or whether it's going down quite markedly.

And that information is being debated on the Hill this week. It may not get resolved by the time of recess and if it doesn't get resolved this week or possibly early next week, there will be a new Congress that will try to answer the same question.

And it is quite possible that the new Congress will decide that the FY11 budget, that is the year that we are in now, will be revised to look like the fiscal year 2008, which is about over a five percent reduction in funding for this year, which maybe doesn't sound that draconian but 70 percent of our grants at NIH are in the out years, they are already committed, so that's five percent against the 25 or 30 percent that remains so it's actually much greater than five percent. It means that the number of new grants that we will be able to fund drops by something like

30 percent in the course of this coming year.

So the opportunity to do lots of new things is going to be potentially curtailed, if not in this fiscal year, almost certainly for next fiscal year.

So I don't want to start out the day with what is a universal bummer, but it's important to know that this is not the same climate in which we created the original Strategic Plan and as we think about adding lots more objectives to this update, we do need to be realistic about what is likely to happen in terms of creating new funding initiatives, at least in the Federal government.

So the final comment is the final bullet up here, which is that the impact of this plan will ultimately be on making a compelling case for the need, the opportunity and the traction we have in this field.

We, by ourselves, will not be funding anything, but we will hopefully provide the guidance and the inspiration from this document to create and support the best new science, even under rather meager fiscal conditions.

So that's the place I wanted to start. Again, I don't want to necessarily be the ultimate downer here, before we even begin the update process, but I think we have to be realistic about what we are facing here and know ahead of time that adding lots of new objectives and creating lots of new pieces of this plan might be helpful but it also might simply have unintended consequences that we want to be thinking about.

Okay, this is what we are about. Let me stop here and, before we get started, see whether there are any issues generally that anybody wants to raise, either those on the phone or those around the table, and if not, we will actually start to dig in.

Dr. Fischbach: Tom? It's Gerry.

Dr. Insel: Gerry, go ahead.

Dr. Fischbach: I just second the comments you have made of everyone's concern regarding the budget and just reaffirm how thrilled I am and everybody is that you are there. And it's going to be a difficult couple of years and we have got to use the resources as well as --

Dr. Insel: Okay. Thanks Gerry. It's a little difficult to hear you, but we got the message. It's just, you are breaking up a little bit. We will see if there is anything we can do on our end to improve the reception.

Dr. Fischbach: Okay, is this better?

Dr. Insel: That sounds good. Walter?

Dr. Koroshetz: The only other thing to mention, I'm not sure how relevant it will be, but there is a new potential funding source for looking at comparative treatments, which is this Patient-Centered Outcome Research Institute that is going to be outside the government but will be funding comparative effectiveness research, and they have an expected budget of, I think, $50 million then going to $150 million in FY12.

They will be considering projects and so some of the comparative treatment things that we are thinking of, that may be another source of getting work done.

Dr. Insel: Good point, actually I think the ultimate budget is $500 million for -- this is PCORI, the Patient-Centered Outcomes Research Institute, but as Walter mentions, this is, although it's in the healthcare reform act as a new initiative, it's not a Federal initiative, it's actually a 510(c)(3) that has 21 members on the board to oversee a process that will guide comparative effectiveness research and the money for it will come from a tax on insurance and Medicare.

And it's not clear exactly what this process will be, but the director of NIH and the head of AHRQ will both be on this 21-member board and the chairman of the board, Gene Washington, has just been announced. There are 19 members in addition to the two Federal members, so a lot of interest in what this will look like, how it will operate. It is possible that they will be subcontracting projects through NIH and AHRQ. We will have to see.

Anything else before we start? Susan, you wanted to make some housekeeping comments?

Dr. Daniels: Yes, I wanted to say to speakers on the phone, if you could please mute your phones, that would be helpful, to keep the external noise down, and to just ask people to use your mics and say your name before you speak in order for the transcriptionist to be able to get that information, and then turn off your mic when it is not in use to prevent feedback between the mics. Thanks.

Dr. Insel: Anything else? Okay, let's go ahead and jump in. I think what we will do is start with Chapter 1. We will cycle back and do the introduction at the end. So that will be up on the screen and you should have received all of this ahead of time so you will have a chance to hopefully do this rather efficiently.

What we are going to do is just to go through by components, the first being what's new in this research area, what have we learned in the last year and I must say that the process here -- well, we ought to recognize that there are a few people who did a lot of work on pulling all of this together, particularly these summaries, to try to give, in a concise way, a picture of what has actually happened since we did the 2010 Plan that might be relevant to going forward.

So the first two sections don't involve objectives. They simply are an attempt to summarize where we have been. I think

Coleen pulled this together for the group, got input from many people in the group, but it was really Coleen's handiwork to get us this language.

So let me see whether there are any issues about these first two sections, either what's new or what are the gaps. Ellen?

Ms. Blackwell: I just had a couple of quick edits in paragraph 2 and paragraph 3, if we could substitute, Coleen, the word "people" instead of "patients" in sentence 4, and in the last paragraph, "children" for "patients."

Dr. Hann: Okay.

Dr. Insel: So we are taking note of these things. Ari?

Mr. Ne'eman: Yes, I have an issue in paragraphs 1 and in paragraphs 4. So look at paragraph 1 first. I think a great deal of people in the self-advocate community will have concern with the comparison of autism with cancer and AIDS.

Dr. Hann: That is question 1, Ari.

Mr. Ne'eman: Oh, I'm sorry.

Dr. Insel: Yes, we are doing chapter 1.

Mr. Ne'eman: Oh, I apologize, I thought we were on the introduction.

Dr. Insel: We'll get there.

Mr. Ne'eman: Please. I just forgot.

Dr. Insel: We'll get there.

Mr. Ne'eman: Apologies.

Dr. Insel: So this is just -- this is Coleen's language on pages 1 and 2 of chapter 1. Anything else? Anybody on the phone?

Okay, let's move on to the part on objectives and you will see that there are five that are raised here. One of them was marked because the subcommittee felt that we needed more discussion from the full group.

Now, I have to say this is one that the subcommittee decided that we would volunteer Dr. Guttmacher to help us with and he will not be here until 1:30 so I think this one will break out. ELSI is his area of expertise and so we thought it might be useful to get his input about the best way to move forward with this.

So if we take that one out, there are four other objectives that are being recommended.

Dr. Boyle: Actually, Tom, there are two new ones and the others are revisions of current objectives.

Dr. Insel: I stand corrected. Okay. Actually, I should probably do this. I should have the chapter leads take us through this because you knew it better. So Coleen, I'll let you -- anything you want to say about any part of this that would help to clarify this for the rest of the committee.

Dr. Boyle: Well, that's what I was going to say about the objectives. They are in reverse order there. But the third through fifth objective that are listed, those are revisions of the current objectives A through C and then the first and the second are actually new objectives.

So the first is a new objective in response to the Miller study on the chromosomal microarray study and it's really trying to examine the positive predictive value and clinical utility of that technology in a clinical setting.

And then the second one was the ELSI issues, and its implications for early diagnosis and early screening for autism.

Dr. Insel: Thank you. So, questions or comments? Okay. So, with the exception of the language about ELSI which we will revisit at 1:30, Della, can we take a quick vote and see where we are at here?

Dr. Hann: Okay, so the changes that have been recommended by the committee, there's a change to paragraph 2 on the first page, to change "patients" to "people," and in the third paragraph to change "patients" to "children." And those were the only changes that I heard that are up for vote, and everyone seems to be comfortable with the rewording, the revisions to the objectives being composed, that's short-term objective C, short-term objective B and short-term objective A, reword, and to accept the first new objective, which is to conduct at least one study to determine the positive predictive value and clinical utility of chromosomal microarray genetic testing for detecting genetic diagnosis for ASD in clinical settings by 2010.

Dr. Insel: Is it 2010?

Dr. Hann: 2010.

Dr. Insel: Too late.

Dr. Hann: We are over.

Dr. Insel: Coleen, do you want to recommend a change in the date?

Dr. Boyle: I will say 2012. Does that sound reasonable?

Dr. Hann: That sounds good.

Dr. Boyle: Thank you.

Dr. Hann: Okay, and then the second new objective that was proposed is on hold until Dr. Guttmacher can join us this afternoon for discussion.

All in favor?

(Chorus of ayes.)

Any nays?

(No response.)

Okay. The chapter carries.

Dr. Insel: And we will move on to chapter 2. At this rate, we will be finished by noon. Marjorie helped us by pulling together lots of comments and discussion about chapter 2. Can you take us through it?

Dr. Solomon: Sure, Tom. What we did to come up with a list of new research areas is first we took the list that was published of recent advances from our committee and we incorporated that in the first section.

We also conducted a review of high impact journals across psychiatry and psychology fields and came up with a list of structural imaging studies, studies showing abnormalities in underlying brain structure and then studies showing things about neural circuits, and so we updated the review to include those.

In listening to your little talk today, we have included some of the studies, the Zikopoulous and Barbas study, the post-mortem study about white matter has been included, but I was reading on the plane the Ecker study and thinking that that might be a good thing to also include, as well as Ashley Scott's study.

So I would like to recommend that we include those. We can put them in after the first paragraph for the Ecker paper and the third paragraph for Ashley Scott's study, which will come after Kevin Pelphrey's study of neural endophenotypes.

Probably the major issue that we talked about in this group was the fact that some of the studies that were previously included in the Strategic Plan didn't neatly fit under any of the short-term and long-term objectives.

So in collaboration with the office, we decided that next year, we will make mention of those in the Strategic Plan in a sort of template they will provide for us so we will be able to track better our progress.

We didn't actually end up including any new objectives. We did tinker with some of the words. On existing objectives, we reworked short-term objective A to include the concept of fever. We reworked short-term objective E to include the concept of wandering and safety issues.

In terms of gaps, we also highlighted the emerging area of metabolomics and just made mention of several implementation issues, just really wanted to emphasize again the need to translate our findings into actual clinical practice.

And we also wanted to compliment the committee on all efforts related to mentorship programs, the T32 and other programs and we did that in our final comments just on what has occurred over the year. So I think that pretty much incorporates our changes.

Dr. Insel: Okay. Comments from the full committee? Walter?

Dr. Koroshetz: For clarification, so under the draft updates, it says studies to investigate metabolic pathway perturbations that affect immune function and methylation. So is that a revision of short-term objective A or is that a new one? I can't remember.

So short-term objective A is for research to identify mechanisms of metabolic and/or immune system interactions with the central nervous system that may underlie the development of ASD during prenatal-postnatal life.

So it doesn't include methylation

in the maladies, but what -- I can't remember what we planned to do with that one.

Dr. Solomon: My recollection was we did include it as a research opportunity but that it didn't come into any of the new short- and long-term objectives.

Dr. Insel: I think the question is about the first bullet.

Dr. Solomon: A revision of the first opportunity?

Dr. Insel: So we are trying to make sure we understand where that gets inserted -- which bullet it refers to in the 2010 version of the Plan. It's on page 14 and 15 of the Plan.

Is it long-term objective A? It says first opportunity, second bullet point.

Dr. Solomon: Yes.

Dr. Insel: So it's not actually part of an objective. It's simply --

Dr. Solomon: No, it was just part of the research opportunities.

Dr. Insel: Got it. Okay. Walter, is that clear?

Dr. Koroshetz: Yes.

Dr. Insel: Okay. Any other questions or comments?

Ms. Lewis: Can I just ask a similar clarifying question in terms of do you have specific language on how you want to rework the two short-term objectives, both A and E, or are we just inserting the word fever and the word wandering? I am just trying to understand how these pieces ultimately fit together, if there is actual language or if we are just kind of approving the conceptual basis of sticking wandering into the short-term objective. I'm just -- it's really just a clarification.

Dr. Solomon: We actually just were going to stick the word --

Ms. Lewis: Okay, that's -- I just wanted to make sure. It just -- okay. Great.

Dr. Insel: So, let me just --

Sharon's question, I just want to make sure I understand this. So for inserting the word wandering, it would read: launch three studies that target the underlying biological mechanisms of co-occurring conditions with autism, including seizures, epilepsy, sleep disorders, presumably wandering and familial autoimmune disorders by 2012.

Dr. Solomon: That was the recommendation of the committee, yes.

Dr. Insel: So wandering is being treated as a co-occurring condition?

Dr. Solomon: It is.

Dr. Insel: Ellen?

Ms. Blackwell: Sorry, my mic. Marjorie, I also sort of struggled with the same question Sharon had, that it would be really helpful for me, if we are just adding a word, I understand that, but because we addressed wandering in chapter 5, I just don't think we need to mention it in chapter two at all.

So it would really be helpful to me if you could actually read back to us what the language would say in opportunity 7 and opportunity, short-term objective A, and then also, I would suggest in the next paragraph, where we have this great reference to the number of new investigators, I think we have a similar reference to that in chapter 7 and that we also sort of ship that over there.

Dr. Solomon: I think actually when we went through everything, we did chapter 2 prior to doing chapter 5 or I can't quite remember, but I would certainly be fine with leaving wandering in chapter 5, and I would as well be fine with leaving mention of mentoring programs and so forth in chapter 7. It's more elegant.

Dr. Insel: Other comments? Alison?

Ms. Singer: One of the reasons that some members of the Safety Subcommittee recommended that wandering be included in both chapters 2 and chapter 5 was because they were really different types of objectives. The objective here in chapter 2 was to try to understand the biological underpinnings associated with wandering, and the objective in chapter 5 really talks about looking specifically at the validity of different types of interventions to either prevent wandering or to prevent the negative outcomes associated with wandering. So they are different objectives.

Dr. Solomon: I understand your point. You are correct.

Ms. Lewis: I guess I would raise the question as to whether or not we know enough yet to consider wandering a co-occurring condition with an assumption around a biological mechanism and put it into the same kind of medical character as epilepsy and sleep disorders, and whether we are prepared to make that set of assumptions, and I don't know that I am comfortable that we have enough evidence base to make that set of assumptions.

Dr. Solomon: I think the argument of the committee was that wandering could be a sort of behavioral manifestation of executive function impairments in planning and organization, but I hear your point.

Dr. Insel: Okay, well, this is the opportunity to hear some different perspectives. We will vote on this in a minute. Ari?

Mr. Ne'eman: I just had a question in regards to this. Is there currently any research which suggest that type of underlying biological mechanism or anything of that nature in terms of research that meets our standards for scientific excellence that would suggest an underlying biological mechanism along the lines of what you are referring to?

Dr. Solomon: I think probably not. I think the relationship between neuropsychological variables and even neural signatures of a lot of symptoms really remain an active area of investigation, and I personally don't know of a study that has linked wandering to any kind of biological mechanism.

Dr. Insel: Geri, last comment, and then we will move on.

Dr. Dawson: So just a couple of thoughts. One is that I remember when the presentation was made that they made the point that in Alzheimer's there is a medical code of Alzheimer's with wandering, and so what we see when a person develops Alzheimer's is that the tendency to develop wandering also occurs which would suggest there is some biological change.

I think the only -- and I actually don't have a strong feeling of whether to put this in here or not -- but the justification for it would be to try to understand whether or not this really has to do with things like impulse control and executive function as compared to some more behaviorally-oriented cause, such as unwitting reinforcement of this behavior or something.

So I do think that by disentangling the cause of it, one then would know better how to treat it.

Dr. Insel: Okay, as I say, we will come back and vote on this having heard some different perspectives. Can we just clarify, Marjorie, the other item was on fever, which goes into short-term objective A, and I am just wanting to make sure that the committee understands what the subcommittee was recommending.

So it says to include the concept of fever. This is the one that says support at least four research projects to identify mechanisms of metabolic and/or immune system interactions with the central nervous system that may underlie the development of ASD during prenatal-postnatal life by 2010. And since we are beyond 2010, that may need attention.

But where would fever go in there?

Just how would this be worded after --

Dr. Solomon: To identify mechanisms of metabolic and/or immune system interactions and fever with the central nervous system.

Dr. Koroshetz: Fever is first and then so mechanisms of fever, metabolic immune system interactions with the central nervous system.

Dr. Insel: Lyn?

Ms. Redwood: Initially, what we were trying to accomplish was not adding new objectives, but being able to incorporate some of the new emerging research that is exciting. There was a study that came out that documented improvement with fever in children with autism and there have also been studies with regard to mitochondrial dysfunction that seems as though fever is a trigger.

So I think if we could somehow get a better understanding of fever so instead of creating a new objective, because we were sensitive to not wanting to make the Plan any longer, we were trying to incorporate this idea into an existing objective, and sometimes that's difficult to do.

But I also wanted to get the point across that it is fever that is associated with both regression and improvement in ASD behaviors.

Dr. Insel: Is there a way, just, I hate to do this, in terms of syntax, I just want to make sure I know what this is going to read like, because Lyn, what I hear you saying is that fever in some ways would be a kind of an example of, whether it's metabolic or immune interactions with the CNS, and so it may go in parenthetically rather than being a major aspect of -- in a sense it's like an example of what -- is that what you are saying, that --

Dr. Koroshetz: Maybe some. It could be completely separate. It could be a temperature effect so the fever, I mean it may not just be metabolic and immune; it could be. So I think putting the word fever in makes sense, fever and metabolic because there was lots of metabolic and immune system interactions that are not associated with fever, but fever seems to be a particular --

Dr. Fischbach: I agree with that. You can -- Can you hear me?

Dr. Insel: Intermittently, Gerry.

Dr. Fischbach: So sorry -- fever is a very -- concept -- and it could -- doesn't necessarily have to -- infection -- so it -- separate -- notion of -- infection --

Dr. Insel: I am not sure we quite got that, but we heard about every third word, or maybe every fifth syllable. Marjorie, maybe let's turn this back to Marjorie and see if we can come up with the final wording on this so that the committee will know what it is voting on.

Dr. Solomon: Okay, support at least four research projects to identify --

Dr. Hann: I think there are -- this is Della. There are two options I think that are available.

Dr. Solomon: Thank you Della.

Dr. Hann: You are welcome. So I think here is one option, which I believe is the one that Walter is suggesting as well as Gerry Fischbach. Support at least four research projects to identify mechanisms of fever, comma, metabolic and/or immune system interactions with and then it continues on.

That is one option. The other option where it is more of an example, would be: support at least four research projects to identify mechanisms of metabolic and/or immune system interactions with the central nervous system, such as fever, which would be parenthetical, you know, in commas, that may underlie da, da, da, da.

So I think those are the two options I heard being discussed.

Dr. Solomon: Thank you. That is

what I was going to say.

Dr. Insel: Lyn?

Ms. Redwood: The second option, where fever, that it would make it -- well, I'm a little concerned with having it underlie the development of ASD during prenatal and postnatal life, because it could actually help, so I guess I would prefer the first, where fever is actually -- mechanisms of fever, metabolic and/or immune. But could we also change it to say either may underlie the development or improve somehow to get the concept in there that those mechanisms could be beneficial or injurious?

Walter, what are -- I see you shaking your head.

Dr. Insel: How about just may influence ASD during prenatal-postnatal life. And I think, if I heard Gerry right, I think Gerry was saying what you are saying Lyn, that this should -- you can't tie it to -- it's not a subtype, it's independent. So Susan or

Della, do you have that language so we can read it? Okay.

Dr. Hann: Just let me say it, just to make sure, okay?

Support at least four research projects to identify mechanisms of fever, comma, metabolic and/or immune system interactions with the central nervous system, that may influence ASD during the prenatal-postnatal life.

Dr. Insel: Okay. And then the last issue was, there's an issue here about regression, just taking language regression out and talking more generically about regressive autism. That was the other major change.

Unless I hear other concerns, I think it's time to take these to a vote. We have got it up. Walter?

Dr. Koroshetz: Just one question, and it's just a style question, is if you look at the many other chapters, the advances are kind of put into prose, and so I am wondering, this one is more of a list, so I was just wondering whether that, for the audience, should we kind of reword it or is it okay as it is, given the audience that it's going out to?

So the first page, where they go the multiple studies, so it's a style question, that's all.

Dr. Insel: Let's let OARC worry about the formatting, they will make this beautiful in some way.

Dr. Solomon: I actually used another chapter as a model, so --

Dr. Insel: Okay, Della, unless there are any other comments --

Ms. Blackwell: I was going to say the same thing as Walter. He was two steps ahead of me. I think it would be really helpful if OARC could have the discretion to just go over all of these chapters because they were written by different people and sort of smooth them to make them more consistent. If everybody would agree to that I think that would be very helpful.

Dr. Insel: Right. I won't need to use your time for this. So --

Dr. Lawler: I just have a minor comment, Tom.

Dr. Insel: Please.

Dr. Lawler: In cases like this, where we have altered an existing objective, I assume we will change the timings. This one has 2010.

Dr. Insel: What does the committee want to do, because that does have implications. I mean, we told the community that this was something we wanted by 2010. Does the -- so if you want to change the timing, it's something we need to do. What's your pleasure on this?

Dr. Koroshetz: If we are going to add something we have to --

Dr. Insel: So what do you want it

to be?

(No response.)

Ms. Redwood: Tom, the only problem I see in doing that, and I agree we are going to have to do it, is when we go back to look at the Plan, when we are evaluating with our research portfolio, is there a way to sort of separate this out into two categories to say there's this addition of fever was added in 2010? I mean, I am just wondering, down the road, how this is going to impact our research portfolio analysis.

Dr. Insel: I think that's a really important point, because it does begin to look like we are moving the goalposts continually, and we can do that, but it's not where we started. In 2009 we had a very disciplined approach to this with -- and the way we set priorities was to put dates on things.

But if the committee wants to say this is one where we will change the date and we will add in an item, then that's totally a prerogative. So, Geri and then Sharon.

Dr. Dawson: I do think it's important to maintain the original dates, just because it will help us monitor, you know, how quickly we are making progress. I do think if we add something new if wouldn't be terrible to add a phrase that said fever added in the 2010 update, you know, just as a -- but I don't think we want to keep moving the goalpost because that will not allow us to assess how rapidly we are addressing the issues.

Dr. Insel: Sharon.

Dr. Solomon: I would echo Geri's comment and Lyn's comment in terms of not wanting to move the goalposts, and secondarily, I think that the unintended consequence of changing that to 2012 is that clearly, there was a delineation in terms of priorities based on dates, and if we are moving this date to 2012, in the context of other dates that are currently set at 2011, we are now saying that this is a less urgent priority than dates that are set against 2011.

So I would agree with Geri that I think we should add the language and, you know, either add a footnote or parenthetical that just says it was added in 2010.

Dr. Koroshetz: We could -- as a compromise we could just put in parentheses -- keep it as it is and then parentheses afterwards, fever studies by 2012.

Dr. Insel: So we have got a couple of ideas of how we want to handle this. Some of this, it seems to me, we can work out in the syntax effort, but anything more substantial that we want to talk about before we take these items to a vote?

Marjorie, anything else from this chapter?

Dr. Solomon: I think that's it.

Ms. Redwood: Tom, really the question I have is I wonder how many more times we are going to face this as we go through the additional chapters, and I think we need to set up sort of a policy now with regard to these updates, because it's either a new objective or a footnote with an asterisk saying the data was added --

Dr. Insel: Right --

Ms. Redwood: Because this is going to crop up over and over.

Dr. Insel: Yes, because we don't want to do a lot of new objectives, I think what we will do is be inserting language, again, that the committee may disagree -- but the easiest thing will be to insert the language and provide the asterisk that provides the new date.

But if you don't want to see the date creep on the full objective, then we will just have to hold the working the way we have it. I see heads nodding.

So shall we read it?

Dr. Hann: Okay.

Dr. Insel: Let's start from the top

and go ahead and get votes on chapter 2.

Dr. Hann: Okay. Here's what I heard. There are no -- wording changes are right now being proposed for the what is new in the gap area. However, there is an overall recommendation for all chapters for OARC to take a look at smoothing language and having a consistent style across the chapters.

Dr. Solomon: Although I would like to add in just a couple of new references, if that's still okay.

Dr. Hann: That's fine. My guess is, I mean I am not going to speak for Erin, she's our writer so she is the one who has the heavy lifting on this, is that we will probably have summary kind of statements and then list references at the end and not some sort of spell out each individual study.

Dr. Solomon: Okay.

Dr. Insel: And there are some typos, which I don't think the committee needs to struggle with.

Dr. Hann: Okay, moving on to --

Dr. Insel: Do you want to vote on that part?

Dr. Hann: Oh. Sure.

Dr. Insel: You've got the first two sections.

Dr. Hann: Sure. First two sections. Any -- those in favor?

(Chorus of ayes.)

Any not in favor?

(No response.)

Okay. Carries.

Moving then to the section on the objectives and new opportunities. There was a change and to the first opportunity. This is not an objective. This is an opportunity, which in your copy of the existing plan appears on page 13, to reword the second bullet, to say: multidisciplinary assessments of brain imaging, metabolic and immunity markers, microbiomics, metabolomics, electrophysiology and behavior.

So it's adding a few things to that second bullet.

The second area listed, it's not entirely clear to me where that goes. I'll be very honest. It says: studies to investigate metabolic pathway perturbations that affect immune function and methylation.

Was that wording, Marjorie, to go to a specific objective or --

Dr. Solomon: Yes --

Dr. Insel: This was for opportunities. This was an opportunity marker?

Dr. Solomon: Lyn, do you recall, I think that was your suggestion.

Ms. Redwood: I think it was one early on when we were writing the narratives and updating the whole chapter that was sort of pulled over from that, but I'm not certain where we decided to put it.

Dr. Solomon: Do you have a suggestion or do you think it's covered now?

Dr. Insel: There is, under the very

first bullet in research opportunities, the second sub-bullet says: multidisciplinary assessments of brain imaging, metabolic and immune markers, microbiomics, electrophysiology, and behavior.

So I think the -- so that's actually the very first one, right? So then, did you want to add immune function and methylation to this, or was that the plan?

Ms. Redwood: Actually, I think the immune function is addressed in other areas, but I don't know that the methylation is.

Dr. Solomon: Yes, let's just add methylation, although it is covered I believe in 3.

Dr. Insel: It is, yes, we have got it. Can we just drop this out?

Dr. Solomon: That would be fine.

Dr. Insel: Okay, so take that out.

Dr. Hann: Okay. So now the -- that second proposed bullet there is now dropped. There is a rewording to the last research opportunity, to drop the phrase language regression, so the opportunity would read: prospective children -- excuse me, prospective research on children both with and without autistic regression, including potentially underlying genetic and other risk factors, including seizures and epilepsy.

Then I believe what the group came down to with regard to the rewording revision for short-term objective A -- hang on one second. To support at least four research projects to identify mechanisms of fever, comma, metabolic and immune system interactions with the central nervous system that may influence ASD during the prenatal-postnatal life by 2010, and then what I heard was then in parentheses to indicate that the fever component was added and is sort of a due date, if you will, of 2012.

Dr. Insel: Shall we vote on that part? So we have got everything except the wandering is now under discussion?

Dr. Hann: Okay, those in favor of the changes that I just walked through.

(Chorus of ayes.)

Those not in favor?

(No audible response.)

Okay, carries.

Dr. Insel: On the phone, any ayes?

(Chorus of ayes.)

Or nays?

(No response.)

Okay. Thank you.

Dr. Hann: Thank you.

Dr. Insel: And then we have the last issue was the what to do about wandering.

Dr. Hann: Correct. There was a difference of opinion expressed by committee members with regard to whether or not short-term objective E should include the concept of wandering or if it should be -- or it should not.

Dr. Insel: So let's go ahead and read it and then we will vote on it.

Dr. Hann: Okay. The current objective reads as follows: Launch three studies that target the underlying biological mechanisms of co-occurring conditions with autism, including seizures/epilepsy, comma, sleep disorders and familial autoimmune disorders by 2012.

If wandering were to be added, it would be added as one of the examples. So it would read: mechanisms of co-occurring conditions with autism, including seizures and epilepsy, sleep disorders, comma, wandering, comma, and familial autoimmune disorders.

Those were the options, so to include or to not include.

Those in favor of including the concept of wandering into this particular objective?

(Show of hands.)

One, two, three, four, five, six, seven, eight at the table.

Those not --

Dr. Shore: Yes.

Dr. Hann: Who is that?

Dr. Shore: That was me, Stephen.

Dr. Hann: Okay, anyone else on the phone?

Ms. Resnik: Denise.

Dr. Hann: Okay, so that is 10 in favor of including the concept of wandering.

Those not in favor of including the concept of wandering?

(Show of hands.)

One, two, three, four, five, six in the room. Any on the phone?

Dr. Fischbach: I am worried that -- because -- I wonder -- how -- self-awareness and how that should -- out.

Dr. Hann: I couldn't understand any of that.

Dr. Insel: Gerry, it's difficult to understand this because we are losing so many of your syllables.

Dr. Fischbach: I will dial in --

Dr. Hann: He needs to come in on a different phone.

Dr. Insel: Okay. Thank you.

Dr. Hann: Okay. Is there is anyone else on the phone that is not supportive of including wandering? Okay, so until we hear from Dr. Fischbach --

Dr. Insel: Well, unless he had four votes --

Dr. Hann: No, he doesn't get four.

Dr. Insel: Okay, let's move on.

Dr. Hann: Okay. Motion carries to include the concept of wandering.

Dr. Insel: Chapter 3 was Geri. Are you going to take us through this?

Dr. Dawson: Yes, so there was a lot that happened in 22010 in terms of new information about causes and so in the new research area we noted some of the new findings regarding genetic risk factors, regarding the role of prematurity and two studies that examined mercury.

We also updated in terms of medical conditions and whether they may be able to provide clues regarding environmental risk factors as they have in other conditions.

We also summarized the findings and recommendations of a conference that was held on environmental risk factors and including those specific research objectives that were identified at that conferences as well as new technologies.

We noted the need to use induced pluripotent stem cells as a way of exploring the biological basis of autism not only in terms of genetic variation, but also in terms of translational toxicology, and we also noted the recommendations of the National Vaccine Advisory Committee, and these were recommendations that were in response to the IACC asking the NVAC to consider the need for research on immunization and autism.

And based on that, we identified several gaps. In terms of gaps, there are --

clearly is a need for suitable model systems to understand environmental risk factors and their interaction with genetic susceptibility.

There was also a need identified for larger and more integrated epidemiological studies that include information about a wide range of potential environmental risk factors, the need for greater collaboration between scientists that are exploring both genetics and environmental risk factors.

We emphasized the need for a better understanding of the role of epigenetics in autism etiology, and then we emphasized, and this is just underscoring what has been identified earlier as a lack of adequate postmortem brain tissue for understanding both genetic and environmental risk factors.

So based on that, we made several recommendations for new objectives, and the first one has to do with taking advantage of special populations in epidemiological studies to inform our understanding of environmental risk factors during pregnancy and the early postnatal period.

And so from the gaps and the new information that was identified, there were really a wide range of special populations that could be informative, so these could be individuals that have different exposure histories, such as prematurity and maternal infection, nutritional deficiencies, toxins, people with different migration patterns, children with and without a history of autistic regression, children who may have had an adverse event following immunization, such as fever and seizures, children with mitochondrial impairments and also a recommendation from the NVAC to study siblings of children with regressive autism.

So we decided rather than coming up with a lot of different recommendations that we would really try to pull this together as one objective that recognizes that by studying particular populations or subtypes, that this may help inform etiology in autism.

The second recommendation came out of the workshop that was held on environmental risk factors, and that was to explore the usefulness of bioinformatic approaches because there really are some new tools that have been developed that haven't really been brought to bear in terms of understanding environmental risk factors in autism.

We also suggested that there be at least two studies that examine differences in the microbiome of individuals with autism versus comparison groups.

The next objective was to have three studies that focus on the role of epigenetics in the etiology of autism and Lyn, this is where we included studies that have assays to measure DNA methylation or histone modifications.

And then, finally, to support studies or workshops that could facilitate the development of vertebrate and invertebrate model systems to explore environmental risk factors and their interaction with gender and genetic susceptibilities because that was identified as such a glaring gap.

Dr. Insel: Very good. Thank you. Comments? Questions? Ellen?

Ms. Blackwell: Thank you Geri. I know that you carried two chapters, so you also had a little bit of an extra load. I just have a couple of questions about the studies at the end.

Being mindful of Tom's note at the beginning where we need to think about budget, where we talked about two studies that examine potential differences, I wondered why we needed two, and also, you cited two examples under the next bullet and then asked for three studies.

So I thought we might want to talk about are these really the right numbers. And then on the third bullet, we didn't have any numbers of studies and workshops. So maybe that's just something that we could talk about for a second.

Dr. Battey: I would favor taking the numbers out entirely.

Dr. Insel: So --

Dr. Hann: I appreciate why you would want that. It's very difficult, then, to do to the budgets, because we are required through the Congressional language to provide budgetary information along with the Plan.

So if we don't have some sense of the numbers of studies or workshops etcetera that the committee is interested in, it's very difficult to do the budget piece.

Dr. Insel: So just to weigh in here, we actually talked about this in the subcommittee because we struggled with it. Obviously, the goal is to get the work done and not to support studies but get answers. So if you could do it in one study, that would be much better than doing it in five.

But we also struggled with the

format that we had already followed and, as Della says, the need by law to be able to provide numbers, and also to have some accountability.

But I hear your concern about using these numbers when you really don't know what they mean. We have no reason to say that four or five studies would be better than one really definitive study.

Geri?

Dr. Dawson: So I just want to make a comment about the two studies on the microbiome and the three on epigenetics, and it is obviously pretty arbitrary.

But the idea behind that is that we really, I don't think, have any published data on the microbiome, and so the idea there was it's a new area, you would want to have a study and a replication or at least to see whether there's consistency across two groups to begin to look at a new area.

The reason for three in

epigenetics, and again this is a bit arbitrary, but it does seem to me to be a very rich area and a lot of different ways that one could look at epigenetics and so I think it calls for that kind of more than two, because there's just a lot of work to be done there and a lot of different ways that one could approach it.

So that is the rationale, and honestly the last one, I just think it was hard to put a number and I would be very open to whatever the committee recommends.

Dr. Insel: Other comments or questions about this? Marjorie, your light is on, question or no, okay. Anyone on the phone have comments or questions?

Dr. Shore: Not here.

Dr. Insel: Okay.

Mr. Ne'eman: Do you mean about this section in general or the issue of the number of --

Dr. Insel: No, the section in

general, so if there's anything else you want to bring up, Ari.

Mr. Ne'eman: I would really like to raise issue with one of the -- with the title of the section, in regards to prevention being mentioned. I think one of the reasons why we are putting in -- we are discussing the issue of ethical, legal and social implications earlier in the Plan is to really ask questions quite like this, as to whether or not prevention should be a legitimate goal or a priority for autism research.

And clearly there are some implications of the first part of that, the first question that we ask in the title: what caused this to happen?

And depending on the answer there, I think that leads to a number of different possibilities with regards to whether or not prevention is one of our goals.

Finally and in respect to the IACC Strategic Plan being a neutral document that attempts to really focus on science as opposed to value judgments, I think a number of people would see enshrining prevention as a research goal with regards to the title of a chapter of the Strategic Plan as a value judgment.

So I would suggest simply modifying the title to read: What Caused This To Happen, and leave it at that.

Dr. Insel: I think members of the committee may remember we actually had this discussion, I think it was two years ago, because the original title was What Caused This To Happen but we had included prevention as a crosscutting theme, and so the committee felt that we needed to address that because there wasn't really any language in the objectives or in the chapters other than this crosscutting theme to focus on this, and it was one of the things we heard also from public comment, was the importance of a real focus on prevention as something that would be an important strategic goal for the Plan.

But this is a matter for the committee to revisit to get a sense of where the full committee is at this point.

Mr. Ne'eman: Let me just add one thing, in regards to when we mention prevention as a crosscutting theme, we do acknowledge that prevention of ASD is not necessarily a universally-accepted policy goal.

We look at prevention of the challenges and disabilities of ASD and qualify whether or not prevention of ASD is a goal of research based on that question around causation, so I think a change to some degree would be consistent with the crosscutting theme, but obviously it is the decision of the full committee.

Dr. Insel: Any other comment on this? Coleen.

Dr. Boyle: Geri, I'm looking over the already existing objectives, I was wondering if you had given consideration of long-term objective D, which is on page 22, perhaps sort of combining that with your first objective, just in light of trying to reduce the number of new objectives.

That one says support ancillary studies within one or more existing, epidemiologic studies, and this could be tweaked a little bit to perhaps incorporate some of the newer ideas that you have within this one.

Dr. Dawson: That definitely would be a possibility. I think one issue there was that I think this objective was really about the utility of special populations rather than -- the epidemiology was almost secondary.

So I think it has a little bit of a different focus.

Dr. Boyle: It does say three epidemiologic studies.

Dr. Dawson: Yes, so we may want to actually --

Dr. Boyle: Change that.

Dr. Dawson: Change it to studies.

Dr. Boyle: Okay.

Dr. Dawson: Right? Because particularly if you think about some of the special populations there, they probably wouldn't necessarily be done with an epidemiological focus, so I think that's a really good point.

Dr. Insel: I'm sorry Geri, so what would it say at this point?

Dr. Dawson: So what is being suggested is that the first objective would instead of saying: support at least three epidemiological studies that take advantage of special population, it would say: support at least three studies that take advantage of special populations or expanded existing databases.

Because some of these may not have an epidemiological focus, especially when we think about some of the subgroups that we have listed here, it would be harder to approach that.

Dr. Insel: Do we need the language that says take advantage of, or could we just say support at least three studies of special populations?

Dr. Dawson: Sure.

Dr. Insel: Okay.

Dr. Dawson: Yes. That's good. While I have the microphone, I did want to point out that with regard to the issue of prevention, that the IACC, which was created as the Creating Autism Act -- that was what created the IACC, that it has defined its duties, and someone had sent this to me, that in carrying out its duties, the committee shall develop and annually updated summary of advances in ASD research related to causes, prevention, treatment, early screening diagnosis or rule out, intervention, access to services and supports for individuals with autism spectrum disorder.

So I don't think we could remove

prevention wholly from the Plan because it's actually part of the charter of the committee as defined by the Combating Autism Act.

Dr. Insel: Ari, you'll get the last word and then we are going to vote.

Dr. Fischbach: Tom, can you hear me?

Dr. Insel: Yes, Gerry we can hear you now.

Dr. Fischbach: Okay. I was a little -- I am very sorry for the -- I am wondering what people have in mind when they say the word prevention and I wonder if most of Ari's feelings -- preventing certain disabling aspects of autism or the onset. What are we talking --

Dr. Insel: So, we got the gist that your question was what do people have in mind when they use the term prevention. We have gone to some lengths to define this in the Plan on pages 4 and 5 of the original document. It's one of the crosscutting themes.

And it clarifies that it's -- I mean it starts off by saying it's critical for research to identify the methods and approaches that can be used to prevent the challenges and disabilities of ASD.

Additionally, if one views ASD as a biological disorder triggered in genetically susceptible people by environmental factors, then prevention can include prevention of new cases of ASD through the identification and elimination of environmental causes.

What is essential for ASD research is to develop the state of knowledge similar to what is now available in fields such as cardiology. And it goes on to describe why that is important.

So that's what the Plan is about, so both of those concepts are captured in the crosscutting theme.

I think Ari had a comment he wanted to make and then we are going to take this to a vote.

Mr. Ne'eman: I mean, it would just seem to me, and just to build on Gerry's point, and on the crosscutting theme, that when we talk about prevention, we are primarily talking about, at least in what we are prepared to endorse, preventing those challenges, and I would be open, I guess, to offer a friendly amendment to my own proposal and suggest that the title should instead read: What Caused This To Happen and Can Challenges Be Prevented or Can Challenges and Disabilities Be Prevented, perhaps just challenges for the sake of brevity, because I think that does fit within the language we provide with regards to prevention.

When we talk about the possibility of prevention of new cases of ASD, we are very clear that that is only under one possibility, a possibility that has not yet been definitively concluded by the research with regards to the possible causation.

So I think in the spirit of

matching this title most closely to the crosscutting theme language that we have, I would suggest the language read: What Caused This To Happen And Can Challenges Be Prevented?

Dr. Insel: Okay, so we have an option for a title change which we can vote on. Anything else before we take these to votes?

Dr. Hann: Actually, I have one clarification question if I could, going back to the earlier discussion about numbers of studies et cetera, and looking at the newly proposed objectives, for the first objective which I know we have some wording changes to that, and we have a date, we have 2012 for that.

The second one has a workshop, which is good. If there could be a date provided for that, I think that would be useful as well. And then the very last objective, support studies and workshops, it has a date but it doesn't have a number with regard to studies and workshops and I would ask that the committee -- I realize it's difficult and so forth, but I think it would facilitate going forward.

Dr. Insel: Geri, could you just plug that in for us?

Dr. Dawson: Sure. So in terms of a workshop that explores the usefulness of bioinformatic approaches, I would say by 2011.

Dr. Insel: Is this something you are doing already? You can tell us if this is something that is already on the books.

Dr. Dawson: Well, yes, so we are working on trying -- planning one of these and Cindy really has taken the lead on this so Cindy. Yes.

Dr. Insel: Do you want to say by May 11 of 2011?

(Laughter.)

Dr. Insel: Okay. Right. That is done. Onwards.

Dr. Dawson: And then the other one would be support -- let's say support two studies and one workshop, a workshop, by 2012. Does that seem reasonable on the last bullet?

Dr. Insel: Okay, we've got language. Della, take us through this. We will start with the title.

Dr. Hann: Okay, there has been an idea to change the title of this chapter. The current wording is: What Caused This To Happen And Can It Be Prevented. The proposal is: What Caused This To Happen And Can Challenges Be Prevented.

Those in favor of the change in title, please indicate now.

(Show of hands.)

One, two, three members in the room. Anyone on the phone in favor of the word change?

Dr. Shore: Here on the phone.

Dr. Hann: Four. Anyone else on the phone?

Okay there were four votes to change. Those not in favor?

(Show of hands)

One, two, three, four, five, six, seven, eight, nine, 10, 11 in the room.

Anyone on the phone not in favor?

(No response.)

Okay, the motion carries then to not change the title.

Dr. Insel: And then going through the first two sections.

Dr. Hann: I heard no changes to the first two sections.

Dr. Insel: So let's get a vote about acceptance as is.

Dr. Hann: Those in favor of the current sections?

(Show of hands.)

One, two, three, four, five, six, seven, eight, nine, 10, 11, 12.

Those not in favor?

(No response.)

Anyone on the phone wishing to vote in favor?

Ms. Resnik: Yes.

Dr. Hann: Okay. Denise?

Ms. Resnik: Yes.

Dr. Hann: Gerry?

Dr. Hann: I think he's in favor. Okay.

Dr. Fischbach: Can you hear me better on this phone?

Dr. Hann: Yes.

Dr. Insel: Ah, that's much better Gerry.

Dr. Fischbach: I took it off speaker. So when I want to speak I'll just pick up the phone.

Dr. Insel: Okay. But don't forget to mute if you --

Dr. Fischbach: I won't. I won't.

Dr. Insel: Okay.

Dr. Hann: Okay, I believe then we had a vote of how many in favor? Thirteen in favor. Those not in favor? Anyone on the phone not in favor of the current wording for the first two sections?

(No response.)

Okay. The first two sections go forward. The opportunities section, there were some proposals for change. I will read those.

The first new objective, the proposal is to change the wording so that it would read "Support at least three studies of special populations or expanded existing data bases et cetera by 2012." The rest of the wording stayed the same.

The second bullet was to support a workshop that explores usefulness of bioinformatic approaches to identify environmental risks for ASD by 2011, was added.

The final bullet, the change was support two studies and a workshop that facilitates, I guess now, the development of vertebrate and invertebrate model systems.

Okay, those in favor of what is written as well as the changes that I just said, those in favor?

(Show of hands.)

One, two, three, four, five, six, seven, eight, nine, 10, 11, 12.

Anyone on the phone?

Ms. Resnik: This is Denise in favor.

Dr. Shore: And I am in favor.

Dr. Hann: Okay, any --

Dr. Fischbach: I am in favor of that.

Dr. Hann: Okay. Those opposed?

(No response.)

Okay, the motion carries.

Dr. Insel: Thank you. We are going to go on to chapter 4 and Geri, once again, you are the lucky person to take us through this.

Dr. Dawson: So, again quite a bit new in the area of research this year and that is summarized on the first page, so it ranges from studies that have looked at combined medication and behavioral interventions to social skills training, cognitive behavioral interventions for anxiety, an RCT of early intervention for toddlers, and then two areas where we discussed some reviews that had been done of the literature, so this environmental scan for interventions for children, youth and adults that was performed on behalf of the Centers for Medicare and Medicaid Services.

We also included kind of an update on a few reviews that had been conducted this year on the efficacy of early intensive behavioral intervention.

In terms of gap areas, there was identified a need to begin to translate the research on genetics and to new approaches for developing drug targets and medications.

There was the information that was presented on the medical conditions that are associated with autism and the need to identify subgroups that have these medical conditions who might be responsive to particular kinds of treatments.

We also summarized the findings and recommendations of an NIH-sponsored workshop on individuals with autism who have not developed functional language by five years of age, and the need to better understand the reasons for this and most importantly, new ways of improving the ability to communicate, particularly through new technologies that are available to help people who are nonverbal.

And then finally, there was a need to address healthcare disparities among people with autism. There was a workshop conducted on this by the NIH as well this year.

And also we noted the new legislative initiatives, including the Children's Health Insurance Program Reauthorization Act and the Affordable Care Act, which have an impact on treatment and the need in particular to develop quality of life measures for people with autism.

So out of that, there were some new objectives that emerged, and one of them was to conduct studies where we examine the methods of intervention that have been shown to be efficacious, how these can be then translated or disseminated into the community, and implemented on a larger scale basis, so, studies that look at the effectiveness of interventions and services in the broader community.

The second objective, which I think we should change 2010 to 2012, is to support at least five studies on interventions for nonverbal people with autism and we have listed a range of possible kinds of studies that would fall under that.

And then finally, there is an objective to support at least two studies that would focus on health promotion and the prevention of secondary conditions in people with autism and I would add, by 2012 since we forgot to put a date.

And that's it.

Dr. Insel: Thank you. Comments and questions? Sharon?

Ms. Lewis: I am a little bit concerned about including language related to a Congressional briefing as a reference. You know what, I apologize, did that get struck? We agreed upon that --

Dr. Insel: I think it, yes --

Ms. Lewis: That is struck?

Dr. Insel: It's --

Ms. Lewis: It just is a precedent and I am just curious, you know, I think that again with our standard around scientific accountability and evidence-base, we need to look very carefully when we are utilizing things like Congressional briefings as a resource and a reference, and I appreciate that that has been taken out. Thank you.

Dr. Insel: Can I raise the inverse question? You mentioned in going through this, Geri, about health disparities, that there was an NIH workshop, but there is no reference for that. Is there a publication or anything you can cite here?

Dr. Dawson: Alice? Do we have a publication? I know you are in the audience. So on the NICHD workshop or we could at least refer to it?

Dr. Kau: Are you talking about the nonverbal workshop?

Dr. Dawson: No, I was actually -- the one on disparities in diagnosis.

Dr. Kau: That's in the works.

Dr. Dawson: I thought we had one this fall, that was August, the one that Cathy Lord and you came and presented on it?

Dr. Insel: So why isn't there a report from that, that we can cite?

Dr. Dawson: Well, actually this focus on healthcare disparities was a recommendation that came out of the other two, but as I was reading it, I was thinking you know, there was actually a workshop, so I think we could add that.

Dr. Insel: Unless there's nothing that has been published.

Dr. Dawson: Yes, that's why I am asking Alice.

Dr. Insel: It's a shame if we don't have to cite. The NIDCD one is cited for nonverbal.

Dr. Dawson: Well, we could certainly cite the presentation to the IACC, right, as the --

Dr. Insel: Right, and report it out.

Dr. Dawson: Yes.

Dr. Insel: Okay.

Dr. Dawson: Okay, I'll do that.

Dr. Insel: That would be on the website some place, for the IACC? So sure, that may be the best thing we have.

Dr. Dawson: Yes. Can you add that --

Dr. Hann: Yes.

Dr. Dawson: Just the presentation -- yes. In that section. Good.

Dr. Insel: Okay, other comments about this?

Dr. Fischbach: Tom, I have a general question that I have been aching to ask and I'm sure that it is an obvious question, but where do the numbers come from? Why five studies and given the budget crunch everyone is facing, is this Congressionally-requested that we give a number?

Dr. Insel: Yes. The number of studies isn't requested but a budgetary requirement is, and we felt the best way to provide an indication of that would be to provide the number of studies.

But we are mindful that ideally you do one study to get the answer and not five studies. In fact, one of the members of the subcommittee very wisely said when we discussed this at a subcommittee meeting that he didn't want this plan to be considered an entitlement or a work program for researchers. He would rather see it actually accomplish something.

So, and I won't tell you who said that.

Dr. Fischbach: Yes.

Dr. Insel: But, so there's -- I think many people in both the subcommittee and the full committee -- Jim Battey just raised the same issue -- have the same concern. We just couldn't find a way out of it that still meets the requirement of the Combating Autism Act.

Dr. Fischbach: Okay, well I just -- you always wonder, worry these things will come back and haunt you and it says at least five studies, or I wonder how that could be -- that should be left up to the staff I think.

Dr. Insel: Well yes, and in many cases of course what we are doing is looking at the portfolio analysis and seeing how it aligns, and there is some value in areas where people feel that there really is a need for multiple approaches, and you will see this in the genetics and epigenetics and a few other areas like the biomarkers, to then be able to go back and look at what is currently being funded and see where the mismatch is.

So it has, I think been helpful in a certain way, but there is no science, there is no rigor that goes into coming up with these numbers. They are simply, I won't finish that sentence, but you get the picture. Ari?

Dr. Fischbach: Yes.

Mr. Ne'eman: I have two issues, one relating to the What Is New area and one related to the Objectives. First is, I just want to make sure we are accurately getting across what the IES review said. It didn't simply, you know, find no research on the other areas outside of cognitive development.

It found one study which showed potentially positive effects on cognitive development and then other studies which showed no discernible effects on communication, language competencies, social emotional development and behavior and functional abilities.

So I would suggest altering the language of the IES study to specifically mention the language that IES used, potentially positive effects on cognitive development but no discernible effects on communication, language competencies, social emotional development and behavior and functional abilities.

It just seems to me that there is a substantial difference between not finding any research supporting advances in that area, and finding research that found no effects. So I will pause for people to review that before raising the other issue.

Dr. Insel: Okay, so the current language says that the model has been shown to have positive effects on cognitive development but not other domains of functioning. So you want those other domains to be specified?

Mr. Ne'eman: And to clarify it found potentially positive effects. I think the study that found indicate positive effects on cognitive development was relatively weak by IES standards.

Dr. Insel: Other comments?

Dr. Dawson: That would be fine with me, potentially positive effects.

Dr. Insel: And then specifying what the other domains -- because it doesn't tell you what the other domains of functioning were.

Ms. Redwood: Is that actually the language from the article or is that our interpretation of the research?

Mr. Ne'eman: Well, I can read the language from the review if you'd like. The specific language that it uses is: no discernible effects on -- just to read one area -- social, emotional development and behavior for children with disabilities, no discernible effects on functional abilities for children with disabilities and no discernible effects on communication language competencies for children with disabilities.

Ms. Redwood: The one I had a question about though was the one that you said found potentially positive effects. Was it potentially or did they say -- I guess I'm questioning was potentially in the --

Mr. Ne'eman: Yes, it was potentially positive effects on cognitive development.

Okay.

Dr. Insel: Okay, so that is a recommendation for changing language at the bottom of page 1 and top of page 2. Anything else?

Ellen and then Ari.

Ms. Blackwell: I just wanted to draw to everyone's attention on page 32 of the 2010 Plan long-term objective A and that is an objective that has been in here for a couple of years now. It looked to me that that potentially, that's chapter 5, might be a little bit duplicative with the new suggested what new research opportunities have emerged.

And this does happen sometimes between these chapters, especially 4, 5 and 6, so I wanted to make sure that we weren't putting things in here twice or maybe there's a way to clarify though so that it's not duplicating what we had in here for 2013.

Mr. Ne'eman: Which one --

Ms. Blackwell: Long-term objective A on page 32 of the 2010 Plan.

Dr. Insel: And you are concerned that it's duplicating --

Ms. Blackwell: Well, this one talks about methods to improve dissemination, implementation and sustainability of evidence-based intervention, services and supports in diverse community settings and the new one talks about community-based studies to look at the effectiveness of interventions and services in community settings by 2015.

Dr. Dawson: I can clarify, I think the --

Dr. Insel: Geri, go ahead.

Dr. Dawson: So I think the difference there was that the committee was interested in the interventions that are actually being used out in the community, whether it was floor time or I think you mentioned TEACHH, there was a number of interventions that are being used by parents out in the community.

The idea would be to actually have research to assess the effectiveness of those, which is maybe -- and I don't think I maybe expressed that well when I described that.

But in any case, this one I think is more on how do we disseminate and implement and sustain interventions, which is more a methodology of dissemination, so it's a subtle difference but I think it's different.

Dr. Insel: Right, and I think the other thing that was driving this, as I recall from the conversations, was the comparative effectiveness agenda.

So these really would be in some ways to ask even the economic question, are those things that are out there worth doing? The original objective that is in the Plan now talks about taking something that has an evidence-base to it and doing a study of how to implement that, and how to disseminate it, which is really quite different.

This makes no assumption about whether it's effective or not. Other comments or questions about any of this? Ari.

Mr. Ne'eman: Yes, it's a relatively minor thing, but I think it's important. We initially had an objective on potential areas of iatrogenic harm, and that was rolled into another objective with the language outcome measures should include assessment of potential harms as a result of autism treatments as well as positive outcomes.

The problem is that is currently on the end of the intervention which I think focuses primarily around communication methodologies. It seems more appropriate around the intervention with regards to community-based study -- the objective with regards to community-based studies.

I don't think anybody has seriously proposed that enhanced communication methodologies poses a risk of potential harm, but clearly when we are talking about testing interventions and treatments and various methodologies that are in the field and that haven't been fully tested, that is a more relevant consideration.

So I would simply suggest moving the last section -- sentence in our second new objective to the end of our first new objective instead.

Dr. Insel: I wonder, Ari, if that is actually an error in the way this was put together, because I think when we talked about it in the subcommittee it was not about the communications piece, it was about these other sorts of interventions. Maybe I am not remembering this right but --

Mr. Ne'eman: Well, that's precisely my point. It seems that this is currently --

Dr. Insel: Right, I think the way it is showing up here is not what we discussed. I think we discussed having it as the end of the first bullet, not the second bullet. So it's a good call.

Dr. Dawson: Yes, I think you're right Ari. Yes, I agree.

Dr. Insel: Any other comments?

Dr. Houle: Yes, I have another comment about that same bullet. I agree with Ari's comment that the last sentence does not really fit in there.

But the second to the -- number 3, when I read that, it may just be a tweaking of words, that studies -- well, studies on interventions for nonverbal children with ASD by 2010. Such studies may include -- then number 3, studies assessing access to AAC for children and adults with ASD who have limited or partially limited speech and the impact of functional outcomes of access.

I mean, are we really concerned with the functional outcomes of someone having access to AAC? Is that --

Mr. Ne'eman: It would seem that we would be if those functional outcomes have an impact on quality of life. When we talk about access, I think we are presumably meaning usage and all of those other things.

Dr. Houle: Okay, well access though in my world does not necessarily mean usage of. It just means that somebody has given you access, offered this to you and you have made a decision whether or not to take it and then I don't see how that could -- you know you are going to study -- I don't know that it's that valuable to have the functional outcomes of say access or not.

Mr. Ne'eman: So let's delete the last two words. I still do think it's important to study whether or not people do have access, but clearly when we talk about functional outcomes, we are talking more about usage. Would that --

Dr. Houle: Let's see. The last two words? Okay -- ASD who have limited or partially limited speech and the impact on functional outcomes. Yes, that's okay. Sure.

Dr. Dawson: So may I suggest alternatively, because I do think it is important to understand the functional outcomes for usage. So couldn't we say studies assessing access and use? Access to and use of AAC?

Dr. Insel: How about impact of use on quality of life?

Dr. Dawson: Yes, because I do think that that is a very important thing to study, not only how many people have access but the importance of using them to functional outcomes.

Dr. Houle: Well, I think that usage would probably be more related to something that is relevant as far as functional outcome studies go.

Dr. Dawson: Yes, that is what I am saying. So rather than taking out functional outcomes, we have studies of access and the studies of the impact of use on functional outcomes.

Mr. Ne'eman: I agree with that, yes.

Dr. Dawson: Yes.

Dr. Insel: Geri, do you want to read it to us? How would this go?

Dr. Dawson: Okay.

Dr. Insel: This is number 3.

Dr. Dawson: This is Della's magic.

Dr. Hann: Well, I have a suggestion.

Dr. Dawson: Oh good, good, good.

Let's use her magic while she is here.

Dr. Insel: Go for it then.

Dr. Hann: Okay. So what I hear is "studies assessing access to and use of AAC for children and adults with ASD who have limited or partially limited speech and the impact of use on functional outcomes".

Dr. Insel: Sharon.

Ms. Lewis: I hesitate to even step in this territory but I will. As someone who is newer to the IACC, I am trying -- I am struggling with the decision to include this in question 4 as an intervention versus a service and support, contextually, in terms of -- I'm sorry, specifically objectives around access to AAC, and just wondering what conversation or backdrop we have had on that in terms of again looking at the bigger, long-term objectives and why you see it fitting in here as an intervention as opposed to a service issue.

Dr. Houle: Sharon, I think it could

be both. I think usage could be an intervention, and access to and sustainability of access to could be a services issue.

Ms. Blackwell: So to provide an example Connie Kasari is conducting where they are looking at whether, for kids who haven't responded quickly to early behavioral intervention, that adding AAC to the intervention protocol, whether that improves outcome.

So that would be more of a treatment but I agree that I think it should be under services and supports as well.

Mr. Ne'eman: It would seem to me that -- I would agree it would belong in both. The one advantage I see to it being represented in question 4 as well as question 5 and maybe one of the things we need to do here is consider making some reference to it in question 5 as well, is that it seems question 4 has a more direct implication on educational practice where it would seem question 5 and question 6 are more oriented around older individuals, but it could fit in either and probably should in both.

Dr. Insel: I think -- so this is an item that didn't get much attention in the very first -- the 2009 Plan. We heard a lot more about it in the following year. We even had a special session about it.

And one of the things we heard was the need for more data, so in that sense I think it grew out of this presentation about the research need as an intervention, but obviously as a service as well.

There was a hand up over here. Yes, Gail.

Dr. Houle: The other thing, it's very small, is in the first paragraph, and it came to my recollection when Geri said they were adding AAC to, and I believe it as young children, behavioral interventions, is that we probably want to say both adults and children, not just school-aged children.

That's first paragraph, third from the last line. Page -- what page is this? Three. Page 3.

Dr. Hann: So Gail, I think, let me make sure we are following you. Oh, there. So I was not --

Dr. Insel: First paragraph, page 3.

Dr. Hann: Right. Oh, comprehensive studies focusing on both adults and school-aged children on the autism spectrum. Is that it?

Dr. Houle: That's it.

Dr. Hann: And what are you proposing to change?

Dr. Houle: Just take out school age, adults and children.

Dr. Hann: Oh, okay.

Dr. Insel: Any other comments, thoughts clarifications? Ellen?

Ms. Blackwell: Can I make a suggestion to address Sharon's comment? Maybe we could add a sentence at the end of the paragraph that starts on page 3 about AAC and just say that AAC interventions cross, cross intervention and service needs for people with ASD.

Would that just sort of refer people back to services?

Dr. Insel: Since we do it in both places, it's covered. It is talked about in chapter 5, yes? Is it left out of chapter 5? Actually, that's yours Ellen, so --

Mr. Ne'eman: So maybe we should talk about making reference to it in chapter 5. It could fit in for example in long-term objective A. We could cite that as an example.

Dr. Insel: So why don't we address it there? Would that be okay and we'll catch up with it at that point. Ari?

Mr. Ne'eman: Minor, minor thing. Just to Della's language, and the impact on functional outcomes, I would just add the words and quality of life so functional outcomes and quality of life.

Dr. Insel: Okay, let's go through and vote on what we have got here. Della, take us through from the top.

Dr. Hann: Okay, the first section. What is new in this research area? There has been a modification proposed that occurs on page 2 of the current draft, to modify the information from the Institution of Education Sciences.

The first line at the top of page 2 would then read: "to have potentially positive effects on cognitive development, but no discernible effects on socio-emotional behavior, functional ability, or communication competencies."

Mr. Ne'eman: And language.

Dr. Hann: And language.

Dr. Insel: And Ari that is from, directly from the report?

Mr. Ne'eman: Yes, it is. I can provide Della with the language so she can make it a direct quote.

Dr. Insel: Excellent. Okay. Moving on.

Dr. Hann: Under what gaps, areas have emerged since last year, beginning of paragraph 2, in a 2010 presentation to the IACC, we will add the web link for the videocast so that people can reference what that was all about.

Looking now at page 3, the top paragraph, third line from the end of that paragraph, will now read: "comprehensive studies focusing on both adults and children on the autism spectrum", deletion of school-aged.

The next paragraph I believe most of it is now gone, except for the first sentence. So the sentence that remains is: "Additional focus is needed to identify and address health disparities for people with ASD" -- oh the second sentence too -- "while attention has been given to closing disparities and access to health care and health outcomes on the basis of raising outcome, little has been done to close this gap for people with developmental or intellectual disabilities including autism."

Mr. Ne'eman: When did we decide to remove the mention of CHIP, the Affordable Care Act and the national core indicators.

Dr. Hann: Oh sorry, my mistake, never mind. It's there. I apologize.

Dr. Insel: I think we were going to keep it as is, as it shows up here.

Dr. Hann: Okay. Sorry, my mistake. Okay. Do we want to vote on those changes?

Dr. Insel: Right, so short of the objectives let's take care of those three or four changes.

In favor?

Dr. Hann: Those in favor?

Dr. Insel: On the phone?

Ms. Resnik: Yes.

Dr. Shore: Yes.

Dr. Hann: Okay. Any opposed?

(No response.)

Dr. Insel: And on the objectives.

Dr. Hann: Okay. Objectives. A sentence will be added at the end of the first new objective. It's the sentence from -- it is currently listed as the last sentence under the second objective, which reads: "Outcome measures should include assessment of potential harm as a result of autism treatments as well as positive outcomes".

That will now appear for the first one. In the second objective, section 3 -- part 3: "Studies assessing access to and use of AAC for children and adults with ASD who have limited or partially limited speech and the impact of use on functional outcomes and quality of life."

I'm sorry yes, to 2012. Thank you.

Mr. Ne'eman: And we are deleting that last -- the sentence removed objective 1. We are deleting it from objective 2.

Dr. Hann: Correct. The third

objective, the only change was to add a date and it is by 2012.

That's it. Okay, those in favor of the wording and the changes that I've just walked through?

(Show of hands.)

Okay, it's unanimous in the room.

On the phone, anyone in agreement with the changes?

Dr. Shore: Yes, I'm in agreement.

Ms. Resnik: Yes.

Dr. Hann: Okay. Any opposed?

Dr. Fischbach: I agree.

Dr. Hann: Okay. Unanimous.

Dr. Insel: Okay. We are through half. It's maybe a good time to take a break. We've got lunch planned at noon and we are a little beyond noon. We are scheduled to reconvene at 1 for public comments and then we will at 1:30 get back into the chapter 5, 6, 7 and the introduction.

So we will see you back here

promptly at 1 o'clock. Thank you.

(Whereupon, the committee recessed for lunch at 12:13 p.m., and resumed at 1:00 p.m.)

AFTERNOON SESSION

1:00 p.m.

Dr. Insel: Can I ask the committee to take your seats? Those of us who are joining from afar either by phone or by webcast, I hope you are back with us. We are going to start with the public comment session. We have received written public comments which are in your folders, and then we have two people who have offered oral public comments.

And so what I would like to ask is that each of them take about five minutes and no more. We will start with Idil Abdull and I don't know if Mrs. Abdull is back in the room yet or not. No sign of her?

Ms. Kim: She is not here.

Dr. Insel: The second comment is from JaLynn Prince. And she is not here either? All right. Let me just ask for your patience for a couple of minutes because I think they are both in the building. They were here before lunch and we will try to make sure they get back.

So Ellen, Lyn was just suggesting that if we have to wait for more than another few seconds we put you on the spot to talk about ELSI issues. Let's see here, because I think what we will do -- I suspect -- okay we have got just a minute, but why don't we at least pose the question to you and so you can be thinking about it, and then when we have time, we will make sure that we get your best input.

Somehow I have a feeling that more time will be even better. So this was a piece of what is in chapter 1 about risk and what the IACC has been struggling with is how to build the ethical, legal, social implications, the ELSI implications into the Plan.

We heard about this through the subcommittee and we had some discussion about it and we decided we didn't have the expertise in the room at the time and we would just wait and get your input when the time came.

But I'm not sure we are going to have time now. Let's see if we have a couple of minutes. Any suggestions you want to make to us at this -- oh Idil is here, so we will come back to this later in the afternoon.

And as Lyn is saying, the hope is we really need to get all this wrapped up today so we don't want to have lots of leftover items to deal with in January.

Okay, welcome.

Ms. Abdull: Hi, I'm so sorry, you guys ordered your lunch early, and Africans are always late. I apologize.

Dr. Insel: That's okay. We are just glad you could get out of Minneapolis to join us.

Ms. Abdull: Oh yes, this is Florida for me, you guys, this is heaven. Well, good afternoon once again. I would like to recognize again and always thank Dr. Tom Insel, Dr. Daniels and Dr. Della Hann. Thank you so much everyone at NIMH. I promise I will not bother you as much. I am going to take a break from here.

I would also to especially thank this time Dr. Boyle of CDC, Dr. Dawson and I don't want to butcher your name but the doctor from NEIH.

I am excited to hear what you will say later today. But I won't talk about Somalis today. I'd like to talk a little bit about autism resources and services.

So first, resources. You have been talking a lot about this today, but where does it come from, how do states get access and then use it, how do universities get resources and then use it, including autism research, and as you know there is the ADDM system. Currently there are only about 10 states that have it and it doesn't include Minnesota. We don't have that.

So how does one allocate the resources without accurate assessment? It's like going grocery shopping for a household that you have no idea how many people live there. You would have to know how many people live there, how many are children and that's the way it seems like.

And so although it will be difficult to get the ADDM in all 50 states, I ask if you can consider at least getting it into half of the U.S. That will give you a better accurate.

And then another area is universities, and why are there not enough of them -- not doing autism research. We need to make sure that at least public universities, including the University of Minnesota, which has been in my opinion sleeping at the wheel about research, that they include autism research, particularly when asking public funds from the state.

But I am hopeful because we are going to be getting a new president of the U of M and we hope that he puts autism research in his forecast.

Then I'd like to just talk a little bit about services. Again, what are they, how do you access them, who pays for what, and how does it really affect children with Medicaid and children with private insurance, and what impact does it have on disparities among minority and immigrant children?

Now, these are questions and concerns that must be addressed by everyone, especially the IACC's subcommittee on services. So I really would like some sort of a solution or an answer particularly from the two co-chairs, one from CMS and the other one from Autism Society because we know that disparities exist for many researchers, including the two doctors, one of which is here today.

Back on October 22, the question is not does it exist. We know it exists. The question is, "Why and how do we fix it?" And you know as a person of color, and as an immigrant, I am just really being tired of being associated with disparity. How about opportunity, progress, success?

Those are the things I want to be associated with. And we know that low-income people usually have Medicaid and unfortunately they are also -- they are mostly minorities, people of color, immigrants.

And so what can we do about it? The first step is for Medicaid to pay the same services that it is asking for private insurances to pay for their own patients and pay for services at a fair market rate that is not an insulting rate to providers.

What does that mean? If I am a provider, I am in business, right? I am going to make money. There is child A that has BlueCross BlueShield. They are going to pay $50 per hour. Child B has Medicaid, they will pay $30. I am a provider. I am going to look at my bottom line. Who do you think I'm going to take? The kid with private insurance, particularly since there is no shortage of them.

So that's one area to make sure we are able to fix that. Another one is that if we are asking -- if we can mandate private insurances to take patients with preexisting conditions, have no limit cap et cetera et cetera, then shouldn't Medicaid also mandate the same for its own patients?

So if we are saying private insurances, you need to pay for intensive therapy for speech, shouldn't we do the same for Medicaid?

I say yes. If it's good enough for Michael Smith with BlueCross BlueShield, then it better be good enough for Michael Smith in Medicaid, otherwise it is unjust, unfair and un-American.

I think we cannot ask private insurances to clean its own act when our own house is dirty. One way to put this to rest and one way to fix this first of all is to put autism under mental health condition and it has just come to my attention recently that apparently under Medicaid, autism is not considered a mental health condition.

So all these years I have been in denial because I thought it was mental health. Apparently it's not with Medicaid.

Finally, how do we make sure that children that have classic or severe autism get access to the same services of children that have Asperger's because right now, most of the providers take high-functioning kids.

Again, Michael Smith with Asperger's, Michael Smith with classic or severe autism, providers will take the less challenging kid, I mean, that's just human nature.

And so we need to have policies that regulate and are put in place so that services should be the same for children with private health insurance and for Medicaid, and also regardless of where they are on the spectrum.

And I know we always say that, we always say that, but there's really no mandate, there's no policy to make sure that these multi-million-dollar providers to follow, and I ask that we have some sort of a national policy to make sure that providers are not cherrypicking our children.

In closing, I always get asked, "Where do you get this energy. You are like a hurricane." And I want to share just two minutes of a story with you.

When I was young, I used to fight a lot with boys and I would fight like a girl but they would beat me up like a boy. So my Dad one day, may he rest in peace, took me aside and said, "I don't want you to tell this to your Mom, but if you are going to keep fighting boys, you need to hit first, hit hard and hit from every corner."

And I would like to -- I would like us parents that have children with autism to hit first, because we know better than anyone else what our kids need, and to hit hard by making sure that we hold everyone accountable and demand transparency, and to hit from every corner, with everyone, including health officials, education officials, elected officials, providers and everybody in between, because our kids need us to be their voice and their biggest advocates. I thank you so much, may God bless you and may God bless all children and people with autism.

Dr. Insel: Thank you very much Idil and we are still responding to your first hit from last time, so we will be, as you can see on the agenda, at 3:15 we are going to be circling back to the issue you raised at the last meeting, and we will have a report out on that issue. So I hope you can stick around for that.

Ms. Abdull: I will. I came for that as well. So thank you, thank you so much.

Dr. Insel: Okay, very good. Thank

you. We also have comment, again another five-minute comment from JaLynn Prince and welcome. Delighted you could join us here.

Ms. Prince: We could be twin sisters separated at birth. Thank you. It's an honor to speak to such a distinguished panel here in the field of autism.

Officially, Madison House Foundation is a newcomer to this arena, being only three years old. But we have had a ring-side seat learning about autism for the past 21 years, as our son Madison has graduated just last week into the realm of those that are adults with autism.

The name of my husband, Dr. Gregory A. Prince, is known to many here, having developed an antibody that is used on approximately 25,000 babies each year worldwide, preventing RSV, a virus that is harmful or fatal to infants.

I have represented the United States as the mother of the Year in 1999 and I have also pursued my passion as a photographer in recording some of the world's major health issues, from leprosy to HIV.

Much of my life has been spent in public awareness campaigns; public health issues are not new to us. When setting up our foundation, we examined the landscape to see where our experiences can intersect with our son's autism and after many surveys, we have seen clearly that it is in the world of dealing with those over the age of 21 with autism.

In our efforts, we have looked at our community, Montgomery County, Maryland, as a microcosm to extrapolate much data and then encourage others in the field of autism across the country to see what is being done, what is not being done and where there is a game of catch-up.

We are looking ahead to view the next 60 years or more -- that just popped up, here we go -- the next 60 years or more, while addressing the immediate needs of this population.

At the top of our long-range goals is housing and the need is huge. Here we go. It would take seven of the country's largest stadiums to hold all of the ASD grade school children in the United States.

I know you are very aware of the statistics, but I think sometimes visuals are helpful. All of these will become adults within the next two decades.

This works just backwards from mine. All right. Looking at the state of Kansas would represent all of those that are on the spectrum.

If we are looking at those affected, let's add Iowa and Arkansas, the parents, the number of parents that are affected when they have a child.

But it doesn't end there. If we include the siblings, grandparents, cousins and immediate family, we are dealing with this type of population, the center of the United States.

If we add Wyoming, this will show us how many caregivers we are going to need or professionals in the field to cope with this number of people that are coming through our system.

While Madison House is targeting housing, we realize that there is a need to have a strong foundation underneath housing to make it work well for our nation.

We need trained staff -- you have talked about that -- but we need to make certain that there is career development.

We need university programs educating professionals in areas that there are no classes for right now, to help these people that make up such a large portion of our population.

There are places like Utah State University that are training people in new arenas that have not been identified in other places across the country.

This can also help siblings deal with their brothers and sisters when their parents have passed on.

We need continuing education for those on the spectrum and establishing curricula so they can learn for a lifetime.

Financial planning is going to be vital. We need more professionals in this area and look beyond what is happening today, to look toward legislation that can help parents participate in taking care of their children.

It is estimated that if we only take those that are most severely affected by speech problems within the spectrum, and multiplying the cost of $3.2 million, that over their lifetimes or over the next while, there will be $3.84 trillion necessary to support these people. That is just a fraction of the people on the spectrum.

We need to deal with safety, much more so than just wandering. We need physicians who can take care of those on the spectrum. We have a huge lack of those trained knowing how to deal with adults on the spectrum.

We need first responders to know what to do. We need police officers to know the difference between someone on methamphetamines or someone who is reluctant to respond to someone in a uniform.

I could go on. I see have some time limitations. Two points that I would like to bring up for you is that many of the things that we are recommending are represented in this illustration right here of the curb.

When curbs were modified for those with disabilities, it didn't just help those with disabilities. Just getting back from New York last night, I saw strollers, I saw walkers, I saw joggers, I saw people taking vending machines up and down curbs. It can help an entire community.

My plea to you as we get into all

of these areas, and I'd love to go over each one of these points with you, I hope that along with your mandate to have responsible research done, that you can project even ahead of your agenda and your mandate for the next year, and look five, 10, 15, 60 years down the road and make some projections so people in the community can step forward.

There are incredible things happening around our country. These people don't know what each other is doing. You can help that.

You can help inform the rest of the country's physicians. Call on our surgeon general. Call on NIH. Let's have CMEs, CMUs, let's have our firefighters and our police forces, that is not going to take away from your budget, but it is going to help with this public health situation that we have of taking care of people for their lifetime. Thank you.

Dr. Insel: Thank you very much and hopefully you will be able to stay around. We are just about to talk about those parts of the Strategic Plan that are relevant to what you were just presenting.

In addition, the way that the committee works is we do have a period at the end of the day to respond and to discuss and to consider public comment further, so if you can stay until I think it's 4:30, that's when we are scheduled to do just that.

Thank you. So, with that as our public comment we are going to go back to the agenda to talk now directly about the next four pieces in the Strategic Plan as we will welcome Peter Van Dyck and Alan Guttmacher, and we think Henry Claypool is joining us by phone momentarily and Josie Briggs should be here within a few moments as well, and we also have Judith Cooper who is now sitting in for Jim Battey from NIDCD so welcome.

We are going to go back to work and we will start with chapter 5. We have left off at the end of chapter 4, and let me invite

Ellen to take us through chapter 5.

Ms. Blackwell: Okay, just -- chapter 5 is the chapter on services and as I mentioned before, I think there is some overlap between chapters 4, 5 and 6 that we are all familiar with by now.

We actually started with a draft of 5 and 6 that have migrated a little bit but you can see that the -- we identify two gap areas in services. One is oral healthcare services. This is particularly an area that you will see in chapter 6 but it's also an area where there are issues for children, and I apologize, I forgot to put the references in here and I will be happy to give them to you Erin.

One is a Kaiser report that is listed in the back and the other is a GAO report that was issued actually just last month, GAO report number 11-96. So we should insert those as references.

Then we talked a little bit in our

subcommittee about mental health services and particularly with the new focus on mental health and the Federal government and in particular what that means for people with autism.

So I apologize, I went too far here. Let me go back to the beginning, which is what is new in this research area. And this first paragraph, it's on page 1, is really a very broad summary of what has happened in 2010 insofar as mostly the Affordable Care Act and I did not get into the weeds here.

This is a very broad summary. It doesn't speak in particular to any provisions of the affordable care act other than to mention them. It just seemed like digging in a little deep would be too much for this update document.

And then as Tom noted earlier, we wanted to mention that MHPEA went into effect, most of it, in January and draw folks' attention to the interim final role that CMS, Labor and Treasury were involved in publishing.

So that's insofar as Federal guidance, is it for now, but in the future I think that we will probably see more coming from CMS.

And again, I talked a second ago about the oral health issues. There were quite a few articles on oral health and people with developmental disabilities and autism and this is a year where many state Medicaid programs have actually reduced or eliminated optional adult dental services.

So I think that that area is definitely coming to the fore. And then we decided to mention a Swedish study that received some prominent note. This is a study that talked about death rates being higher in people with autism, higher than an expected rate, and also insert language here about the interest in health and safety issues, that that started.

So, since I started with page 2, I am actually going to skip these gap areas but you can see that they follow from the oral healthcare articles and the discussion on page 1, the mental health system.

So what we did was, we decided to go back and look at the objectives that are in the present plan, which are sort of broad-based and see if there was a way to focus these new things into what is already in the Plan.

So the first one is in terms of looking at a policy and practice coordination model that we thought a really good one would be to look at coordination between state and local mental health agencies that serve people with autism.

The second one is the new objective that I referred to earlier, and this is an offshoot of the work of the Safety Subcommittee, but it is phrased in a way that is a little broader, to develop and test the effectiveness of at least two strategies or programs to increase the health and safety of people with ASD, for example parent, caregiver, individual training to prevent wandering, early warning system for wandering, emergency preparedness, elimination of seclusion and restraint, reduction of unnecessary incarceration, that consider principles of self-determination and personal autonomy.

And I did speak with Lee Grossman yesterday and he mentioned that we might even want to add a couple to this list: caregiver abuse and bullying.

So that would pretty much fill up that list. And then the third project builds on the three long-term objectives that are already in the Plan, focusing on one project that looks at the cost benefit of actually providing dental services, including routine, non-emergency medical and surgical dental care to adults with ASD, as compared to emergency dental treatment or no treatment.

And then second, to look at a study focusing on the provision of dental services to people with autism in a more general way.

Third, to look at training for oral health professionals. And then while we were talking earlier, I think it might be appropriate to add a reference number 4 here, to support the study's reference in chapter 4 regarding augmentative and alternative communication.

So lots in chapter 5.

Dr. Insel: Comments, questions? Ari.

Mr. Ne'eman: So one area that I think is particularly important to mention here that we don't mention is the Affordable Care Act brought about a very unique opportunity to expand service provision to a population that currently does not have it on the autism spectrum, those individuals on the spectrum who do not meet an institutional level of care.

I think you actually make reference to this, Ellen, in the section on health reforms, and including targeting to people who do not meet traditional institutional level of care program requirements.

If states are going to take up that option, which is exceedingly promising for serving folks on the spectrum, particularly adults, who currently don't have access to any kind of service provision, it would be exceptionally valuable to see research geared at what are the most effective types of service provision to that population.

So I would suggest that we add in an objective reading: support at least three studies developing and evaluating effective program models for service provision to individuals on the autism spectrum who do not meet an institutional level of care.

This would seem to me to be a policy development that cries out for more research.

Ms. Blackwell: Ari, it seems to me that what you are talking about might be more of a demonstration than a study and it might be wise to wait. I'm wondering, we haven't seen any states move in this direction yet, but wouldn't such a study only be able to take place after states have inserted such coverage in their Medicaid state plans, if in fact they do elect to use it in the manner that you described?

Mr. Ne'eman: Not really. I mean, the issue being that what I am talking about is there is a very long history of DD services through the waiver programs for people who do meet an institutional level of care, but there hasn't been the same level of research into what is effective service provision for people who do not.

Now, states are not very likely to take this model and create some type of entitlement without the research beforehand that's going to show whether or not that type of service provision is going to be effective, what kinds of services should be included in the benefit.

So really what I think would be valuable would be to see some studies looking at developing these program models and testing their effectiveness.

We don't need to wait for states to take a Medicaid option to apply it across the whole states, to just see with a specific sample size, how some of these services would do.

Dr. Insel: Marjorie?

Dr. Solomon: As I look at the Strategic Plan and the existing short-term and long-term objectives, I really don't see any preference given to people who rise to the level of needing institutional care versus those who don't.

So I think that really to a large extent those concerns are addressed in the current plan. I think we went for basically the most inclusive approach possible and I think that the existing objectives really would incorporate anyone on the spectrum.

Dr. Insel: Other thoughts or comments? Ari?

Mr. Ne'eman: I do see that point and one possibility here is to incorporate this into one of the existing objectives, which is very possible. I think it might easily fit in well with long-term objective A, or some of the other options.

The concern I have here is, generally speaking there is a fairly extensive history and a fairly extensive research literature around services for people who are currently eligible for Medicaid waivers, so that's people who do qualify and do meet an institutional level of care.

We don't have a very large research literature on other populations, so with that in mind, I do think it could be valuable to explore that as a potential gap area, much as we are racial and ethnic minorities, for example.

Dr. Insel: Ari, I thought originally when we talked about this in the subcommittee, you were going to dress up this area a little bit in the first paragraph about what is new, by referring -- this is the section 1951 or something --

Mr. Ne'eman: Section 1959 -- yes, Ellen made reference to the substance of it. My impression was that you didn't want us to be calling out specific sections of the ACA.

Dr. Insel: Okay, so the group felt it was better just to hit the substance and not the actual numbers. Okay.

Mr. Ne'eman: And we do have the substance.

Dr. Insel: And the substance is there. All right. It seems like the committee is sort of, as I watch around the room, everyone is looking at their papers very carefully, and maybe, Ellen, you could just help us to understand a little more, with these objectives, what's the science that you had in mind. What's the research, specifically that would do this so that it would never have to be done again?

I guess, I'm struggling -- your comment about this being a demonstration project to Ari, about his recommendation, I sort of wonder about some of the rest of this, whether we are -- whether we are really clear with ourselves and whether it will be clear to readers what experiments we are recommending.

Ms. Blackwell: Are you talking about Ari's comment about section 1959 in particular Tim, or --

Dr. Insel: Actually, all the way through this. It's, you know, so develop and test the effectiveness of at least two strategies or programs to increase the health and safety of people with ASD that consider principles of self-determination and personal autonomy.

I guess I'm trying to understand what you -- what the group was thinking, how is this different from interventions that were talked about in the previous chapter, what would be the actual -- what would be the ideal proposal that would satisfy this objective?

Ms. Blackwell: Well actually I think that this objective was rooted in the Safety Subcommittee, it was sent to me by Alison as an objective to put in chapter 5 and when I started looking at it, it looked to me that it was a much more general issue regarding health and safety beyond just wandering and an early warning system for wandering, that there really isn't a place in the Plan now to look at -- I mean we didn't focus much on these type of health and safety issues before.

So we were trying to signal that these are areas, I believe, where we feel like there could be some room in the Plan where there wasn't space before. Alison, do you have any other comments?

Ms. Singer: This really came out of the 2010 Swedish study which was originally part of chapter 6 which we then, in the subcommittee, decided to move to chapter 5.

And what this study did was it brought to our attention the fact that people with autism spectrum disorder were dying at a rate that was greater than the general population and I think -- and the two causes of death that were specifically cited were accidents and sudden death -- unexplained death and epilepsy or SUDE.

And I think what we were trying to get at with this objective was to dig deeper with regard to what are really the causes of the increased rate of death, which we get at in chapter 2, and what are some ways that we can develop and test interventions that both prevent the increased rate of death relative to wandering and that also, as Geri pointed out in the subcommittee, reduce the negative outcomes associated with some of the safety issues.

So it was really those two things that we had proposed from the Safety Subcommittee, and then I do see that Ellen expanded what we sent in to include other issues of safety, which I think could also lend themselves to study or programs but when we submitted this, we were specifically looking to expand the work in that specific study that focused on issues of greater likelihood of death due to safety issues.

Ms. Blackwell: And I would certainly say that seclusion and restraint could be at the top of the list for that category.

Ms. Lewis: I guess I would say that I think that the language is broad enough that it allows to get at both and really, given the number of areas related to health and safety that we might want to address, I think that this is an approach that allows that flexibility, you know, because again in terms of studies and evidence base, we may have a more substantiated body of information around seclusion and restraint, and seclusion and restraint deaths relative to wandering and I think what Ellen has tried to do here makes a lot of sense in terms of looking at strategies broadly as it relates to safety issues.

Dr. Insel: It does feel like they are two very different themes that are wrapped together and then complicated by the final section about principles of self-determination and personal autonomy, which isn't usually an issue that you would think about in terms of a research -- an experimental plan, but maybe that goes more with this territory.

I just raise it because it feels different than most of what we have talked about today.

Ms. Blackwell: That was actually language that the Safety Subcommittee had suggested and I believe and I believe that Ari had recommended for this particular objective. I mean, I'm fine with taking it off, but it was something that both subcommittees wanted in here.

Dr. Insel: What does it mean? Maybe it would help just to -- so can somebody just unpack, what was the subcommittee wanting to -- the full committee rather -- to look at with this?

Ms. Blackwell: I think what I heard, and again I wasn't participating in that meeting, was that there were issues related to particularly concerns about people who wander being, you know, restrained unnecessarily or against their will or in ways that weren't respectful of their own -- maybe Ari, you could do a better job of explaining this than I am.

But the idea was not to make it sound like people were being incarcerated to keep them from wandering, for example.

Mr. Ne'eman: So I simply provided the areas around principles of self-determination and I think my original language was freedom of mobility, but personal autonomy somewhat fits in that.

And I guess if I were to provide an example of what I -- of you know, the kinds of things that concerns me, and that I think bring up the need for stressing that sort of language, for example in the written version of some of the oral public comment, there is a line here that says: In a group home here in Maryland, a client was able to flee the premises and end up in Montana on a bus with no money.

But generally speaking when we are talking about adults, with or without disabilities, people do have a right to leave and generally speaking when people -- those people I have known, those people within our organization, friends of mine who have left a group home or have left another setting, have done so for a reason, generally speaking caregiver abuse, lack of control, lack of personal autonomy.

So the concern I raise here is, when we talk about safety, we have to recognize that that is obviously a legitimate objective but it is one that has to be balanced against the fact that, when we are talking about adults, people do have certain rights to self-determination, freedom of mobility, personal autonomy and so on, and you know, safety concerns do not cancel those rights out.

Dr. Briggs: Tom?

Dr. Insel: Welcome Josie.

Dr. Briggs: Thank you. Just perhaps this would be less ambiguous if the phrase “consider principles” were moved so that it read: develop and test the effectiveness of at least two strategies or programs to increase health and safety of patients with ASD, while simultaneously respecting principles of self-determination, and then the examples.

Perhaps then the intent here would be clearer. By the way, the same issues arise with elder care.

Mr. Ne'eman: It is remarkably similar. I think that the only thing I would add is that I think particularly because, in the DD world, we are talking about he full scope of a person's life, it's even more important to prioritize these types of things.

Dr. Insel: Lyn.

Ms. Redwood: I am wondering if we couldn't possibly separate this out from children wandering to adults who are purposefully trying to escape a situation that you describe Ari, because I do think there's a difference with a child who has escaped for whatever reason into an environment that could be very dangerous to them.

And this had to do with the tracking technology and we were proposing some type of method of being able to track these children when they do escape because time is critical in terms of recovering them before they are injured, and if we can keep that separate from the adult issues, I am wondering if we really need the line in there at all if we are looking at the issues that were brought before us by the National Autism Association at our last meeting.

Because I think that was more the focus of the Safety Subcommittee at the time, and you know, I am having a difficult time with thinking of a child in terms of self-determination when they are not able to care for themselves.

Mr. Ne'eman: So, one of the concerns I would raise there is how are we defining child? You know not too long ago, I received information about one of our chapters was dealing with a situation in which a 15-year-old had fled the home because of an abusive situation and had sought help from authorities.

If we are medicalizing the act of wandering, then I worry regardless of age, and clearly there is a difference with very young ages and very old ages, but there is somewhere in between.

I worry regardless of age, that we are going to be placing people in a situation where attempts to escape truly abusive situations are not respected.

So that doesn't mean we don't address this wandering issue. Clearly as a part the scope of broader health and safety issues, it's something that requires more research.

But whenever we are talking about it, I think we do need to be taking into account those considerations of self-determination, personal autonomy and freedom of mobility.

Dr. Insel: Geri.

Dr. Dawson: So I agree with what Ari is saying really, that I think Lyn, any time we are thinking about interventions that might have to do with limiting a person's intentional behavior or impulsive behavior, whatever, and that they could lead to ways of not respecting that individual's sense of choice or autonomy, that there is always that tension, even with a child.

And so it does -- I think it makes sense to say that any time we are trying to come up with programs where we are trying to look at safety, we should always have in mind that we do it in a way that allows the person the most sense of choice and autonomy.

And so it just -- it kind of recognizes that we are always going to be struggling with that tension for these kinds of interventions. I mean I think it comes up even with children, you know, do you -- if someone is bolting out of the classroom, how do you choose to, quote, restrain them? And how can you do that in a way where you are still respecting their autonomy? Should you restrain them?

These things always, I think, call up these sticky issues that one always wants to have in mind when you are developing these interventions. But that doesn't rule out, of course the point you are making, which is that clearly, with children, it's different than adults and also doesn't undermine the seriousness with which we want to respond to these safety issues.

Dr. Insel: And the research question in here -- maybe that's what I am stuck on, I am still trying to figure out why this is a research issue.

Dr. Dawson: Okay, so the research question would be let's stay with a child, because I mean I clinically have dealt with this situation many times in a classroom setting, where you have a child who literally is bolting out the door and it's unsafe, or have gotten out of the playground and so what are the -- what is a good intervention that we know has been empirically shown to be effective in that situation?

You know, when you go to a school and try to do an intervention, they want to see the data. So if I do this, is it actually going to reduce the chances of this happening?

And I could imagine several different possible interventions that one might try and so you know, I guess that's what I would see it as. Or maybe it has to do with an intervention that has to do with education of parents and teachers around this issue, and then does this actually reduce the prevalence or the frequency of this kind of situation and reduce accidents?

Dr. Insel: Walter and then Gail.

Dr. Koroshetz: I think the way the conversation is crystallizing, we are talking about an intervention and it seems like this goes in the previous chapter on interventions, what works.

Dr. Insel: Gail?

Dr. Houle: Perhaps the objective, the word develop in there might not be the best word because for developing and testing, you have two different ideas here, one is to develop the strategies and the other is to test the strategies.

So my question would be, are we looking at comparative testing of strategies to address the health and safety, or are we looking at developing new strategies and then testing them?

Dr. Insel: Coleen?

Dr. Boyle: I was just going to reinforce what Geri said. I guess when I read this I think of some of the work that we have done in terms of the Learn the Signs Act Early campaign, so an education and communication campaign aimed at parents of young children who have Autism Spectrum Disorder in terms of getting them more aware about these issues, and evaluating them.

So there is a clear research

component to that, to make sure that the messages work, that they are effective, that they change behavior.

Dr. Insel: So it sounds like evaluation. I'm still not sure whether this -- I'm still listening for the science, and the question -- Sharon?

Ms. Lewis: And that is where I'm going too, in terms of reading through this again, I guess I keep coming back to what is the science, what is the research telling us in terms of what are the most pressing safety and wellness issues that we should be focusing our energy on?

And what are we suggesting here? I mean I think, you know, we are saying that we understand that there are health and safety concerns, broadly. We have given some examples.

But should we be stepping back from this and first looking at the need for the identification of the most pressing safety concerns, whether it is caregiver abuse issues or wandering or seclusion and restraint, as the first effort in identifying and defining the problem before we are putting forward a request for the development of strategies to keep people safe.

Do we know enough, I guess is my broader question and taking us back even one more step.

Dr. Insel: So that's I think a different question, which is creating an objective around doing research on health and safety issues, which is different than creating interventions for the issues that you haven't yet fully characterized.

So I guess what you are suggesting is maybe there is an earlier step here before we go to the intervention side, just defining what is the target, which is a scientific question. I mean, it starts with mortality. Question is, what are the drivers for that?

And actually one of the things,

Ellen, in the description of that Swedish study, I think the mortality increase, it's not just an increase, it's a 5.6-fold increase. I mean that's a very dramatic increase in that population.

It's probably worth actually providing the number when it's that extreme, and then asking the question, can it be replicated anywhere else, do we have data that looks like that in the United States, what would be the drivers?

It's a whole series of issues that one might want to consider before jumping in with interventions, but that's just a different perspective.

Mr. Ne'eman: So I am not going to weigh in as to whether or not we should just have a general health and safety one or one that looks at interventions and services strategies, but I do want to raise that if we do decide to take the approach of looking at strategies to address health and safety, increase health and safety, one area that we may wish to cull out as a field of study to which there has been substantial work done in the intellectual and developmental and disability arena, is that of alternatives to guardianship.

Guardianship for adults with intellectual or developmental disabilities is increasingly recognized as a very over-broad brush in terms of very often resulting in taking away people's rights because of a challenge in one particular area of self-direction.

And so a number of strategies have been explored and developed and studied in the DD/ID world as to less restrictive measures of ensuring health and safety.

So if we do decide to take an approach that looks at methods to increase health and safety, I would just say that culling out alternatives to guardianship within that, might be an opportunity to build upon an existing base of research literature.

Dr. Insel: Geri.

Dr. Dawson: I just want to give two examples of research studies. So -- and also I would say that at least in terms of some of these we do have data, and that is the mortality study, because at least in that study they are saying accidents and sudden death due to -- unexplained death due to epilepsy.

So for example, if one implemented a certain kind awareness program or even a physician training program around the assessment and monitoring of epilepsy in adults with autism, so I think a lot of people are not aware for example of the new data that suggests that with every year that goes by in adulthood, there is an increasing prevalence of epilepsy in adults, which means that during adulthood, you should be monitoring and thinking.

And also there is interactions with

epilepsy medicine that can lead to deaths, and so a lot of -- you can imagine a program that would be aimed at reducing mortality due to epilepsy -- and then --

Dr. Insel: So I get that completely and I think there would be huge needs to do even a campaign around safety and I just don't see what the scientific question is here. If there's awareness that mortality is being driven by let's say epilepsy in this case, then it seems like there's a really important educational task in front of the community.

But what is the experiment there? What's the science that we need here?

Dr. Dawson: The question would be, is that campaign effective in reducing mortality? What if it absolutely had no impact?

Dr. Boyle: That is health communication research, whether or not you can change behavior, you can modify behavior through selected interventions.

Dr. Insel: And do you think we know enough now, from the research that has been done, to say this is ready to push forward with new practice, new campaigns, those kinds of things? Or is there still -- what I am really trying to get at here is, kind of building on Sharon's comment, is there still a scientific question that needs to be mined around the drivers, and what the issues -- what the safety issues are?

This has gotten very confused because obviously what is written here is conflated by two very different ideas, one of which is protecting children and potentially adults, based on issues about emergency preparedness and wandering and another one that has to do with seclusion and restraint and incarceration.

And I think part of what the committee was struggling with before was how you take those two quite different ideas and put them into one sentence with the same goal.

But I am asking a different question, which is before we even get there and think about interventions, do we need some -- is there a need for more research or is this really done and we know enough that we are ready to go ahead? Alison?

Ms. Singer: I think in other areas of the Strategic Plan we have handled issues like this by using a short-term and a long-term objective, so maybe this is an area where we need to split this objective into two, and have the short-term objective focus on collecting data to understand the scope of some of the safety issues and then the longer-term objective could be The evaluation of programs designed to prevent the safety issues from happening in the first place, and secondarily to prevent the negative outcomes of some of the trigger events, and handle it that way.

Because I do see your point, that we do need to collect data. I think the Safety

Subcommittee also recognizes that we need to collect data. But I also think that we are at the point where we also know that children are dying from wandering-related incidents every day. I mean you can't go online anymore without reading a story about a child who has wandered away from a highly-supervised environment and most of these stories end tragically.

And so I think if we separated them, we would be able to recognize both that we need to have data in the short run, and that we need to have evidence-based interventions in the long run, but not too much in the long run.

Dr. Insel: Geri.

Dr. Dawson: So I guess my concern is that we may not be addressing the sense of urgency there, because I guess I would say that you know, we don't need to collect a whole lot of more data on wandering, right, before we say can somebody creatively come up with an idea about how we could intervene in this.

I just don't -- I just think that we are -- it's a little bit too more of an intellectual approach to something that I see as a much more urgent, public issue, and I feel the same way about this issue of screening for epilepsy in adults and things like that.

I just would hate to say, you know, let's put that off to three to four years down the road. So that's my only concern.

Ms. Redwood: I would like to collect some data just right now in the room, from parents of children with autism. If your child has ever escaped from you or gotten away where you didn't know where they were, or you were concerned about their safety, please raised your hand, because I know my son has.

So when you look at the families in this room, we are well aware of this, and this is one of our biggest nightmares and so I just don't know how much more research you need for some thing that we are seeing every single day.

Dr. Insel: That's why I'm sort of coming back to the same question about, is this really -- is this where you want to do the science, or do you just want to move ahead and do something without saying let's spend two years studying it further?

I mean if you are going to put out a campaign, you evaluate the campaign, but that's not research, that's an evaluation component, and I -- again, I want to set a pretty high bar for what we put into a research plan update to make sure we are really addressing the most rigorous science and especially if we are talking about flat or diminishing budgets and we have to make choices.

Where do you put this with respect to everything else we are talking about, if there's a sense from the committee this is so urgent that we need to act upon it rather than spending another two or three years designing experiments about it?

So I am hearing a lot of different strains here, but I don't think there is a place where there's a consensus yet about how this should be managed.

Mr. Grossman: Hey Tom, this is Lee.

Dr. Insel: Welcome.

Ms. Redwood: Was that we did lack data, we lacked mortality data, so there is an objective I believe that has been added into the chapter 7 for infrastructure. No? It didn't get added?

Dr. Insel: Well, so it's either one or the other, either we need more data so we need to do the science to try to figure out what the issues are, what are the safety issues, or it's -- Sharon.

Lee, are you -- are you?

Mr. Grossman: Yes.

Dr. Insel: Go ahead.

Mr. Grossman: Yes, I have been listening for a while because I think that your comments regarding -- the question here is very important, because I have been troubling, and I'm looking into this the last 30 minutes as the session goes on and I am having a hard time figuring what it is.

Lyn asking the question of the parents in the room who struggled with the issue of wandering, I can raise my hand, I have gone through that many, many times with my own son, and it is an extremely urgent issue.

And I think if it becomes a research or scientific issue, we are going to lose the momentum on what really is a crisis now in safety and health-related issues for people across the entire lifespan.

So I'm not really sure what the scientific question should be. I do know there is an incredible sense of urgency in the community to address these issues of wandering, address caregiver abuse, the victimization, bullying, and all these issues that are related to safety.

So I guess if I was to advocate one way or the other, if it is going to delay further movement towards this committee finding another alternative to doing an awareness campaign and doing more education -- having to find definitive answers to research, I would say get rid of the research and let's just move forward with what I think we all know needs to be done in terms of awareness and education, to raise this as a critical issue that we can address in a faster manner.

Dr. Insel: Marjorie?

Dr. Solomon: I think it is obviously an incredibly important question, as witnessed by the public comment that we have seen here, and even just a little survey done of parents. But I do hear what you are saying Tom, and also Walter, it's hard to know whether this is intervention research, services research.

So, one way to maybe highlight that we view this as being very important, but something that may not have risen to prime time yet, would be to put it instead as a gap area that has emerged, that we see the real need for more thought about this whole issue, that we might ultimately be able to surface some meaningful either intervention projects or services projects.

Dr. Insel: Alison?

Ms. Singer: I just wanted to respond to Lee. I mean, I don't think anyone at the table is advocating slowing down or not feeling a sense of urgency and I don't think anyone would want to have anything in the Plan that would compromise our sense of urgency.

But I think we have to focus on what this committee can do, and what this committee can't do, and this committee, as Tom said earlier, does not have funding. We do not do awareness campaigns. We do not have the ability to fund.

What we can do, what this committee does do, is it creates a Strategic Plan that identifies the key issues for funding. So by putting it into the Strategic Plan, what the committee can do is identify it as a gap area and indicate that this is an urgent need that needs to be addressed by people who can do awareness campaigns and organizations that can fund research.

But Lee, I disagree that, you know --

Mr. Grossman: I am still wondering what the scientific question is, as Tom put it. I don't mind there being the awareness and putting it in as a gap area. I was just trying to respond to what Tom was saying as where is the scientific question oriented.

Dr. Insel: Geri?

Dr. Dawson: Well, I would like to advocate that this is a Strategic Plan for autism research, and I guess when I think of the word research, I don't think of just being in a laboratory and doing the hard science.

But I actually think, you know, there's a field of education research, there's health services research, et cetera. A good example is, in education, if you go and give a workshop and educate teachers about something, it actually has almost no impact on teachers' behavior.

Right, so through research they have learned that you have to follow up with technical assistance, and there is x, y, z you have to do. You have to include certain kinds of activities during the training if you want to change teachers' behavior in a classroom.

So that only occurred because somebody actually did a study, and they did one with a workshop only and one with workshop and technical assistance, and they showed that this is the impact on behavior.

So I guess I do see it as research. It may not seem like hard science, but it certainly is research.

Dr. Insel: So let me see if I can pull some of these many threads together and I'm not sure this is going to satisfy anybody. But if we take out the verbs and change them, instead of saying develop and test the effectiveness, say evaluate at least two strategies or programs to increase health and safety of people with ASD.

And then, the same parenthetical comments apply, it says the training to percent wandering, warning systems, emergency preparedness -- I would then break it there and say: while still considering principles of self-determination and personal autonomy or what Ari had first used which was personal mobility, and then in parentheses, considerations of seclusion and restraint, reduction of unnecessary incarceration.

I think part of what I heard from the beginning of this conversation was that those are two very different concepts that had all been put together in the same place. If we think about evaluation, it gets us away a little bit from questions about developing interventions, and if you think that these are things that are going on or will be going on immediately, then it means that we look at their impact and determine which ones are actually of some value, because there are often unintended consequences where you make things worse, not better.

Does that help at all, or does that get us any closer? Ari?

Mr. Ne'eman: So I guess two things real quick. First, the language I would suggest is self-determination, personal autonomy, freedom of mobility and alternatives to guardianship. But second, you know I just am concerned with the idea that those things are only relevant in the context of restraint and seclusion and incarceration.

I think they are actually incredibly relevant with regards to wandering and warning systems with respect to wandering. We just did a project with self-advocates becoming empowered in the National Youth Leadership Network through other self-advocacy groups and actually, to give credit where it's due, it was funded by the Administration on Developmental Disabilities to get the perspectives of individuals with disabilities living in, very often, residential service provision settings like group homes and other types of residential service provision settings, as to what living in the community really meant.

And one of the biggest priorities people had was whether or not they had the right to leave their house when they wanted to. So, I mean, I think these civil rights considerations don't just apply to one segment of these lists of examples around health and safety.

There is a broader scope of issues, all of which really need to be considered and balanced against those critical civil rights and self-determination concerns.

Dr. Insel: Well, we have spent over a half an hour on this one, two lines here and we can't really take much more time with us without endangering the rest of the Plan, so, Ellen, I'll give you the next word and then we're going to make a decision about how to go forward.

Ms. Blackwell: Well I was going to suggest a way maybe we could move forward. I've been listening to all this and it's helpful, but I think that maybe -- I do think that we should keep all these issues together, because for example, seclusion and restraint is not an issue that is limited to adults, for example, nor is incarceration.

So I am still okay with keeping all these issues as a list of potential targets for a campaign, but I was thinking that one way it might read, and see what you think is: evaluate at least two strategies or programs to increase the health and safety of people with ASD through awareness and education.

And then put the parentheses and list all of these topics including the ones Lee suggested: bullying, caregiver abuse, and Geri suggested seizure disorder, epilepsy, I don't know if we want that in here or not.

And then I would still put the period after self-determination and personal autonomy. I think guardianship is an entirely separate issue although I don't disagree with Ari that it is a worthy issue.

I'm not sure that it came up in any of our discussions when we were in the committee, nor did it come up in any new research for 2010. So it might be something that we want to discuss in more detail next year. But I'm not sure it belongs in an area where we are talking about health and safety.

So that's my suggestion, to sort of close this bullet.

Dr. Insel: All right, we'll take

that as a proposal. And then let's move on and see if there are any other comments about other items that are in this section before we move to votes. Ari?

Mr. Ne'eman: Yes, just one thing very briefly. I do hope that we have the chance to put on the table other proposals around language with respect to that, because it would seem to me that there are people -- that there are a lot of perspectives, some I agree with here, and some I don't, that might want to see language included on the safety and health issue that is different from the language that has been put forward.

But the other issue I wanted to raise is -- we make reference to this in the comments -- is we should -- I think we should, with regards to short-term objective C, increase the number of models, policy and practice for coordination we are talking about.

So we already mention in the

existing plan one example, needs of transitioning youth, we are culling out this other example, which I agree with, coordination among state and local mental health agencies. If we are naming two examples and we are only funding two models, it would seem that that doesn't leave much discretion. I would suggest revising two to five.

Dr. Insel: So we have another proposal there. Anything else for this chapter before we start to vote?

We are going to need to move on, so let me turn this over to Della and we will walk through this.

Dr. Hann: Actually, I have a point of clarification, if I may. I don't quite understand what the changes are that are being proposed in the very last bullet, because there are three objectives that are listed and then there's a series of studies afterwards.

It's not clear to me -- do you want those added to each objective or --

Ms. Blackwell: For example, number -- I probably should have been more specific Della, and I apologize, but C for example obviously falls into -- the third one falls into new objective C, do you see?

Dr. Hann: Okay, does that mean then that number 1 would fall to A and number 2 would go to B?

Ms. Blackwell: Yes, I think that's how we had those. I think that's right, yes.

Dr. Hann: Okay. Thank you.

Ms. Blackwell: And then I -- did the group want to add the reference to AAC here as number 4?

Dr. Hann: But where would that go?

Ms. Blackwell: Well --

Dr. Hann: We're out of objectives.

Ms. Blackwell: I mean, we had talked previously about putting some kind of a reference to AAC in chapter 5, or referencing chapter 5 in the chapter that it was in, and so I wasn't sure how we left that.

Ms. Lewis: Could a reference to AAC be added to the short-term objective C in terms of the integrated and comprehensive community-based supports and services that enhance access to services and supports self-determination, economic self-sufficiency and quality of life, as a parenthetical example or as an including statement, under short-term objective C?

You know, so after their families, again parenthetically, which may include access to alternative and augmentative communication systems?

Dr. Insel: Am I the only one -- looking at this, it just seems odd that for all of these long-term objectives, the only examples we have in the whole universe of services to be concerned about are the dental examples? Is that something we want to do for this plan? Is that the most important priority for all the things that people on the spectrum need?

No question, that's important, but if you are going to -- do you want to cull this out for each of these objectives?

Ms. Blackwell: I wouldn't say they are the only ones, Tom, because we had that long discussion about health and safety and then we dealt with the new focus on mental health, too, so --

Mr. Ne'eman: Those were all things of short-term.

Dr. Insel: Sharon?

Ms. Lewis: I guess the same thought strikes me in terms of the focus on dental and, you know, both in terms of gap areas and research opportunities and I go back to, you know, were there issues that were identified in the services' one-day session that should be highlighted here, and/or other issues that I think certainly have come out as emerging issues that we have heard about here, and just wonder if we need to revisit this a little bit more.

I mean, not to diminish, I know that a lot of people, and Ellen, you certainly have done a huge amount of work in getting to this point, but the same thing strikes me that this is a lot of focus on dental and mental health without acknowledging the broader service needs more specifically.

And maybe we don't have anything that has emerged in this past year specifically that needs to be updated. I have a personal bias in terms of the seclusion and restraint issue, and perceive that that has certainly been an important topic of public policy conversation across the country in the past year, and I would argue that that may be a gap area, and I don't know Gail, if the Department of Ed wants to jump in on that particular perspective.

Dr. Houle: Alexa has already said the Department is not jumping in on that at the last meeting, so --

Ms. Lewis: But, you know, I think

that given the public policy debate around seclusion and restraint, it certainly is an area that has emerged in the past year.

Dr. Insel: Well, this is something that we can vote on. I think it's a question for the committee. I just raised it because I think we talked about it a little bit in the subcommittee, it was -- I think Ellen made a compelling case. But whether this is something the full committee is comfortable with or not, I just think you need to look at it.

Dr. Hann: So along those lines, I am wondering, since -- as a possibility to consider, the issues of dental services etcetera, might that serve better as a research opportunity and you could take what is currently listed as number 2 and reword it as an opportunity to include in the opportunities section.

So therefore it would relate to everything that is here because it's an opportunity.

Ms. Blackwell: I think one of the challenges with this chapter was that our charge was to go back and look at what research had been published in the past year, and that's what -- that's -- Sharon, so that's exactly what I found.

Now if I missed something on papers on seclusion and restraint, then maybe I did, but when I went back and looked at the research itself, these were the topics that came up. There were articles on oral health. There were articles on death, which raised the health and safety issues, and then we decided that we would include this introduction on the legislative initiatives that happened over the past year.

So that was sort of the bed of rock that started chapter 5. So I'm not saying that there aren't other issues but those were the research issues that popped up in 2010.

Mr. Ne'eman: Well, just to be clear, just one brief thing. My understanding, and Tom, maybe you can weigh in on this, is that we had agreed in the Planning Subcommittee that we were going to be responsive both to new research and new policy developments that required additional research.

So that would seem to me to speak to both the restraint and seclusion issue and the non-institutional level of care issue.

Dr. Insel: Right, that's what we talked about, and it's really, you know, it's a question for the full committee, what you want this update to look like, and it's really a question of where to set the bar, how many things you want to add into the Plan, and whether these are compelling enough to call for additional studies as objectives, or whether they are, like the products of the work groups that we had, really identifying gaps in areas of opportunity.

Della, I think we need to move on, so let's go ahead and begin to see where people sit with this.

Dr. Hann: All right. Section -- the first section, what is new in this research area and what have we learned in this past year.

While there was discussion, I did not hear any changes suggested. Those in favor of the section?

Dr. Insel: I recommended actually adding more specifics about the Swedish cohort so that it's clear. It says here that: "had a higher than expected rate," but a rate of 5.6-fold is more than just higher. That's pretty dramatic, so I would recommend adding details.

I think whenever possible we should provide numbers to go with these reports so that there is some rigor.

Dr. Hann: Okay. So adding the details with regard to the degree to which it has increased.

Dr. Insel: Right.

Dr. Hann: Okay. Anything else?

Those in favor of that change?

Everyone at the table has raised their hand. Anyone on the phone, those in favor?

(Chorus of ayes.)

Mr. Claypool: I guess we all are.

Dr. Hann: It sounds like there's -- let's see, it's Henry and Lee and Stephen and a fourth person?

Ms. Resnik: And Denise.

Dr. Hann: And Denise. Thank you. Okay. So carried. Next section. Gaps. What I heard was that references will be added to the first bullet. I didn't hear other changes to the gaps. Anybody else?

Mr. Ne'eman: I just had one question, very briefly. The reference. When we look at it. If it refers to both ASD and ID/DD, I would hope that we would also reflect that in the change. I don't know what article it is referring to.

Dr. Insel: Is there a reference, do

we know, before we make a commitment to this? Ellen, we do have a reference? Okay.

Ms. Blackwell: Yes.

Dr. Insel: Good, okay, let's move on.

Dr. Hann: Okay. Those in favor of the change to add the reference and if it includes the ID/DD population to indicate so, whatever. Thank you.

Those not in favor?

On the phone, those in favor?

(Chorus of ayes.)

Those not in favor?

(No response.)

Okay, motion carries.

Okay. I think we are going to take the opportunities section by section if you don't mind. The very first one that is discussed concerns short-term objective C.

There has been a proposal to add -- to increase the number of studies to five, so it would read: implement and evaluate five models of policy and practice level coordination, et cetera, et cetera. We will get to the et cetera. I know there's changes there too. Okay.

So that's the first part. The second part is to add a second example, so currently we have one example in this, with at least at the very end of the current objective, with at least one project aimed at the needs of transitioning youth.

There's also now an additional one to support at least one study to evaluate a model of policy and practice level coordination among state and local mental health agencies serving persons with ASD.

And then there was a third model suggested in terms of the AAC which wasn't really fully spelled out as something to also consider.

So how about this? Why don't we walk through this one piece by piece, because I think people have different feelings for different sections.

First those in favor of modifying it to read from -- to go to five models as opposed to two?

Those in favor? No? Certainly.

Ms. Redwood: I am so sorry, I am just curious, before we change that, do we already have some that are happening now? If we already have two now, from our research portfolio analysis, did that -- was that a gap area where we didn't have any, and I am just trying to understand the justification for adding three more.

Mr. Ne'eman: The justification, if memory serves, is that we now have two, possibly three examples for what we are referring to.

So if we have three examples, or even two, and we are only funding two models, then it would seem to leave out a great deal -- would seem to preclude flexibility for new opportunities.

Dr. Hann: Further discussion on the number of models? Okay, hearing none, let's go back. Those in favor of increasing from two to five?

Okay. One, two, three, four, five, six, seven, eight in the room.

On the phone, those in favor of going from two to five?

Ms. Resnik: Aye.

Mr. Grossman: Aye.

Dr. Hann: Okay. So that brings us to nine, right Susan? Ten. Okay there's ten in favor, so it passes.

Dr. Insel: You want to take a vote of opposed?

Dr. Hann: I can. Those opposed?

One, two, three, four, five, six, seven, eight in the room. Those on the phone?

(No response.)

Okay. Ten in favor, eight opposed. Carries. Goes to five. I feel like I'm playing bingo. Sorry.

Okay, next part of the same objective is the wording that was proposed. You actually have it before you in the draft. It's in pink, at least that's what color it printed out, I don't know for those of you on the phone. And it is to add a suggestion of another model which is to support at least one study to evaluate a model of policy and practice level coordination among state and local mental health agencies serving persons with ASD. Yes?

Ms. Blackwell: I think that it might be easier just to say with at least one project aimed at the needs of transitioning youth and one project aimed at mental health services coordination.

Dr. Hann: Okay.

Ms. Blackwell: You see what I'm saying?

Dr. Hann: Yes I do.

Ms. Blackwell: Yes.

Dr. Hann: Okay. Further discussion on that? Okay, those in favor of adding the additional mental health services coordination as another example?

Okay, one, two, three, four, five, six, seven, eight, nine, 10, 11, 12, 13, 14, 15 in the room. Those on the phone?

Ms. Resnik: Aye.

Mr. Grossman: Aye.

Dr. Hann: Okay. Those opposed?

(No response.)

Okay, 17. It carries to add that. Then the last was the addition -- and I don't really have the wording for this but it has to do with the communication piece, the alternative, right? Sharon?

Ms. Lewis: Thank you, Ari. So one way to possibly address this would be after ASD across the spectrum and their families, you could add a parenthetical that says: "which may include access to alternative and augmentative communication" as again another example because I think it ties into whichever set of research priorities you are doing as a component of that.

Dr. Hann: Okay. Any further discussion with regard to this particular piece of this one?

Okay. Those in favor of adding the clause: which may include access to AAC, to follow after families, essentially? So it would read -- it goes forward and it says, "quality of life for people with ASD across the spectrum and their families, which may include access to AAC, with at least one project" -- and then we go into the examples of the projects.

Those in favor?

One, two, three, four, five, six, seven, eight, nine, 10, 11, 12, 13, 14, 15.

Those on the phone?

Ms. Resnik: Aye.

Mr. Grossman: Aye.

Dr. Hann: Okay, 15 plus two is 17.

Mr. Claypool: I think I didn't make it.

Dr. Hann: Oh, there's Henry too, that's another one. Great. Thank you.

It carries.

Dr. Insel: Okay, second bullet.

Dr. Hann: Second bullet.

Mr. Ne'eman: Point of order, actually, may I make a suggestion --

Dr. Hann: Okay, here we go. I think I have -- I think I got most of what you said, Ellen. Ellen was the last to speak on it. Ari?

Mr. Ne'eman: I just wanted to suggest -- it would seem to me that there are a few different sub-votes within this. I would suggest we vote on those sub-categories, and then since there was some discussion as to whether or not we should include at all, after we have an idea of what the precise language is going to be, we vote on the objective as a whole.

Dr. Insel: But if the majority of

people don't think it should be included at all, why would we want to spend time dissecting the different sub-parts?

Mr. Ne'eman: Because some people may decide on whether or not it should be included at all based on what is in the sub-parts.

Dr. Insel: I see heads shaking. Let me suggest that we -- I think actually there's a sense from the group that they do want to include it, Ari, so I don't think that is likely to be a problem.

But if there is considerable angst about including this at all, should -- can I get a sense from people whether it's even worth discussing? I think most people want to include something, so let's go ahead and start to unpack it.

Dr. Hann: Okay. Why don't I try reading what I heard and then if we need to unpack it, we will? How's that? Okay?

What I heard was: evaluate at least

two strategies or programs to increase the health and safety of people with ASD, through awareness and education, e.g. parent, caregiver, individual training to prevent wandering, early warning system for wandering.

I heard the addition of caregiver abuse, bullying and then emergency preparedness, elimination of seclusion and restraint, reduction of unnecessary incarceration, while simultaneously considering principles of self-determination, personal autonomy, personal freedom -- freedom of mobility and alternatives to guardianship. Thank you. Discussion.

Dr. Koroshetz: So, I would really like to separate two things. One is clear events associated with mortality. I think, given what we know, I think our responsibility is to isolate what is causing the death and seeing what can you do to prevent it.

I think we have got to do that. I don't know who wants to say which of the issues, but clearly the accidents, the wandering and the sudden death and epilepsy are leading to the mortality. So I think we should be very straightforward and just say that this is a target and period. And then add -- potentially add other things that have also been pointed out as important.

Dr. Insel: So this goes back to Alison's suggestion at the beginning that we add in a very brief, short-term bullet, that says: support research on health and safety issues contributing to mortality.

That's not in there now. Geri?

Dr. Dawson: And I wonder if then, we could say: including studies of its prevalence and strategies for prevention, or reducing.

Dr. Insel: Right. So I really want us to move through this because we are never going to get finished if we keep -- and I think the fact that we have spent so much time on this speaks to the fact that it probably wasn't fully baked in the subcommittee and we didn't have a chance to do this in the way we needed to there. That might argue for putting it into the 2011 -- 2012 plan instead of 2011, but if we can get it, let's try to get it done here.

So we have got now a new bullet, which Della will read -- Alison will give us language maybe?

Ms. Singer: Well, this is the first time we have heard the phrase: alternatives to guardianship. And I don't even really understand what that means. So I think we need to look at this without the alternatives to guardianship phrase included.

Mr. Ne'eman: So my concern with respect to that is -- I brought up the alternatives to guardianship issue in the context of the concern that this is not building upon a sufficient base of research literature as to what these strategies are, Tom's concern.

I think the value of having that in there is that that's a previously-established base of research literature that talks about how to address issues of health and safety for individuals with intellectual and development disabilities, while still keeping in mind those principles of self-determination and personal autonomy.

Making that connection could be very important if we want to ensure that researchers don't lose the opportunity to build on what is already existing in this field.

Dr. Insel: The more I listen to this, the more I think none of this is ready for the Plan. I really feel like we had a task in the subcommittee to vet all of this, to have these discussions in the six meetings that we had over the last year and for us to be now trying to flesh out what we are talking about in front of the full committee is just not acceptable.

So, you know, I think if we can't get clear on what we want here, I am going to suggest we just wait and do this in the next update, because I don't think it's ready for prime time. We haven't talked about it and this is the first time many of these issues are coming out on the table. We are getting a lot of language that nobody understands.

So there are two items here. One is the idea that we would do a short-term research project to at least understand more about the drivers for mortality and try to replicate and get statistics. And that sounds like short-term, and I think we can put together some language for that.

The second issue is the evaluation of strategies to reduce that, and the safety ones, and that's where I think we are really struggling. So let me get a sense from the group, do you want to maybe do the short-term one and then come back and do the long-term one at a later date?

I see a lot of heads shaking. Maybe that is what we need to do, because I don't think there's clarity or consensus about what this is. Lyn?

Ms. Redwood: I'm wondering if we couldn't do the short-term one and the long-term one that you just suggested, the way you worded it, and the way that Walter worded it.

Dr. Insel: Geri.

Dr. Dawson: Yes, I agree, I think what's really confusing is adding -- keeping adding on new concepts and new topics, and I guess I think it would be disappointing if we couldn't say that we would like to conduct some studies to examine the prevalence of mortality and strategies to prevent or reduce it including mortality and related to wandering, or something around wandering.

I mean, I would hate to take that out when we have created a subcommittee around safety. But I think what is really confusing us is we keep trying to put more and more into this and it's raised a lot of issues that we haven't had a chance to discuss that we could perhaps discuss in 2011.

But if we kept it smaller, I think we could move forward. I still feel a sense of urgency around that and so I would be disappointed to leave that out completely.

Dr. Insel: Judith, and then Ari.

Dr. Cooper: I am getting concerned about having fair discussion of the rest of the Plan, because this has dragged on. I would like to propose that we vote on the two variations of the short-term and perhaps the long-term and see if we can get closure, because it's just not fair to the rest of the Plan.

Dr. Insel: So, last comment Ari, and then we are voting.

Mr. Ne'eman: You know I actually do support the idea of looking at some strategies in the context of the long-term but I do feel it's very important, if we are creating a research objective, that we include the necessary safeguards around these items.

So, what I would simply communicate here is that I think it's going to be very necessary if we are going to include these strategies to include that language around self-determination, personal autonomy and alternatives to guardianship.

I would hate to see us fund research in 2011 that doesn't incorporate those things simply because we haven't had enough time to discuss these issues prior to 2012.

Dr. Insel: All right. Della, take us through what we have got.

Dr. Hann: Okay. Okay. What I saw in terms of looking at people around the table was the there was some enthusiasm for two objectives, one on the short-term that would look at the issues that are affecting the higher rate of mortality in individuals with ASD and be able to have a better understanding of what those issues are. That's not the way the thing would be worded, obviously, but that's the sentiment.

And that would probably be a shorter-term goal, and that then there would be a second goal that is similarly worded to what we have before us. Walter just handed me something that I think matches somewhat what was discussed, which was, I'm going to modify a little bit, evaluate at least two strategies or programs to increase health and safety of people with ASD that contribute to reported increased mortality, related to accidents, wandering, and the epilepsy issue. He has the abbreviation here but I know that's what it is, the epilepsy finding, that was from that report.

Mr. Ne'eman: Are we not including caregiver abuse and restraint and seclusion?

Dr. Insel: That wasn't in Walter's recommendation. Do you want to -- we could -- there are certain places where we have options

A and options B. Sharon?

Ms. Lewis: I guess my perspective is I'd like to see a long-term objective because I think these safety issues are important and I don't -- again, what I am hearing is that we don't have consensus on what the priorities within those safety issues should be.

So I'm wondering if we want it without the explicit examples, you know, because it feels like it's either the kitchen sink or nothing, and so I guess my inclination is to support the short-term objective.

I think we have agreement that we need to look at mortality and potentially serious physical injury, but on the long-term to specifically go to the wandering and epilepsy issue based on one study of 120 people seems pretty extraordinary in terms of our earlier conversations around accountability and science.

Dr. Insel: So why don't we start

with the short-term objective and see if there is support for that?

Dr. Hann: Okay. The first short-term objective was to examine the issues -- study the issues affecting the increased mortality, essentially. We will have to word it a little bit better than that.

Dr. Insel: I'm not sure we want to presume there's an increase from the U.S. We have one study, so we want to support research to examine the mortality and I would say safety issues related to mortality. I think Walter had language for that.

No examples and no presumptions about what the drivers are.

Dr. Hann: I would actually suggest we just say health and safety and not necessarily mortality, just cut the mortality part off too, because it isn't just death, it's injury as well.

Dr. Insel: Okay, we have got language.

Dr. Hann: So, studies to examine the health, safety and mortality in individuals with ASD. How many studies?

And by when?

Dr. Insel: Two studies by 2012.

Dr. Hann: Okay.

Dr. Insel: In favor?

Dr. Hann: Everyone in the room has raised their hand in favor. Those on the phone?

(Chorus of ayes.)

Dr. Insel: Okay.

Dr. Hann: Okay. Sold.

Dr. Insel: Now, the long-term issue. So, Sharon had a recommendation that we take out any examples and we simply evaluate at least two strategies or programs to increase health and safety of people with ASD. Is that -- Sharon, did I get that right?

Ms. Lewis: Yes, with the language consistent related to --

Ms. Blackwell: Awareness and

education -- and can we --

Ms. Lewis: -- self-determination.

Dr. Hann: Wait a minute, I'm sorry, Sharon?

Ms. Lewis: Yes, but keeping the consistent with the principles of self-determination language.

Dr. Hann: Okay. So then that would be: evaluate at least two strategies or programs to increase health and safety of people with ASD that simultaneously consider principles of self-determination, personal autonomy and freedom of mobility.

Mr. Ne'eman: Do we want to vote on the inclusion of --

Dr. Insel: We will vote on that afterwards. Okay, Ellen?

Ms. Blackwell: Initially we had said evaluate -- we had the language about awareness and education in there. Do folks want that in? It somehow dropped off -- okay, fine.

Dr. Insel: We are one minute away from going into chapter 6, so if it doesn't get in now, it is not getting in.

Dr. Hann: Okay. Those in favor of what I read, with the -- it stops -- well, anyway, those in favor of what I read.

Okay, we have -- wait I'm sorry -- one, two, three, four, five, six, seven, eight, nine, 10, 11, 12, 13 --

Dr. Insel: It's unanimous.

Dr. Hann: 14, 15, 16, 17.

Dr. Insel: On the phone?

(Chorus of ayes.)

Dr. Insel: Okay, and then we wanted to consider additional language from Ari about guardianship.

Mr. Ne'eman: I just put in -- right now we have self-determination, personal autonomy, freedom of mobility --

Court Reporter: Could you turn on your microphone?

Ms. Resnik: We can't hear you Ari.

Mr. Ne'eman: Right now we have self-determination, personal autonomy and freedom of mobility. I would just say self-determination, personal autonomy, freedom of mobility and alternatives to guardianship.

Dr. Insel: So let's see if there's acceptance of that idea from the full committee.

Dr. Hann: Those in favor of adding the alternatives to guardianship?

One.

Mr. Ne'eman: I guess it's just me.

Dr. Hann: Anyone on the phone?

Mr. Grossman: Aye.

Dr. Hann: Two.

Motion does not pass.

Dr. Insel: And we are moving on to the final objective modification here, which is around the three dental objectives to be --

Dr. Shore: This is Stephen Shore. I am going to have to take off for a series of meetings and teachings but I am encouraged with the good work that is going on. It's really hard work that is being done and I thank everybody for helping people with autism to lead fulfilling and productive lives in the future.

Dr. Insel: Thanks Stephen.

Dr. Hann: Okay, the third proposed objective, which is actually three, would be -- the first part would be in addition to long-term objective A, so that long-term objective A would read something similar to the following: test four methods to improve dissemination, implementation, and sustainability of evidence-based interventions, services and supports in diverse community settings, with at least one study on the cost benefit of providing comprehensive dental services, including routine, non-emergency medical and surgical dental services, dental coverage and sedation dentistry in adults with ASD, as compared to emergency and/or no treatments. Discussion?

Dr. Insel: Lyn?

Ms. Redwood: Can we take out adults, because children have dental needs as well?

Ms. Blackwell: Lyn, the reason I wrote it like that was because a lot of the evidence that has come out this year is that -- in fact, it's cited in there -- is that in Medicaid programs that serve adults, kids are entitled to dental services.

So the problem is -- what's happening in the states is that the dental services are coming out of the adult side of the Medicaid program, not the child side. Does that make sense? Does that help you at all?

The second objective I think does get to kids, or the second -- number 2 here.

Dr. Koroshetz: Can't we just put it as a new objective on dental care?

Ms. Blackwell: Yes, sure we could do it --

Dr. Koroshetz: Just do a whole new

one --

Ms. Blackwell: Do a whole --

Dr. Koroshetz: I think if you put it in all the others, it kind of makes people think --

Ms. Blackwell: Yes.

Dr. Koroshetz: It kind of takes away from that.

Ms. Blackwell: Yes I agree.

Dr. Hann: Okay, now we have two different opinions. Okay, so I am trying to understand, are we moving away then from the idea of adding these to each of the long-terms and having an additional -- one new long-term objective with regard to dental care and services? Okay.

Dr. Insel: So the language could simply strike out the first part of this and just say -- the one, two and three would then fold into a single objective.

Dr. Hann: Correct.

Dr. Insel: And we can probably work

the syntax accordingly.

Dr. Hann: Correct.

Ms. Blackwell: Would we accept the date 2015?

Dr. Hann: And then the number of studies that you would like also would need to be --

Dr. Insel: Those are in there.

Dr. Hann: Just add them up? Okay. Okay.

Mr. Ne'eman: Are we planning on voting on the issue of whether or not to include an objective around individuals who do not meet an institutional level of care?

Dr. Insel: Why don't we deal with this one and then we will deal with anything else that comes up? So the -- we do need to vote on the dental issue.

Dr. Hann: Okay, those in favor of having a new objective focused on dental care that would take each of these, that's 1, 2 and 3, that is listed here as examples and then have an introduction about support for studies on dental care including things as the following, by 2015.

Okay, those in favor?

(Show of hands.)

Okay, one, two, three, four, five, six, seven, eight, nine, 10 -- it's unanimous in the room. Oh, it isn't, I'm sorry, one abstention. Sorry.

Okay. Those on the phone?

Ms. Resnik: Aye.

Dr. Hann: Okay, one. Those opposed?

(Show of hands.)

One in the room. Anyone on the phone?

Mr. Grossman: Aye.

Dr. Hann: Two. Okay, so the motion carried to have a new objective on dental care and services.

Dr. Insel: So, Ari, you want to add another objective to this chapter, which we haven't talked about as far as I know within the Planning Subcommittee, so we are not going to get to the other three chapters that we need to do if we stay on this.

Mr. Ne'eman: We did discuss it briefly in the Planning Subcommittee with respect to 1959. I think our thinking was that this could be an area to connect to the Affordable Care Act discussion, but in the interests of time, given that it did seem that the idea didn't attract a great deal of support when I first brought it up, I would be willing for us to move on to the next chapter.

Dr. Insel: There's always next year, and those of us who have been at this for three years can attest to that.

Ellen, chapter 6.

Ms. Blackwell: Okay, we will move to chapter 6. I'll try to get through this as quickly as possible. Ari had suggested adding language about the ADRC so I added a new paragraph here at the top, you know, about the ADRC's project.

The second paragraph really deals mostly with adults and education. I noted that OARC had written a note over here about the Japan study and the reason I left that in was because Marjorie had suggested a sentence right after it where if I pulled it, it didn't make sense.

So if we -- you know, it just seemed like they fit together so that's why I left that sentence in. Marjorie, maybe you can speak to that.

There were a couple of studies about quality of life and independence. We talked a lot in the subcommittee about the Iceland study and underdiagnosis of people with ASD as their primary diagnosis, probably also happening here in the United States.

I also added a little paragraph here about interventions for adults that was an outcome of the study that Geri mentioned earlier in chapter 4. As far as gap areas go, the main gap area, I think, that we talked about was the fact that there isn't a lot of research on adults and I'm perfectly okay with OARC's comment about moving it to what's new. I think that would be fine.

We can certainly footnote the state budget prediction in the second paragraph. Actually, that came from the Fiscal Survey of the States, December 2010, from the NGA and NASBO. So, Erin, I'm happy to give you that.

Ari had asked for some information added about older adults and the -- actually, Jennifer helped with this, Sharon, so there's a little dash here about the UCEDDs and cross-disability aging issues.

The subcommittee, the Strategic Planning subcommittee talked a little bit about participatory action research and also community-based participatory action research, so I'm fine with OARC putting that back in. I actually took it out because ADD was using the PAR model.

And then, as far as what new

research opportunities have emerged, we talked a lot about housing in the subcommittee, so I noted that we had identified housing previously as a research opportunity and we might want to move that into the -- an actual objective area along with other areas that we talked about which were successful life transitions including from post-secondary education to adult services, aging, employment, sibling relationships and day programs.

These were all topics that came up in the Strategic Planning subcommittee as gap areas.

And then let's see, this last one, oh, this was a suggestion by Ari, and also something that the Strategic Planning subcommittee seemed to support pretty strongly, that it's important to include people with ASD and their families in the scientific research process. So that was something that we wanted to add.

So very briefly, and quickly, that's chapter 6. Comments? Sharon?

Ms. Lewis: I have a question about the second paragraph on the first page, where we are citing the various articles, and the sentence: people with ASD may need more assistance and oversight than those with other developmental disabilities.

Is that a particular cite?

Ms. Blackwell: Yes, Sharon.

Ms. Lewis: And is that --

Ms. Blackwell: I think I bundled them all in. I actually had them together at one point and then I tried to condense a lot of the research so I'm happy with taking it out if you like, unless I go back and cite it specifically.

Ms. Lewis: I just wonder whether we need a specific reference to that and some context because that's a pretty broad statement.

Ms. Blackwell: Okay.

Dr. Insel: So are we taking that out?

Ms. Blackwell: Ye, I'm fine with taking it out.

Ms. Lewis: Strike.

Ms. Blackwell: Just strike it.

Dr. Hann: So we're striking?

Ms. Blackwell: Yes.

Dr. Hann: I am sorry, Ellen, I was still working on the previous chapter. Are we striking the language about the one report from Japan?

Ms. Blackwell: My microphone's off -- oh, here we go. It just seemed like Marjorie's comment didn't make sense to me without that sentence, so I'll defer to Marjorie here, if she has a suggestion.

Dr. Solomon: I actually think it's a pretty important point, I mean I think the issue of -- most of the studies of individuals with autism and transitioning to adulthood were written a long time ago when the definition was different.

So in a sense I don't know that that is a particularly seminal study. But I think the point that was made by Marsha Seltzer's group that has conducted the longitudinal study, that kind of paradoxically individuals with higher-functioning forms of autism spectrum disorders tend to do worse because they lose their services, is really important, and that does dovetail with what we have put in the objectives.

So I guess I would be inclined to either keep it, or to make the point that I am saying in another way, without citing it, but to keep the point -- the sentence that starts "however."

Ms. Blackwell: I thought it was okay to leave it the way it is, because it just seems like a nice counterpoint to Marjorie's addition.

Dr. Hann: Any other discussion with regard to the first section about what is new?

Ari?

Mr. Ne'eman: Yes, I had previously provided language that I don't see here and so I would like to discuss, including the new Federal focus on employment of people with disabilities -- oh wait, never mind. Scratch that.

Dr. Hann: Okay, the gap areas? Discussion there? So we are moving the first one to the what is new? Is that correct? Okay.

Dr. Insel: The comment that some minimal improvement is predicted for state budgets in 2011, is there a reference to support that?

Ms. Blackwell: Yes, Tom, I think you were out of the room when we talked about that. That is straight out of the Fiscal Survey of States that NGA and NASBO published this month. So I apologize. I thought I had it in the references but --

All right, are we ready to move to the opportunities and objectives, for discussion? It looks like we are. Discussion?

Dr. Insel: So maybe -- I'm sorry if I missed this -- but just to frame this a little bit, this really comes out of the policy opportunity that we talked about at the beginning of the day, the opportunity to do comparative effectiveness research and the possibility that there actually could be new funds for that purpose. Ari?

Mr. Ne'eman: So we had discussed, in relation to policy opportunities, two possible new short-term objectives, one relating to older adults and the other relating to employment and I think they were both rolled into this broader transition objective.

I think that's appropriate with regards to employment, but with respect to aging, that would seem to be a little bit different. All of these other things: post-secondary education, employment, day programs with regards to successful life transitions, seem primarily, although not exclusively, focused on people leaving the school system at age 18 through 21, whereas the aging and older adults issue may deserve an objective unto itself given we are talking about a very different age range.

Dr. Insel: Geri?

Dr. Dawson: Related to Ari's point, and I sent that late so I apologize, but I got from Joe Piven a report out on the NIH-sponsored meeting on adults with autism and aging so we probably want to put some language in there about the outcomes of that.

Dr. Insel: So, given that, Geri, since we haven't seen that, would that support Ari's comment about putting -- there is a comment here on aging, it says: including from post-secondary education to adult services, aging, employment, sibling relationships and day programs.

Do we need something more about the specific needs of people on the spectrum as they age?

Mr. Ne'eman: And that's precisely my point. I think the aging does not belong in this particular objective. All the other things are relating to post-secondary transition. Aging is relating to an entirely different life period.

Ms. Blackwell: Ari, if you hearken back to new objective C, which is on page 36 of the Plan, that is the one where we were talking about culling out these areas and I don't really think any of them are specific to transitioning youth. It just says adults --

Mr. Ne'eman: Well, no, we say adults --

Ms. Blackwell: Over 21.

Mr. Ne'eman: I'm sorry, number 21 or number 36?

Ms. Blackwell: No, page 36, new objective C, from the 2010 Plan.

Mr. Ne'eman: Right. Right. And I guess, technically speaking, someone who is 23 and somebody who is 68 are both over 21 but it would just seem to me that those are very different realities with very different issues that might require very different lines of research.

Dr. Insel: And you know, if in support of that, we have a report that is going to go into the front part of this, it does seem as if we have already made the -- taken the stance that this needs to be a separate consideration.

So would the way to handle that be simply to put in a part 3 and take aging out of number 2 and number 3 would be as a target for study, aging for people on the spectrum.

Mr. Ne'eman: We could do that. The one concern is it's still in the framework of over age 21, so my preference would be for a new objective but if we include it through it being a subcategory in new objective C, I would be comfortable with that too.

Dr. Insel: Well, it's already in

there. I think just -- but, as you point out, it's a little silly to say post-secondary education and then make aging the next element of that, so why don't we move it down to number 3, and consider it separately? Marjorie, anything?

Dr. Solomon: Yes, I was wondering, actually when I was looking at some of the lifespan studies, I was noticing that National Institute on Aging actually funded some of those, and I was wondering whether there might be a strategic reason why we would give it its own point so that they might look at the Plan.

Dr. Insel: It wouldn't help. They don't have any money.

(Laughter.)

Dr. Solomon: Okay.

Dr. Insel: They really don't have any money. So, okay. Anything else on this?

Ms. Blackwell: I did get the materials from Geri, I just wanted to say, but they came in a little bit late, so I really didn't have time to integrate reference to that meeting that we talked about in the subcommittee, but we could certainly include, you know, a sentence on aging in the beginning, if everybody is comfortable with just drafting a mention of the meeting, which I think was in March of 2010.

I think the subcommittee thought that was appropriate but again, the timing was bad as far as getting this material together, so I'm perfectly okay with separating aging into number 3, I think that's fine if folks want to do that.

Dr. Insel: And just to clarify, this isn't -- we are late on this report, not because of anybody here. It wasn't our meeting, but it was a meeting that was supported elsewhere and we were trying -- it's not yet published but Geri was able to get a pre-print or something that could at least be cited, so, okay. Anything else on this chapter before we take this to votes? Della?

Dr. Hann: Okay. First section, what is new. There are now two changes that have been proposed. The first is to strike the sentence in the second bullet that begins: "people with ASD may need more assistance." That sentence, strike that out. And the second part to change would be to add a bullet or a sentence on the aging meeting that we were just talking about.

Any further discussion on the what is new?

Those in favor of those changes?

(Show of hands.)

One, two, three, four, five, six, seven, eight, nine, 10, 11, 12, 13, 14, 15 in the room.

Dr. Insel: On the phone?

Ms. Resnik: Aye.

Dr. Insel: Opposed?

(Show of hands.)

We have one. On the phone?

Ms. Resnik: Aye.

Dr. Insel: Two opposed.

Dr. Hann: Okay. Okay.

Ms. Resnik: This is Denise, mine was an in favor vote. I don't know if I was off mute at the time.

Dr. Hann: Oh.

Dr. Insel: All right.

Dr. Hann: So that's just one opposed then. Okay.

Mr. Claypool: And I don't know -- did I vote? This is Henry. Aye.

Dr. Insel: Thank you, Henry. Gap areas that have emerged. What do we have there, Della?

Dr. Hann: Oh, I should have -- so the first bullet, the continuing lack of research on youth, that bullet is actually to be moved to the what is new.

And I believe that was the only change that I heard for this particular section. Discussion?

Okay, those in favor?

(Show of hands.)

One, two, three, four, five, six, seven, eight, nine, 10, 11, 12, 13, 14, 15, 16, 17 in the room.

Ms. Resnik: Aye.

Dr. Insel: On the phone, anyone else?

Mr. Claypool: Aye.

Dr. Insel: Okay. Anyone opposed?

(No response.)

Moving on to the objectives.

Dr. Hann: Okay, for objectives, the first one mentioned in the update has to do with new long-term objective C from the 2010 Plan, in terms of adding some specificity to it, where essentially the objective would stand as-is and then it would have: "The following topics should be targeted for study: one, the community housing, which is there listed; two, successful life transitions for people with ASD including from post-secondary education to adult services, employment, sibling relationships, and day programs; and now three, aging in people with ASD."

Dr. Insel: We can fix the language but the concept is there.

Dr. Hann: Okay. Discussion?

Those in favor?

(Show of hands.)

One, two, three, four -- I think we did, this is 17 in the room.

Dr. Insel: On the phone?

Ms. Resnik: Aye.

Mr. Claypool: Aye.

Dr. Insel: Any opposed?

(No response.)

Okay. Next.

Dr. Hann: Then the last bullet, under research opportunities, there really -- there was no change to that which is currently proposed in front of you. It would be an opportunity to state "It is important to include people with ASD and their families in scientific research process, the use of models such as participatory action research, et cetera et cetera." Discussion?

Those in favor?

(Show of hands.)

Okay, everyone in the room, that's 17. Those on the phone?

Mr. Claypool: Aye.

Ms. Resnik: Aye.

Dr. Hann: Okay. We are done for six.

Dr. Insel: Okay. You are scheduled to have a break, but I think we need to keep going here to get as far as we can before the next agenda item, which is in a mere 10 minutes.

So let's start on chapter 7 and I believe Coleen is going to take us through this. This is a big one, but --

Dr. Boyle: Yes, this is definitely a long one, and --

Dr. Insel: Okay, but I'm not sure it's as controversial so --

Dr. Boyle: No, okay, and I wanted to say this is definitely a committee work and reflects the work not just of me but of many others.

So I'm going to run through this pretty quickly and if there's any points that need clarification, please, those that have contributed, speak up.

So again, this is the infrastructure, surveillance piece and it represents a number of issues on infrastructure, data sharing, biobanking, information communication and dissemination and then resource, training and resource development as well as surveillance.

So for what's new on data sharing, we highlighted two new opportunities, one on the Autism Informatics Consortium, which was essentially trying to accelerate discovery of making informatic tools and resources more useful to researchers.

And the second one that was

highlighted was the National Database for Autism Research and the opportunity that there's now over 10,000 participants enrolled in NDAR.

There's been much activity in the biobanking world and we have highlighted a number of biobanks and the current status of those including the Autism Treatment Network, the Simons Simplex Complex, the Autism Genome Project, the Autism Genetic Resource Exchange, the NIMH genetics repository, the NICHD brain and tissue bank for the developmental disorders program and the Autism Tissue Program with the whole brain donations.

Under "surveillance," we highlighted the progress made by both the ADDM network as well as the National Survey on Children's Health, and another of contributions from individual contributors in terms of better understanding about evaluating the changes in autism prevalence.

From an information communication

dissemination standpoint, we have highlighted that there have been several reviews of intervention in quality and effectiveness and that there has been considerable work at the state level in terms of task force or DD councils that are compiling service plans in terms of their current state of knowledge.

Relative to research workforce development, we have highlighted what has been accomplished through ARRA funding, and this is mostly from an NIH perspective in terms of grantees, trainees who have been supported as well as the Director's Pathfinder Award, which is not autism-specific, but clearly has presented opportunities for individuals examining or doing autism research.

So that's the new opportunities and the new opportunities, I don't know if anybody wants to add to that as I've gone through that fairly quickly.

In terms of gaps that --

Dr. Insel: Yes, comment --

Dr. Boyle: Go ahead.

Ms. Singer: On the research workforce development, the area in purple, I think what we had talked about including there, was making reference to the fact that although many researchers' work was being supported by ARRA funds, that the committee had concerns about what would happen in 2011 when that funding dried up. I think that was the issue that we had talked about culling out.

Dr. Boyle: Okay. Should we include that as an area of gaps perhaps? Or do you want to put it right there?

Dr. Insel: Well, so what is there doesn't have anything to do with autism.

Dr. Boyle: Right.

Dr. Insel: So I don't think you want this particular program because it is probably irrelevant.

Dr. Boyle: Yes, on page three?

Dr. Insel: Yes, bottom of page

three.

Dr. Boyle: Okay.

Mr. Ne'eman: Let me raise the context as to why that was included. My understanding in our initial discussion was that we were going to make mention of the opportunity and the need to invest in the inclusion of individuals with disabilities, including individuals on the autism spectrum, in the research workforce, and that that was part of the context as to what new developments in that broader conversation was going to be considered.

I don't see that language here but I do recall us discussing that in the Planning Subcommittee and on some of the previous phone calls.

Dr. Boyle: So, Ari, that is under six in terms of -- on page 6 at the bottom, so: "In addition, continued efforts to enhance diversity in the research workforce are needed."

Mr. Ne'eman: So my suggestion would be that given the focus of this committee, that we particularly cull out the inclusion of people with disabilities and individuals on the autism spectrum as part of that, so as to call attention to a particular focus there.

Dr. Insel: So specifically on the Director's Pathfinder Awards -- okay.

Mr. Ne'eman: I am referring to the page 6 language. Yes.

Ms. Singer: I think the point I was making was I am not certain that that is the reference to the ARRA funding that we had talked about. I think what we had talked about including there with regard to the ARRA funding had to do with our concern about the funding drying up, and what happened to those workers who were employed in the field of autism research when that funding no longer became available, as opposed to talking about the Director's Pathfinder Award.

Dr. Insel: But Alison, that -- so

the issue you are bringing up, which is a really major issue for those of us thinking about NIH-funded research, is probably not a new research area. It's more of a gap, right? And it's a looming gap, and a concern.

I guess I would have to say, given changes in budget, it's a gap area that has emerged in the past year or maybe in the past -- since November 2, let's put it that way. So it's maybe worth adding language there.

I still want to go back, because this piece that is in purple, I don't think -- it's true, true and unrelated. It's not connected to anything that has to do with autism as far as I know, as opposed to the previous paragraph where we have identified 60 trainees who are being supported to be in the autism workforce.

Dr. Boyle: We can delete that. It wasn't my addition so I'm not --

Dr. Daniels: OARC was asked to add the stuff on the Director's Pathfinder Award by Ari because he was calling out the part of that award that targets individuals with disabilities, but when we really looked at that program, it's really for all under-represented groups including women and minorities et cetera.

Dr. Insel: Moving on.

Dr. Boyle: So in terms of the gap areas, looking at data sharing, the IACC identified a number of short- and long-term priorities for increasing the utility and harmonization of major autism research informatic resources and we have a complementary new objective that goes along with that.

Within the context of the Affordable Care Act, there's an unprecedented call for the use of or transition, really, to electronic health records and this clearly provides an opportunity, not necessarily a gap, but an opportunity to consider the use of electronic health records in terms of better understanding the services of people with autism and a number of other research opportunities.

With regard to biobanking, I think there is a consideration for integrating biologic information into phenotypic or phenotype selection and, to this end, I think there's the need for the establishment of a robust network of clinical research sites.

Evaluating -- and again this gets back into the idea of a platform for conducting comparative effectiveness research and clinical trials on novel autism treatments, so again, perhaps, utilizing that comparative effectiveness resource that we heard about earlier.

Surveillance-wise, I think there is a particular challenge in keeping consistency in the number of surveillance sites, so we can get a better sense of trends in autism over time, as well as better data to characterize the population of children impacted by the level of cognitive impairment and subtypes.

From a communication information dissemination perspective, while there are many efforts going on at the state and local level in terms of developing plans for ASD and other DD-related services, I think there's also many gaps in terms of finding this information, both in terms of what is available from a public and private resource perspective.

Let's see. I know there's a lot in relationship to the translating, potential translating from the IACC Services Subcommittee workshop that was held in November, and there was a particular interest in research that is meaningful for teachers and family members, so that was a gap that was identified through that workshop.

And there's also a body of literature that AHRQ has put together in terms of this whole idea of knowledge transfer, a framework, and it was felt that this body of work could clearly be used as a guide in helping frame translation research or provide a useful guide for autism research translation efforts.

Research workforce development, we culled out some specific areas if emphasis, including health services research, translational research, which complements what I just talked about in terms of AHRQ, as well as international collaborative studies.

Dr. Insel: And this might be the place for Alison's comment then.

Dr. Boyle: Yes. So moving on, does anybody else have any questions on that part, the gaps? Okay. On the --

Dr. Lawler: I had a question, Coleen, about the biobanking and I don't know, maybe it's just the term that doesn't really seem to fit in under that paragraph, but definitely, I think, the last two sentences about "need high-throughput screening tools to evaluate gene-environment interactions." That doesn't really seem to fit there to me. I mean, the rest of what you are talking about is through the network of clinical sites, and making data available --

Dr. Insel: But we talked about, first thing in the morning we talked about using iPS cells from a biobank for just that purpose. So that's kind of -- there's a paper just out in Cell that says this is the future, and the idea is that actually could be part of a biobank.

Dr. Lawler: Maybe we need to specify that, because that's one potential screening tool, but when I think of screening tools, there's many others as well, so it just wasn't clear to me.

Dr. Boyle: Okay. So the objectives, first one is easy, objective B, we just changed the date. I think it was 2010. We changed it to 2011 and that has to do with the State of the States assessment, something that CMS is working on.

Our revised objective D, we added newborn bloodspots as an opportunity for inclusion in biobank, as well as, I think the last part of this, I don't have a colored copy of this, so I think the last part of this is new as well, which is yes, support should also be included to provide an international web-based digital brain atlas, so that's the new part.

And then the next five objectives are actually new objectives. The first one is to establish a robust network of clinical research sites offering clinical care in real-world settings for conducting comparative effectiveness research and clinical trials for novel autism treatments. So again, that clinical research network.

The second one is to create an information resource for ASD researchers to share information to facilitate data sharing and standardization of methods across projects.

Number -- actually, C, which is not a number, C, I'm actually going to have to turn to Geri on this one because I was going back through my notes and I'm not -- I don't feel like I know enough to say that one. Geri, do you remember where that one came from?

Dr. Dawson: This actually came out of -- Cindy, maybe you can help me with this one, so new objective C. I think this was a resource that we talked about coming out of the workshop, the NIEHS workshop, facilities to develop promising vertebrate and invertebrate model systems, making these models more easily available and supporting approaches to the development of high-throughput screening technology.

Dr. Lawler: Yes, I think this arose out of some conversations from the -- and some discussions about if you were at an institution and you had access to a core facility that specialized in technology x, that would provide a means to sort of expand autism researchers' scope of the kinds of studies that are being collected, so it was really in the context of adding core facilities to existing institutions as opposed to regional centers.

Dr. Insel: Okay.

Dr. Boyle: We were just saying it was in chapter 3 as well, at least -- okay, that's fine.

So, D is to create an information resource for ASD service providers, researchers, families and people with ASD which serves as a portal to obtain the most recent evidence-based reviews and plans for intervention, services and support, sort of trying to focus on that gap in translation and information.

And then the last one is on the next page which is to conduct a meeting in 2011 which will establish standards for data collection on phenotyping and imaging protocols.

Dr. Insel: Comments, questions. Sharon?

Ms. Lewis: I am happy to see the objective D in here and wondering if the subcommittee was aware that the Administration on Developmental Disabilities invested close to $2 million this year in exactly a project that sounds a lot like this and wondering if we need to duplicate that or if you are advocating for something different?

Dr. Boyle: No, I wasn't aware -- we weren't aware of that.

Ms. Lewis: Yes, see, the Administration of Developmental Disabilities awarded close to $1.9 million to establish a National Autism Resource and Information Center targeted to families, researchers, providers looking at evidence-based practices.

Dr. Boyle: Yes. Good.

Dr. Insel: Do you want to take it out?

Ms. Lewis: I guess my question is,

do we -- if this is an objective that has been funded by the Federal government, do we need to include it?

Dr. Briggs: It would look good on our portfolio.

(Laughter.)

Dr. Insel: So that is the opposite of moving the goalpost down, that's moving the goalpost behind you and you can't do that. That's not permitted here.

Ms. Lewis: Okay. All right.

Dr. Insel: I think we just lost an objective.

Ms. Lewis: I'm sorry.

Dr. Boyle: That's fine.

Dr. Briggs: In terms of what's accomplished --

Dr. Insel: Oh, good point, that's right. That's what you call a save. We need a few more of those. Any other comments? So we will move that to the what's new. Ari?

Mr. Ne'eman: Yes, this is very

brief. I remember us discussing in the Planning Subcommittee the need for adult surveillance or surveillance to ascertain incidence of adults on the autism spectrum. I wonder if we couldn't modify new objective L to just, after "in younger and older age groups," put comma, "including adults," just to ensure that that is represented.

Dr. Boyle: Ari, I think it's already here, so new objective L, oh yes, it has older -- is that what you said, older and younger age groups? Yes, that's what I was thinking. You want adults.

Mr. Ne'eman: Including adults.

Dr. Boyle: Okay.

Mr. Ne'eman: I think some people, unfortunately, might interpret that as just meaning adolescents or teenagers.

Dr. Boyle: We could say "children and adults," just do that. Would you be okay with that?

Mr. Ne'eman: Yes, "children and

adults" where?

Dr. Boyle: So instead of "younger and older," we would say "children and adults."

Mr. Ne'eman: That's perfect, thank you.

Dr. Boyle: Okay.

Dr. Insel: Anything else from this? Ellen?

Ms. Blackwell: I just have a quick question. Coleen, thank you for doing such a great job. On new objective A, and I may just be being stupid here, what is clinical -- what is clinical care in a real-world setting? Are people going to understand what that means?

Dr. Dawson: So the difference would be establishing a biorepository where you have phenotype and genotype and other kinds of biological data that was created by recruiting people into a research project as compared to real-world clinics that, as they come in, and actually the trend in other conditions is to use the electronic medical records, that kind of data, and mapping that onto the biological information, and you get a very different sample of people when you are all-comers coming into a clinic and what kind of conditions are showing up and how do they map onto the way treatment is used and improving quality of care in that context, versus a research database.

Dr. Insel: So in the spirit of, again, already accomplished, isn't this the ATN?

Dr. Dawson: The ATN would be a good example, except for that it doesn't have the biorepository, which is a key, I think, component in terms of being able to begin to look at targeted subgroups and targeted treatments that relate to subtypes.

Dr. Insel: But it's been funded to collect DNA, plasma and urine from four of the 14 sites, that's what it says here. So it's already under way.

Dr. Dawson: It says four of the 14 sites?

Dr. Insel: Yes, to establish a comprehensive biorepository for the ATN.

Dr. Dawson: Well, right, but it's four sites out of 14.

Dr. Insel: I'm just wondering if -- is this really -- does this rise to the level of requiring an objective if it's happening anyway and we have already cited it as an accomplishment? There's also the large-scale HMO research network which we have just spent $3 million on doing the same thing for 13 million or 17 million covered lives.

Dr. Dawson: The only thing I would argue is that funding four sites to collect -- and I'm not talking just about the Autism Treatment Network, in fact I think I'm not supposed to talk about the Autism Treatment Network from my list of recusals, but in terms of actually establishing a robust network where there is a funded biological data and patient data, that hasn't been done yet.

So yes, there's been a step in that direction but it hasn't really been accomplished.

Dr. Insel: And this Simons collection wouldn't --

Dr. Dawson: That's definitely not a clinic base. That's anything but a clinic base.

Dr. Insel: Right. Yes.

Dr. Koroshetz: It sounds like you want to add something on to something existing. This looks like you are starting up a whole new research network.

Dr. Dawson: Well, I'm not going to try to talk about a specific network, because I think I am not supposed to do that, but what I am saying is that in other conditions, one way to have -- there's been rapid progress, is when there has been a network of clinical care sites where there is mapping of the data that is collected in the clinical context with biological information that is collected.

Dr. Insel: Yes, no, I get you. I guess the only question is, again, the verb. Is this to establish a network or to expand existing networks? Because actually there's more than one. So --

Dr. Dawson: So maybe we should say -- to enhance?

Dr. Insel: Yes, enhance existing networks or enhance networks of clinical research sites. Any additional issues here, comments?

Della?

Dr. Hann: I just wanted to point out that it appears that there has also been a recommendation to delete an objective, objective M.

Mr. Ne'eman: I thought we were deleting the recommended revision, not the objective.

Dr. Hann: Just the objective. Okay.

Dr. Insel: Okay. We are going to

take this to a vote, and again, Coleen, you did an amazing job in pulling a lot of things together on the resources side, which if nothing else, just having this catalogue will be helpful for the new publication.

Dr. Hann: Okay, so under "what is new in this research area" and "what have we learned," the one, two, three pages essentially, the first three pages of the update concern -- actually four -- concern that and there was -- the change that I heard was to delete the section in purple at the end of page 3 that deals with the Pathfinder Award.

Discussion?

Those in favor of the section?

(Show of hands.)

Okay, Cindy? All right. So everybody in the room. Anybody on the phone?

Ms. Resnik: Aye.

Mr. Grossman: Aye.

Mr. Claypool: Aye.

Dr. Hann: Yes, you're right, thank you, Susan. Susan just corrected me. We were also going to have to add the new ASD program, the resource that you have created, Sharon, to add that to the what is new section. I assume that would go under information and communication.

Dr. Insel: Right.

Dr. Hann: Okay. The new portal.

Dr. Insel: Okay.

Ms. Lewis: And I can send you a little blurb.

Dr. Hann: That would be great, thank you very much.

Dr. Insel: So what about gaps?

Dr. Hann: Gaps. There was a discussion with regard to the biobanking, if there needed to be examples of the kind of screening tools. I don't really know where the group came down on that. And then there was a change to the section on workforce development to add a sentence or two about the fact that the ARRA funding is ending and there is concern about the new investigators that were brought on board through that process.

Mr. Ne'eman: I think we had also proposed including in the last sentence on the research workforce development, "including greater involvement of individuals with disabilities and in particular individuals on the autism spectrum."

Dr. Hann: Okay. Tom, did you want to provide anything about the screening tools, say anything more?

Dr. Insel: I don't know what to say about the screening tools. It says here "currently there is a need --" I think there should be a "for" in there "-- for high-throughput screening tools to quickly evaluate gene-environment interactions relevant to ASD." I think Cindy's point was that since it's under the biobanking category, it seems like it doesn't fit but I think now --

Dr. Lawler: I think maybe just

either a phrase that you are really referring to the induced pluripotent stem cells --

Dr. Insel: We could put in parentheses, i.e., iPSCs.

Dr. Lawler: Right.

Dr. Insel: Okay.

Dr. Lawler: That would remove my objection.

Dr. Insel: Put that in there.

Dr. Hann: All right. Okay, so then just quickly, then so there will be that addition of that parenthetical for biobanking with regard to the iPS cells, there's changes to the workforce development section about ARRA funding and its discontinuation as well as the need for considering the adding people with ASD to the workforce.

Is that it?

Dr. Insel: Yes.

Dr. Hann: Those are the changes. Further discussion? Those in favor?

(Show of hands.)

Okay, everyone in the room. You are abstaining?

Dr. Briggs: I abstain.

Dr. Hann: All but one, she is abstaining. Anyone on the phone?

Ms. Resnik: Aye.

Dr. Hann: Any objections? Folks on the phone?

(No response.)

Okay. Moving on to the objectives. There have been proposed wording changes to revision for objective B, D, that have been proposed. In terms of new objective A, it now begins "enhance networks of."

I'm sorry, say that again, Walter?

Dr. Koroshetz: It should be to enhance network --

Court Reporter: I'm sorry, could you use your microphone, please?

Dr. Hann: Okay, yes we had to change all of the -- yes, okay.

Dr. Insel: We will deal with the

syntax.

Dr. Hann: Okay. The second one, create an information resource. I didn't hear any discussion with regard to that one.

Mr. Ne'eman: I thought that was the one you were striking.

Dr. Hann: No, that's the last one, D.

Mr. Ne'eman: Oh, sorry.

Dr. Hann: C, I also did not hear any discussion with regard to that. D is now part of what is new, would be deleted from the section and there is an E on conducting a meeting. Now some of these do not have, I think -

Dr. Insel: On the meeting, Geri, wasn't there a meeting in 2010?

Dr. Dawson: There was, I'm not sure how we got that on there.

Dr. Insel: I think we did it already.

Court Reporter: Could you use your

microphone, please?

Dr. Insel: Use your mic.

Dr. Dawson: Sorry. There is the August 2010 meeting that is summarized in the What's New section.

Dr. Insel: Right.

Dr. Dawson: But I think they are going to have ongoing meetings, so --

Dr. Insel: Yes, but I would respectfully drop this one out in view of the fact that it is already mostly done.

Dr. Hann: Okay.

Mr. Ne'eman: And have you incorporated the edits to L?

Dr. Hann: Yes, I knew there was something else. Thank you. And then there was an existing objective L, on page 41 in the Plan, expand the number of ADDM sites in order to conduct ASD surveillance in children and adults.

And then there's a semi-colon and it goes on. Okay. Discussion, further discussion about these?

Those in favor of the changes?

(Show of hands.)

Okay, now we do have everybody in the room.

Those on the phone?

Ms. Resnik: Aye.

Mr. Goldman: Aye.

Dr. Hann: Okay.

Mr. Claypool: Aye.

Dr. Hann: Right. Done.

Dr. Insel: Okay. So we have done the seven chapters. We still have the introduction to do. We have got some agenda items in front of us as well. Some people have to leave at 4 o'clock. It is now 20 till four. I am going to recommend -- well, let me see what the group wants to do.

My recommendation is that we attend to some of the agenda items. We may be able to do those quickly, see whether there are any additional issues there that we need to focus on and then with the time left, go back to the introduction and try to knock that out. Is that okay?

So, can we move to the next item on the agenda, which is the report on the Somali community autism issue from Coleen Boyle?

Dr. Boyle: Could we have a five-minute break?

Dr. Insel: A break? A break?

Dr. Boyle: Just a bathroom break.

Dr. Insel: We could do a five-minute break but not a six-minute break.

Dr. Boyle: Okay.

Dr. Insel: And then we need everybody back so we can get -- we are so far behind schedule I want to make sure we get this done.

(Whereupon, the committee members took a brief break at 3:40 p.m., and resumed at 3:45 p.m.)

Dr. Insel: If I can have your attention, let's quickly get focused on this next issue which is the report on the Somali community and I know there's been a lot of conversation about this. Coleen, Linda's not here, but Cindy can help us with us, as well as Geri, have all been involved. Coleen, you want to lead us off on this?

Dr. Boyle: Sure I'd be happy to, and I will be brief here. So Linda, Geri and I have had the opportunity to discuss how we can collectively assist in a more formal investigation into the prevalence of autism in Somalis living in Minneapolis, Minnesota, following up on Idil's talk to us at the last meeting.

And collectively, we will be able to provide funds for a study of the prevalence of autism in Minneapolis among Somalis and non-Somali populations.

The prevalence investigation will include something comparable to what we had done in Brick Township, which would be both a review of records as well as case confirmation by the examination of the children there.

We did have an opportunity to discuss the possible pending study with the Minnesota Department of Health and they are very pleased with the potential support, and we actually have begun to develop a concept piece for an FOA.

One of the challenges right now is with the continuing resolution, the CR, and the funding constraints that the Federal government has, so what we are looking into are possible funding mechanisms and Autism Speaks is not hampered by such challenges, so hopefully we can still begin this investigation this year or shortly with at least the initial support from Autism Speaks and then add our Federal funding onto that.

So there's been a number of discussions both within the three major partners as well as internal, so we hope we can move forward.

Dr. Insel: Thank you great.

Dr. Boyle: You're welcome.

Dr. Insel: Cindy?

Dr. Lawler: Sure, NIH has committed a total of $150,000. Four institutes that are contributing, child health and development, mental health, the center for minority health and health disparities and NIEHS, and to date, NIEHS, has had discussions with CDC about possible funding mechanisms to conduct this study.

We are in the process of drafting an interagency agreement between NIH and CDC that will allow us to transfer funds and finally, I just want to make the point that as I am sitting here today I think this small study incorporates lots of the positive features that we have talked about and we would like to see in other studies in the Strategic Plan.

In terms of efficiency, it's really building on some infrastructure and some knowledge gain from previous surveillance efforts. It has been critical and will be critical that CDC has maintained this positive relationship with state and local health departments in that area.

We have got a very strong interest and advocacy from the affected community and last but not least, this really does demonstrate the cooperation and sort of coalescence of different partners around this urgent public health need.

So I think it's a very positive sign.

Dr. Insel: Geri?

Dr. Dawson: I really just want to underscore what Cindy just said and Autism Speaks has committed $100,000 to the study and we are willing to kick the study off while the Federal government works through some of the issues around the budget, and we are just very pleased to be able to respond to this and I think it has not only scientific value, but also potentially clinical utility that could go a long way. So we are very, very happy to be a partner in this.

Dr. Insel: That's great. This is a wonderful example of what the IACC can do. After a day of slogging through the Strategic Plan you might have forgotten that. But we actually can do something and make something happen quickly and maybe it just doesn't feel like it today.

Dr. Insel: I just had one question I wanted to check with you about, as you launch this. There is this other case, this other community in Sweden of Somalis with a higher prevalence of ASD, and it's been reported by Chris Gillberg and others.

I don't know if anybody has contacted them or whether there's any interest in trying to find out where they are with their studies because they may have some hints or maybe there's a way to actually get some additional information. It's such a great opportunity to have another community of the same ethnic group, perhaps the same ethnic group, we'd have to find out, with the same kind of result, independent, completely independent.

So it seems like it would be worth turning over that rock and finding out more about it.

Ms. Resnik: This is Denise with SARRC, I believe our research director Chris Smith did reach out and I'll find out where he is at, but I don't have a report on that.

Dr. Insel: Great. Thanks Denise. Anything else about this particular issue? So thanks to Idil for bringing this to our attention. I guess it was really just the last meeting, so a lot has happened quickly and we will look forward to hearing more from you at the next meetings about where we are at with respect to the study.

Can we move on then, to the subcommittee on safety? And Alison and Lyn were the co-chairs on this and let me just turn to you to ask you to quickly get us up to date with what the subcommittee is thinking about.

Court Reporter: Could you use a mic? I'm not picking her up.

Dr. Insel: Idil, use this microphone.

Ms. Abdull: I'm so sorry, I'm probably out of line, I apologize. I just want to say mahadsanid which in Somali, it means -- in English it means thank you so much from the bottom of my heart. Thank you so much.

(Applause.)

Dr. Insel: Well, we owe you some gratitude. This was an opportunity you brought to us, not a problem and I think you can tell from the response that people are excited to have this chance, so this is -- it's nice to be able to move quickly on something.

Safety.

Ms. Singer: So the Safety Subcommittee was commissioned at the last IACC meeting on October 22nd. It followed in response to a presentation from the National Autism Association related to autistic wandering.

The committee is charged with focusing on issues related to safety in general. The first issue we are charged with tackling, according to the last meeting, is wandering, but we also want to take up issues of restraint and seclusion and other issues of safety.

And our first task that came out of the October 22nd meeting was to draft a letter to Secretary Sebelius with regard to the issues associated with autism-related wandering.

So we had our first committee meeting on November 29th and we worked on drafting a letter to Secretary Sebelius.

The letter focuses -- it starts out by speaking about the very tragic story that was brought to the full committee at the last meeting about Mason Medlam that his mother Sheila so courageously shared with us and again, I want to just extend my thanks and appreciation and admiration to Sheila because that is not an easy thing to do and she really -- that was very heroic.

The letter also includes names of other children who have died as a result of their autism-related wandering, and it focuses on several of the issues that came up at the last IACC meeting.

And we call specifically for five action items in the letter. The first is to collect data on the issue itself, looking at the scope of the issue, how many children are involved, how many children have died, how many families are involved.

I think we have talked a lot today about the need to collect this data. Many times throughout this process people have said, "Well we don't actually have good data on the scope of this project", so I think that, we all agree, is an important first step to collecting this data.

The second action item in the letter to the Secretary is to develop and test programs to prevent -- first to prevent wandering incidents and those programs would be parent training, individual training, and then also, as Geri pointed out, we wanted to separate prevention of negative outcomes associated with wandering and that's where we would include first responder training.

The third action item in the letter to the Secretary focuses on coordinating with the Department of Justice to determine whether or not we could expand AMBER alerts to include children with autism who have wandered away.

Right now there is really a hole in the system in that children with autism are not covered under AMBER alerts, and they are also not covered under silver alerts, which are designed for older adults who have dementia or Alzheimer's-related dementia.

But our kids who have cognitive disability or intellectual disability who wander, are not covered by either the AMBER alert or the silver alert.

Okay, these are not actually the slides -- okay. The fourth item in the letter is to develop a medical sub-classification that is focused on creating a medical code for autism with wandering, or other similar neurological disorders that would be similar to Alzheimer's with wandering.

And then the fifth action item in the letter to the Secretary calls for us to meet with the Department of Education and to develop guidelines regarding parental notification of wandering incidents that take place in school.

Ms. Redwood: Go back to the last slide.

Ms. Singer: Okay, so as far as the letter right now, the safety committee has been emailing furiously over the last couple of days subsequent to our meeting. There was some additional concerns about the letter raised in the last couple of days, so for that reason the letter is not included in the materials today.

But we all agree that this is an urgent issue and we plan to finalize the letter and bring it to the full committee at the January meeting so that the committee can review the letter and take action.

So, the actions we have taken so far as a subcommittee are we had our first meeting, the second one was we submitted four new objectives to the Strategic Planning subcommittee. These were considered at the December 3rd meeting of the Strategic Planning subcommittee.

Two of those objectives moved forward out of the Strategic Planning Subcommittee and we actually voted to include those today in the Strategic Plan.

So, the action items before us

today are actually not now to review and finalize the letter, because as I said, there was some concern expressed over the last couple of days from some new committee members who wanted more time to review the letter.

So in deference to them we are going to wait and bring the letter forward to the full committee at the January meeting.

But the other items that we need input from the full committee today are to discuss and approve the idea of having Lyn and myself and other members of the committee go and meet with the Department of Justice and with the Department of Education to start to talk about some of these issues, specifically around the AMBER alert and whether AMBER alert can be expanded to include children with autism who wander, and to meet with the Department of Education to talk about whether there are some guidelines in place that are either not being implemented or whether we need to develop guidelines so that can parents can be informed when fleeing incidents take place during the school day on school grounds.

So that's one action item, and then the next action item is in order to move forward with our more general work as a Safety Subcommittee, we wanted to issue an RFI to get information from the public with regard to what are the most pressing issues and where should we be focusing our attention next and I think Lyn wants to speak more about --

Ms. Redwood: We have to go back to the other one.

Dr. Insel: Lyn, you will use your mic?

Ms. Redwood: Okay, there was actually one right before that. Right. There were concerns that there may be other safety issues that we are just not aware of in the autism community so we thought it was important to go out with an RFI to survey parents and their families to find out what other safety concerns might be out there that we could help effectively address.

There are sort of two options for collecting this information that I wanted to share with the committee today to get feedback in terms how to move forward with an RFI, if the committee agrees that that is a good initiative, a good mechanism to use to obtain additional information.

One would be to -- we'll go to the next slide -- ask a very broad-based question -- there -- what safety concerns are the most urgent for people with ASD and their families and just see what we get from that request.

The second would be a little bit more specific with specific questions, like "What are your top three concerns relating to keeping your child and your family safe?", "What situations or settings in your community have been particularly challenging?"

I know I have heard from parents that their child was abused on the school bus and it was caught by a camera. So things like that, "Where we can be aware of where some of the gaps might be?"

Have your concerns changed as your child has gotten older, and I think that's an important issue too, especially when adults move into group home situations or they are outside of the home, what are some of their safety concerns then.

And another issue that was brought to my attention, and I think Lee actually mentioned this today, is family members also being injured by their children or adults when they have meltdowns, and that there really is not a mechanism in place to help these families.

They oftentimes go to the emergency rooms and the emergency room doctors don't know how to deal with them, or mental health facilities are full, and so these families are at a breaking point.

I received a desperate email from a family on Thanksgiving where their son had slammed their younger 13-year-old son into a stove and they were just at their wit's end with what to do.

So I think that's another big concern that we need to try to address as well. Also to find out from families what resources they think would be helpful to keep their child safe and their families safe.

So those are just five that I wanted to throw out and suggest as part of the RFI, to get feedback from the committee, if there were additional things we should include, if we think it would be better to go with just one broad question, or to help break it down into specific areas that we have already heard from the community that are concerning.

Dr. Insel: Great. Judith.

Dr. Cooper: Great. It seems like the broad option would allow you to solicit responses from care givers and teachers and clinicians, whereas the specifics are all hearing from the families.

So I didn't know whether all you really cared about was just hearing from the family or how you are going to send this RFI out, like if we do an RFI through NIH, it would just go out to everybody, versus maybe you know if you sent it out through some of the voluntaries.

So just a thought, the broad is really broad because you will get more and I didn't know which way you were hoping.

Ms. Redwood: I think that's a good point in terms of also engaging the other stakeholders, the educators as well, so that is a very good point.

Dr. Koroshetz: Just to mention in terms of epilepsy, the sudden death and epilepsy issue is quite big in the epilepsy community and there's a lot of resources and NINDS is actually embarking on a fairly large effort to try and understand and prevent it. So I think it may be an opportunity for at least on that side, for people with autism who have kids with autism, have epilepsy, may benefit from taking part or looking at those kind of resources.

I'm suggesting that if there is increased mortality due to epilepsy in the autism community, they may -- it may be important for them to interact with the epilepsy community which, unless we kind of pushed them, they otherwise might not do.

So there are for instance, I don't know how good they are, but there are materials out there which say that maybe you should be sleeping on your back instead of on your stomach, and then taking part in the research might be important.

Dr. Insel: Alison?

Ms. Singer: Citizens United for Research in Epilepsy or CURE is an advocacy group that has really taken up the SUDE issue.

So we may want to reach out to them and invite them to invite their membership to participate in this RFI.

Dr. Insel: Ellen and then Sharon.

Ms. Blackwell: Sorry. Well, as far as the RFI is concerned, one of my overriding comments would be that the questions seem to be aimed at children when they probably should be aimed at a much larger group including adults, because certainly all of these apply to adults as well as children, but I wanted to just take a step back for a second from safety, because I think that today's earlier discussion, especially when we talked about the objectives related to safety which are in chapter 5, the services chapter, really lead me to believe that these are issues that are directly related to services.

So I think that we just need to think for a minute, do we really need a separate Safety Subcommittee, because these are services issues? So to me, it just seems a little bit more fluid to put these issues back into the aegis of the Services Subcommittee.

That's my first suggestion.

And my second suggestion would be that since we keep talking about seclusion and restraint, which is indeed one of the largest issues related to safety, that I would propose that Sharon take over the Services Subcommittee. She is well positioned to, probably more than anyone in the United States, to look at seclusion and restraint issues.

So I'm just kind of wondering why we have a separate subcommittee that's addressing this subset of services issues and suggesting that maybe we contract to go back the way we had things before and maybe make a few tweaks. Comments?

Dr. Insel: So maybe we can circle back to that larger question, but I think before we get there, whether this is done in this subcommittee or a different subcommittee, we still have an issue in front of us about how to gather information.

What strikes me is the course of this conversation, which is actually kind of interesting. We started with this tremendous sense of urgency and we heard these really horrific anecdotes from people who, as Alison said, provided really kind of heroic testimony for us to tell us this is a problem that we might have overlooked or hadn't heard much about.

And I think all of us felt the need to do something right away and that was part of what drove the creation of the subcommittee and the idea that we want to send a letter and to think very quickly about policy.

But the deeper we have gotten into this, and I applaud this group for thinking about this, is that I think you began to ask questions about what do we really know here and what don't we know, and maybe before we make recommendations either to the Secretary or anybody else, we ought to make sure we have got as many facts as we can and at least put the story together in a way that is a little bit clearer.

At the same time, there's this great urgency to do something and I am hearing in what you have presented and also that sounds like what the subcommittee is going through, that tension to both do something quickly but also to get information at the same time so we are informed about what the complexity of the problem is. Alison or Lyn?

Ms. Redwood: You are exactly right Tom, and Alison and I obviously share this strong sense of urgency over this issue and we are sensitive to the fact that we don't have a lot of data on this right now to move forward with and it is all anecdotal data from families but we hear it over and over and over again.

So one of the suggestions or initiatives that Alison took upon herself was to look into using the IAN database to be able to quickly send out a survey to I don't know how many -- is Paul still here?

Dr. Insel: It's 25,000 is that --

Ms. Redwood: Right.

Dr. Insel: 35,000

Ms. Redwood: So we have a proposal from IAN to be able to do that and we have a budget and I just got an email a few minutes ago, several of the autism organizations have each chipped in $5,000 each to fully fund this project. So that will be moving forward and hopefully we will be able to get some of that necessary data.

But I think we need to get it from all directions, so I think having the RFI, using the IAN database, will all be very helpful. And hopefully, Alison do you have a time line for when that project -- we will form a subcommittee that will help to create the questionnaire along with stakeholders, and hopefully get that out within the next month or two.

Ms. Singer: Yes, I think we are

going -- I am going to meet again tomorrow with Paul who unfortunately left right before we had a chance to tell him the news that the study is now fully funded, so it's nice that we could say that this committee, like the group that is working on the Somali issue, is also moving forward and taking action and really expressing, really responding to this very urgent need.

So I want to thank Autism Speaks, because they are also funder, Autism Science Foundation is a funder, and then, I'm not even sure which groups voted today to fund, it's hot off the --

Ms. Redwood: The Autism Research Institute and also the Global Autism Collaboration, which is a newly-formed global advocacy organization.

Dr. Insel: And my understanding is that if you use IAN, the data come back very quickly so we are talking about days not weeks or months, right?

Ms. Singer: I don't know if Paul would commit to days.

Dr. Insel: Geri, what does it take? When they did the fever survey they got those data back quickly. What would it take for them to do this?

Ms. Singer: I can show you the Plan, we have a proposal.

Dr. Dawson: I think it will be months, not days but it will be within the year for sure I would say. But they have to develop the survey and I think it depends on how much you decide to have community input into the survey and that sort of thing, but once it's done, then I think it goes very quickly.

Dr. Insel: So some options then, so the RFI is one possibility, using the IAN network in parallel would be another, there may be other sources of information from studies that are going on, you know, the HMO study may be a useful way to look at some pieces of this as well, which looks at health outcomes of families as well as the people with ASD.

Are there other sources of information? What I am getting at is I think this is really very healthy that we are taking a close look at putting the data together before we start thinking too quickly about what the policies ought to be.

Anything else that people can come up with as sources? Geri?

Dr. Dawson: I don't know whether the health outcomes study, whether there are any data that have to do with accidents for example, that might be able to be derived from that, but that's another potential source of information.

Dr. Insel: Yes, exactly, that's a why I was thinking we could probably use that as well, that is not -- that's still coalescing so it's not going to happen over the next couple of months but we will have some of that. Coleen?

Dr. Boyle: So we are doing just -- I'm not sure this is going to pan out -- but we are doing an analysis looking at the multiple cause of death tapes and looking at the proportion, it's basically a proportional mortality analysis, looking at autism and all causes of death, not just injury-related causes of death, so that might again give -- glean -- give us some information.

Another idea which would be sort of a quick and easy one to do, is to follow up on the studies that were done in the early 2000 in California with the DDS system, where they linked -- okay, is that being done?

Dr. Dawson: So we actually have done that and that paper is under review, so that -- yes, that was the mortality paper out of California, yes, and so -- and we have analyzed it for individuals with autism and people with autism plus epilepsy and epilepsy alone and I am sorry I don't have all the data on the top of my fingers, but the paper has been written, it's under review and actually we just got feedback, it's going to be out -- they've accepted it pending revision.

Dr. Boyle: Well, the remarkable finding about the California data and the Swedish data, I mean they were very comparable, with an excess in girls and women as well as excess associated with epilepsy. Geri?

Dr. Dawson: I'd be happy to give an informal report on that next time if you are interested.

Dr. Insel: I think that would be great and then next time, going back to Ellen's suggestion, maybe if one of the other tasks here is to put together a letter, because we said originally that in the spirit of what's in the Combating Autism Act, we are obligated to let the Secretary know about emerging issues that we want to inform her about.

And it could be, by then the committee, the subcommittee will have some more time to actually hash this out to something that everybody feels comfortable with, they can bring it back to us, and then maybe we can revisit Ellen's recommendation that we could declare victory at that point and we could ask Sharon to -- Sharon doesn't look happy about this -- whether to consider a change in the services work group. Does that make sense? That's one of the other things we might talk about in January.

Ms. Redwood: I don't know how Alison feels but I would sort of continue to like to be involved in this and have it be a separate initiative because I do think it's very time consuming and I know the Services Subcommittee is already very busy.

So, and I think there is a sense of urgency. If we get to a point maybe next year, when all of these issues are addressed, then it could be rolled over. That's my personal opinion.

Dr. Koroshetz: Yes, I agree. I don't consider it a services issue right now. I think it's more understanding interventions, what works, what doesn't work. So it's more hardcore research at this point.

Dr. Insel: Ari?

Mr. Ne'eman: So the one concern I would raise is it would seem to me that the number of the areas that we want the Services Subcommittee to be addressing, such as restraint and seclusion, such as service provision in the context of housing, work force, a number of other areas have direct implications on these issues of safety.

So I think we do need to give some thought as to how to form a closer connection there. I do think these are services issues.

Dr. Insel: How about we revisit this in January? We can talk further about it at that point, get a more well-developed letter, and by that time we will have hopefully some information, Geri, you will report back to us on the mortality story that has already developed.

So, great. Anything else for feedback for this group?

Ms. Redwood: Tom, I really sort of need to know, with regard to the RFI, because that process will take at least a month in the development and then if we put it out for six weeks, I would sort of like to get approval today.

From what I am hearing, the committee seems, if we were funding this project through IAN, we can get more granular, so I guess from what I am hearing, that is going to be primarily families.

If we want to catch educators and a broader group of stakeholders then we should just go out with the one broad question with regard to safety. So, Della?

Dr. Hann: So I think that's great and what you may want to do is embed in the text of the RFI those other kinds of issues just to sort of help people sort of -- because the one broad question, it's like well, where do I start?

So you might want to, just sort of as examples of things that could be included in their discussion. That's the first point I wanted to raise as a possibility.

The second point, I just wanted to clarify with regards to timing, even if the committee agrees with the RFI, it likely will not go out until the end of February. So I just wanted to be clear on that. That would be the earliest and to be able to get it out onto the "street."

And I think those were the major points. I think the other point I would just ask you all to think about, because I think given some of the public comment that we have received on this issue and so forth like that, and the compelling need for some people to feel like they have -- they do -- they have a very legitimate story that they are trying to convey, you may want to consider the amount of characters to which you wish to allow people to respond.

I say that just because of our experience with RFIs and the volumes of information that can come in.

Dr. Insel: We've been there. It's a familiar debate. Anything else about the RFI? There clearly -- the subcommittee is looking for some feedback from us. Ari?

Mr. Ne'eman: I would just briefly say that before the RFI goes out, I would think it important for us to review it to ensure that we have some questions in there that will be -- that we will welcome input from adults on the autism spectrum, and that there will be the most relevance to those experiences.

Dr. Insel: Just a point of clarification on timing. Is this something that we could talk about further in January before -- and still have the RFI go out in February?

Dr. Daniels: What I am hearing with regard to the Safety Subcommittee is that we would need to continue the discussion about crystallizing this RFI and then possibly discuss it again in January.

You may -- the committee can approve that you are doing it, but it sounds like the committee would like to see something a little bit more carefully fleshed out than what has been presented today. And so the Safety Subcommittee should have time to work on it between now and then.

Dr. Insel: It might also be helpful to have the IAN document too at that point.

So sounds like enthusiasm for going ahead with this, but question about actually what the details would look like and having another discussion about the specific questions.

On DOJ and DOE, what's the sense of

the committee?

Dr. Houle: If you are preparing a letter for the Secretary of HHS, you could also -- it could also be addressed to Secretary Duncan of the Education Department about this issue.

Ms. Singer: Really what we wanted to do here was just collect information for use in the letter, and we were told that we couldn't approach anyone in the Department of Justice or anyone in the Department of Education for the purpose of fact-gathering without the approval of the committee.

So that's really what we are asking now, is if we can go and meet with someone at DOJ, and get information about the AMBER alert, and if we can go and meet with someone at the Department of Education, and get information about whether these guidelines maybe already exist and we are unaware of them, or maybe it's an issue of implementation, we don't even know.

So this is really for the purpose of fact-gathering.

Dr. Houle: Okay, well, I --

Ms. Singer: We wouldn't meet with the Secretary, we would meet with the administrative person or staff person who could give us information.

Dr. Houle: Well, I think that there might be two assistant secretaries who possibly come to mind with having some information of this nature. One would be Kevin Jennings with the office of safe and drug-free schools and the other would be Alexa Posny, office of special ed and rehab services. Those are the two people that come to mind.

But I'm not, you know, I'm not entirely sure, this is not my area of expertise, I don't know whether states have guidelines for school districts, that's something I don't know.

It would have been a good question to ask Bill East when he was here, the director of the NASDSE, National Association of State Directors of Special Ed, because he probably has -- would have the best reading on that of anybody.

And so that may be somebody you want to consult as well in your work that you are doing.

Dr. Insel: So what's the sense of the committee about having the subcommittee consult with these others? Ari?

Mr. Ne'eman: At the risk of volunteering others, I think it might be a good idea to have both the safety and the Services Subcommittee chairs at these meetings given that there seems to be an intersection with both issues being discussed.

Dr. Insel: Any concern about members of the committee approaching DOJ or DOE? Okay. And if so, we are talking about Alison, Lyn and anybody else who would be interested?

Ms. Blackwell: I think Ari just

volunteered me and Lee.

Dr. Insel: Or Sharon.

Ms. Blackwell: Sharon?

Ms. Lewis: Yes, I am happy to volunteer.

Ms. Blackwell: Is Lee still on the line?

Mr. Grossman: Yes, I am here.

Dr. Insel: Okay. What else do you need from us? Okay, we will hear more from you in January. Right, it's moving along. Services subcommittee. Quick update. Ellen.

Ms. Blackwell: So, Lee, I know that Lee is with us too, so I may defer to you. Lee is that okay?

Mr. Grossman: Yes, but I'm limited and there's going to be some background noise.

Ms. Blackwell: Okay. Well, we had our Services Subcommittee, our first workshop -- we can talk about the potential second workshop in just a moment -- here on November 8. It was here in Rockville.

I have to say that this was a wonderful meeting. For those of you who weren't there, I would strongly -- and for the folks out in the hinterlands over the web -- I would strongly urge you to use these links to access the workshop slides.

If you want to sit through the Videocast, you can do that too, but I have -- you can see, just from the slides, these are double-sided. This was a really intense meeting, a long day and we took a look at a lot of very important topics which I will go through also very quickly.

The point of the meeting was to inform some recommendations for Secretary Sebelius, which we are still negotiating a time line for those recommendations, probably early 2011.

We wanted to talk to the committee today about the possibility of having a second meeting to look at some of the topics that are remaining after this first meeting.

The introductory session, as Gail just mentioned, included Bill East, who leads the nation's state special education directors; Nancy Thaler, who is the Executive Director of NASDDDS, the developmental disabilities director; followed by Charlie Lakin, who gave us a wealth of information about what is happening in the home- and community-based services arena, and generally what is happening to people with disabilities across the United States, especially in this current fiscal environment.

The subcommittee did have a meeting subsequent to this November 8 meeting where we talked about some potential recommendations, and I can tell you that just based on this first session, we might make a recommendation related to additional research on family support services.

But again, we have to meet again to talk a little bit more about what the substance of those recommendations will be.

The second presentation was Mike Head. Some of you may know Mike. He has been around the mental health arena for a long time. He leads the Michigan Mental Health and Substance Abuse Administration and Mike and Jim Conroy talked a lot about self-direction and self-determination and how we can wrap those concepts into all programs for people with disabilities.

So my guess is that we might want to make a recommendation surrounding self-direction and self-determination.

The third presentation, very interesting, Don Clintsman -- as Henry will attest, Washington state is one of the few states that has developed a universal assessment type tool that serves many populations.

So Don went through kind of a broad overview, but this is a very interesting tool, caused the state to really look very closely at how they are assessing people, and to do it in a much fairer way that is really based on needs not on diagnosis and it sort of equalized the playing field, not just for the people being assessed, but also in terms of giving the state legislature accurate predictions about what costs could be forecasted.

So I thought he did a great job and that really supported a potential recommendation for standardized assessment in Federal programs.

The next presentation, wonderful, Kevin Ann Huckshorn, Larke and Sharon are very familiar with Kevin Ann. Just spoke very movingly about how to prevent and ultimately eliminate seclusion and restraint in all settings, community settings, institutional settings. She just did a fantastic job and I think that again, her presentation would probably support a recommendation to significantly reduce and potentially eliminate seclusion and restraint.

So again, this draws a strong link between the efforts of the Safety Subcommittee and the Services Subcommittee.

We also, our next presentation was from Carrie Blakeway from the Lewin Group, she is actually a consultant that works for CMS on direct service work force issues, and Erica Robbins who is head of the Money Follows the Person demonstration in the state of Ohio.

And Carrie and Erika talked a little bit about the need to create incentives for states that offer quality training programs, how to strengthen labor and work force partnerships and adopt cross-program population training approaches for all people with disabilities.

The next program, a joint presentation from Sheldon Wheeler, who did a wonderful job explaining a transitional housing program that the state of Maine sponsors. This is done with state funding, primarily targeted to people with mental health needs.

And Joe Wykowski from Community Vision, Joe talked a lot about what happens when people actually get into their own homes, and I think Sheldon certainly made a pretty good case that supporting mechanisms to enhance housing support options for people with autism and developmental disabilities, including perhaps a demonstration that would support temporary housing assistance could come out of this presentation, but if you look at Sheldon's slides you will certainly see a strong case for the cost-effectiveness involved in providing people with housing.

Our next presentation, this was a really good presentation also, Lisa Crabtree from Towson talked about the center there, it's a university center that provides mostly social supports for people, adults with autism who are students of the university and others who live in the Maryland area.

Jim Sinclair who funded Autism

Network International, a passionate advocate, self-advocate, and Julie LaBerge, from the Wisconsin Bonduel School District, I always pronounce it wrong so I apologize to Julie if she is listening.

But Julie, who has two children with autism, talked about her on-the-ground efforts to create peer-support programs in elementary, middle and high schools in Wisconsin and just sort of a grassroots effort. I thought it was very interesting.

So I'm sure we might want to hone in on making some sort of recommendation to support peer-support programs for all people with autism.

Our last presenter, John Martin, what a dynamic guy. John is presently the director of the Ohio State Department of Developmental Disabilities, a real visionary.

And John talked a lot about systems integration and how states can better integrate multiple community-based support programs and John and Nancy Thaler also sort of honed in on the need to further explore and perhaps expand the Federal role in ID/DD autism services issues.

So again, if you weren't able to hear these programs, I hope you will at least take a look at the slides, because they are fantastic and really offer up a wealth of information on services issues.

Larke Huang, who is not with us today, told me this was just the best meeting she had heard in years. So I think that speaks a lot to the quality of our speakers and their preparation.

So one thing that the Services Subcommittee wanted to ask today is if the committee would be willing to consider a second meeting, perhaps in spring of next year, to address some of the issues that we didn't get to. Although we had a really full day, we couldn't get to all of these, and this is just sort of what Denise calls our parking lot list of issues and I'll just go through them up here very quickly.

You can see that it is a long list and it does include again, some of these safety issues: wandering, early warning systems, emergency preparedness, so there is this overlap between the two subcommittees.

So Lee, do you have anything to add? I know you are on the phone here.

Mr. Grossman: Yes, I think the day went really well. There was quite a bit of information to take in and I was happy to see how forward-thinking many of our speakers were. There were great models that were presented. I sent the information that was presented to many, many people for them to start thinking about how they will develop their programs and their services.

I think it's important for us to continue the dialogue and have this next workshop. We do have enough information now, that was already discussed at the Services

Subcommittee, about specific recommendations to the Secretary and I believe we are meeting in January if I am not mistaken to put pen to paper on most of that, and then be able to present -- though I'm not sure if we'll make it for the January IACC meeting -- but to present those recommendations.

Because I think that it is imperative for us to start coming forward with recommendations regarding services to the Secretary and we shouldn't wait until yet another workshop.

The committee may have other, the Services Subcommittee may have other recommendations that they want to include in addition to what came out of this first workshop, and I think that we should be very open to that as well.

With that, I'll stop my presentation.

Dr. Insel: Well thanks and congratulations to both of you. You have done a terrific job in pulling this meeting together. I also heard just great praise for the quality of the meeting, the speakers who were there, but also, especially Ellen, your ability to kind of keep this all focused, so that was great.

Comments from the group or suggestions? They have now a request to the full committee about whether to do another meeting. I'm amazed that you are already wanting -- maybe you are hoping Sharon will do it. I'm not sure.

But the question in front of us is whether there should be another Services Subcommittee meeting and if it's going to be in the spring of 2011, you would need to start planning it right now.

Ms. Resnik: This is Denise and if I could offer a few comments and observations, and first to Ellen and to Lee, thank you very much for your leadership and energy behind putting the conference together.

One of the comments that I have made repeatedly, as it relates to the recommendations for services and public policy, has been more speaking to process in terms of how we go about prioritizing the many recommendations that are being evaluated right now, beyond the speakers that were heard during the workshop.

Plus, while we did hear some creative approaches, I do believe that there are some other innovative approaches that do not rely solely on the private -- the public sector as we saw in many presentations, the cliff of increased demand and fewer and fewer resources.

So I'd like to appeal to Ellen and Lee and this committee and maybe the Services Subcommittee, identify process for how we go about selecting the future speakers and those on our parking lot, if you would and other topics, as well as how we go about prioritizing what's next as it relates to the public policy and where we focus our energies.

It's not unlike what we have discussed most of the day in terms of the Strategic Plan. There are so many priorities in front of us and without some type of process or litmus test or benchmarking I think it's going to be very difficult to get where we want to go.

Dr. Insel: Alison?

Ms. Singer: I completely agree. I think the meeting that was held did a great job at really focusing in on the public sector, but at the end, I was really feeling like I wanted to hear about what was going on in the private sector. I think that if we look at the aging population of kids with autism, when more and more kids started to be diagnosed at two and three, it was parent organizations that got together to form schools.

And now, it's really parent-based organizations that are starting, as our kids get older and older, that are coming together to form, to work on the issue of housing, and it’s parent organizations that are coming together to focus on the issue of supported employment.

So I think if you are going to do another workshop, which I think would be a great idea, I would really encourage that the private sector have a little bit more focus and that some of the ideas that are bubbling up in a lot of these private sector initiatives come up more.

Dr. Insel: Great, Ari?

Mr. Grossman: This is Lee. I agree with what Denise and Alison have said. One of the key areas that I think Ellen and I want input from the Services Subcommittee, is how we are truly addressing this sense of urgency. I am not sure if this first workshop did that.

I walked away, kind of even though it was great information and it was great material and moves us forward, I'm not really sure if it got us to that point of really looking at what our priorities should be, and really moving forward in an urgent manner on what needs done, because next year is going to be a significant year in terms of services and supports for people with all disabilities concerning the fiscal situation that we are in.

Dr. Insel: So, Ari?

Mr. Ne'eman: I actually wouldn't agree that the next workshop should be primarily focused on the private sector and private pay systems. I have a couple of concerns. First, I don't know that this current workshop was exclusively focused on the public sector. The presentation on self-direction for example, a number of the presentations on research, one of the presentations on peer support included some non-profit sector work.

But second and more relevantly, the vast majority of services and supports and education for individuals both adults and children on the autism spectrum are publicly funded either through Medicaid or through special education funding or through any one of a number of other options and part of the reason for that is when we talk about private pay options, we are talking about very limited ability to scale up to reach the very extensive, unmet need that exists, and frankly, very often, serving a population that doesn't include individuals from low-income backgrounds or individuals from minority or urban poor or rural poor backgrounds.

So you know, I think if we are talking about where we are going to see the most likelihood of policy recommendations that's going to serve to improve the situation for individuals on the spectrum and our families, a strong public-sector focus is always going to be necessary.

Ms. Resnik: A point of clarification if I could and I'm sorry I'm not in the room to put my hand up, but what I'd like to clarify, Ari, is that oftentimes through the private sector and some private/public/non-profit collaborations, we can inform future public policy, based on replicability and scalability and also cost impact.

And that's where I feel that the private sector and some of the collaborations and some of these innovative collaborations may better inform what we might be able to do.

Mr. Ne'eman: And I do respect that. It's just the one issue I would raise is I think a lot of those situations that you are describing do still have substantial public sector components.

You look at some of the more innovative service-provision models that are coming out of Medicaid and some of the things in terms of the introduction of self-direction which Jim Conroy spoke about earlier, some of the things around supported employment and customized employment, that kind of innovation does happen and generally the role of the private sector in there with regards to disability services, very often is provider organizations that receive Medicaid reimbursements or that participate in the Social Security Administration ticket to work program or things of that nature.

I just feel like if we are talking about service provision that's going to make a meaningful impact on the vast majority of individuals on the spectrum and family members, we really can't focus in on private pay options.

Dr. Insel: Lyn.

Ms. Redwood: I just had a comment. Back last year when we were working on updates to the Strategic Plan, if you remember we had had workshops previously to update the Plan that were fairly extensive, and we decided instead we would have focused workshops and there were three opportunities that we discussed. One was the environment, one was treatment and then another was services. And at that particular meeting, several people spoke up. I know Cindy said that NIEHS was doing one on the environment. AS was doing one on treatment. So services was sort of selected by default, since we weren't doing a workshop on that.

So I would like to recommend that this go -- that the full committee think about this in terms of updating our Strategic Plan for next year, because that will be on our agenda the first of January, how we want to do that process, to talk then about where the gap areas are and what we would like to see this next year for workshops.

And I am just sort of wondering, since we have just had a services workshop, does the committee have a budget for workshops, are there a certain number that we can have a year, and what are some of the gap areas that we might want to consider since we have just done one on services. Are there other things that rise to the top of urgent needs that we might want to consider?

Dr. Insel: So I think what's happened here is they have given this parking lot of -- and we can go back a couple of slides where there is that list and it's pretty extensive. So I'm not sure that there's -- that's what Denis was talking about -- a setting of priorities for figuring out, of those eight or 10, maybe there are 12 potential topics, what would be the most important one to really stay focused on.

I think there are even more, is there one more slide? Maybe not. Okay. So, but still there's at least 10 or so topics up there. We are not going to, I don't think we are going to have time to conclude today which of those would be the right one, but this is again something we can take up in January and maybe have it circulated in the meantime, and people can think about it and come to the next meeting with a sense of where they think would be the most important place, if we are going to do an additional meeting, as you are suggesting Lyn.

Ms. Redwood: And to consider how that is going to help us update the Strategic Plan so, what are the areas that are really lacking in that, that we could use additional information.

Dr. Insel: So the only caveat I would think about with that is that since the Strategic Plan is specifically on research, we may want what we do in the services arena not to be so much research-oriented as thinking about policy or other issues that are important for changing what happens in the autism universe.

So this particular effort, for instance, was not linked to the Strategic Plan as much as to just hearing about what the needs were.

So there may be still an

opportunity to do that as well. But as you say, I think this is a reason why the whole committee should be involved in thinking about it.

Ms. Blackwell: And I think I have to add that this is a great discussion but, in the sense that we were going to be writing recommendations to the Secretary, we wanted to make recommendations that were within her purview.

So that was kind of where we went with talking about systems. Where would the Secretary be able to make changes that would impact the systems that serve people with developmental disabilities including autism?

So that was one reason why we started part 1 or, potentially, part 2 this way.

Dr. Insel: So we have got the slides from that meeting which as Ellen says, everyone should take a close look at. There was just tremendous accolades for what you have done.

We have got now a recommendation of 10 or so potential topics for an additional meeting. We'll leave those in the parking lot for now but let's plan to have people take a look at them. We'll discuss it again in January and come up with a theme. It'll probably get pushed off beyond spring because, by then it's going to be awfully late to do a spring 2011 meeting, but with the intention that we have an opportunity to do a follow up meeting of some sort.

We also have a question on the table about the Services Subcommittee and what its leadership will be like and we can revisit that as well with you.

Is there anything else before we go to the final agenda item which is the discussion about public comment?

Okay. We had two public comments. There's also a lot of written comment that is in your folders, which I hope you have taken a look at. We have reserved a little bit of time for you to either reflect back on comments of what we heard today or to add further discussion to anything that has happened. So, Coleen.

Dr. Boyle: I just had a quick question. Did we decide to table the introduction? I stepped out of the room.

Dr. Insel: No decision has been made but we have 15 minutes left and we will have to see how much discussion there is about this item on the agenda to see what kind of time we have left. Any further conversation about public comment?

Dr. Briggs: It seemed like both of the public comments revolved around services, so I would like to hear from the Services Subcommittee with regard to what their feelings are towards the public comments

Ms. Blackwell: I was even going to suggest in the interest of time that I could just talk to Idil but it is up to her.

Otherwise I can just respond to her comments, what would you prefer Tom?

Dr. Insel: Well there is one -- so she did raise this issue about Medicaid and mental health and autism. So mental health is covered and autism isn't.

Ms. Blackwell: Here's what I got. And I hope I didn't mash it up here. But Idil you talked about provider rates, and I just wanted to say that in Medicaid, I understand what you are saying, but states have to assure the Centers for Medicare and Medicaid Services that the rates that they pay to providers, which they set, are sufficient to serve numbers of people participating in the program.

So certainly the economy and other factors have resulted in states in some cases reducing provider rates, so we do watch closely to make sure that states are assuring us that people have access and that that is in fact true.

So that's simply the way that the program is set up but yes, some states have reduced provider rates, that is true.

As far as children accessing services, the early periodic screening diagnostic and treatment program, EPSDT should assure that children receive medically necessary Medicaid services. It's a pretty standard and generous set of services, whether they are in the approved state plan or not.

So if a child is denied a service, and he or she is a Medicaid participant, that child always has the right to appeal the service denial and -- we talked about appeals before, but children certainly do have access if they are Medicaid recipients to a rich array of services.

And then I think thirdly, you mentioned what Tom was echoing, that in Medicaid autism is not a mental health condition and I am a little bit confused by that because certainly autism is in the DSM-IV and the DSM-IV TR so again states in some cases decide what populations and in what programs who they are going to serve.

So again, because Medicaid is a state-based program, there could be differences in who is served and what diagnosis is served. So, but I have never heard that autism in Medicaid is not considered to be a mental disorder.

Dr. Insel: Ari?

Mr. Ne'eman: I am actually very glad that the issue of Medicaid providers and physicians was raised because it has certainly been the experience of many people within the Autistic Self-Advocacy Network and our chapters that this is a very big issue, that there are a lack of providers, that there is a scarcity of providers that take Medicaid.

And I recall a story from an email I received recently about an individual on the spectrum who is also a wheelchair user who discovered that the only doctor in his county

-- it was either a doctor or a dentist, I think it was a doctor -- in his county that took Medicaid did not have an accessible doctor's office and he couldn't file a complaint about the lack of accessibility because it was the only doctor in the county that took Medicaid.

So I mean I don't know to what degree the Secretary -- I suspect the Secretary doesn't actually have very much authority over this and that legislation may be needed to look more closely at this issue, but I think what this really shows is that the autism community at large needs to be more actively engaged in the general disability policy and general health policy discussions, because this issue around a lack of sufficient providers and a lack of sufficient physicians who take Medicaid, is not just an autism issue, it's even not just a disability issue, it's an issue that really all people who have substantial populations in low-income category and in diverse socioeconomic statuses face, and my hope would be that the autism community can form some coalitions to address this at the legislative level.

Dr. Insel: Other comments from what we heard? A lot of what we heard from JaLynn Prince was what we ended up talking about in the course of chapters 5, and 6, especially issues around housing, employment, education of first responders, a whole range of issues important for transition to adulthood.

Anything else to reflect back? Okay, we have got -- yes.

You may if you want to -- you have to come to the table and use the mic.

Ms. Prince: I'll sit. Thank you. Though we may be new perhaps we can help you with part of the discussion because of the research that we have done over the last three years, both in services and in safety.

If we can be of any assistance and help provide the labor that we have had to help with the shortfall with the economic funding, let us help you in that way if we can be a voice, and we are here and if there is any way that we can be of assistance to the committee with any of the research that we have done, we would like to make those services available to you as well. Thank you.

Dr. Insel: Just to clarify, so we is Madison House Foundation, which is --

Ms. Prince: We are Madison House Foundation.

Dr. Insel: Which is local here.

Ms. Prince: It's local but it's national. We have been using our microcosm in Montgomery County, so we -- look locally, act globally, and we have been brought into a lot of national conversations and we see a lot of wonderful service providers around the country that are doing innovative things and if we can help you with names of some of the innovative things that we have seen and the discussions that we have had with first responders and how that is a movement across the country but there needs to be an impetus.

This committee could be the impetus. It could be the voice that directs people and in a way gives more communities permission to do the things that they think they need to do but sometimes are afraid to do because it is a large commitment, but if they know that it is part of the national movement and moving toward helping a lot of people, your voice could be very important.

Dr. Insel: Okay. Thank you very much. And again as always, we appreciate getting input from those who come forth for public comment.

We have about 10 minutes left and in the spirit of using football metaphors all day, you might think it's time for a Hail Mary pass, but it's actually not going to be possible for us to do the introduction in this period of time.

There are two issues that still

remain to be done. One is the introduction. The other is an issue around ELSI that we decided to punt again, same metaphor, on earlier in the day because Alan wasn't here yet, and maybe in 10 minutes we could resolve that issue, which would put chapter 1 to bed.

So Alan, if I could put you on the spot, let me read you what we are dealing with in chapter 1 so you have a sense of --

Dr. Guttmacher: Is that the second full paragraph on page 2?

Dr. Insel: Page 3, conduct at least five studies of the ethical, legal -- do you see it? It's highlighted.

Dr. Guttmacher: Yes.

Dr. Insel: Here is the issue we talked about in the subcommittee and we decided just to wait until you were around to put us straight. Should these be independent studies? Should these be components of existing studies? Should we back up here and learn a little bit more about what the issues are? Is this the time to hold a meeting?

We really need some input on this issue because none of us have the experience.

Dr. Guttmacher: Right, and I think there are several contexts here and I think we probably can do this in 10 minutes. One of them and Tom and I talked briefly about this over lunch, is the question about are there studies that have already been done regarding other conditions that might be informative regarding autism.

There certainly are features of autism that create some distinctive, possibly unique, but at least distinctive issues but there are many that are quite thorny that have been explored before. That doesn't mean that there are concrete answers et cetera et cetera.

But before deciding perhaps what avenue to go down, it might be good to avail ourselves of those. What kinds of things am I talking about?

Well, for instance early in the document where we talk about gaps et cetera, and this is obviously to address those gaps, there have been research -- there's a fairly abundant research that has been done on other disorders in terms of questions for instance of prenatal diagnosis, which comes up here when one has a spectrum, literally and figuratively, of disorder that you are dealing with for instance.

And for instance, in terms of Down syndrome, there is certainly a spectrum of function, of quality of life et cetera et cetera, the experience by different individuals with Down's syndrome, that's something for which there has been prenatal genetic testing done for decades. It's something that has been examined for a lot of the ethical, legal and social implications, a lot of the questions about decision-making, other kinds of things have been looked at.

Now again I think the issues are

somewhat different, but that that example might be informative, as well as the question of course that whether it be prenatal testing or testing of newborns et cetera, that if one finds some kind of a genetic variation which seems to either confer risk for or even say that one will develop a specific development or health condition, again there is experience in this sort of question of genotype, phenotype correlation.

For instance cystic fibrosis, which is in some way sort of a textbook autosomal recessive, we know the genes involved, what are the -- how come we don't have very tight knowledge of genotype means, you have CF, if you have the variants that are associated.

Well in fact with cystic fibrosis, while there is one gene involved, obviously a much simpler story than the genetic implications in autism, even in that gene there have been well over 1,000 variations that have bee now seen.

And some of those variations, there is very clear evidence that they cause a certain severity of disease, the vast majority of the time if not all the time, but there are many others for which we don't have full knowledge of what they mean.

And again there is a lot of experience, sometimes in prenatal testing, very often in newborn testing, of what does it mean when you get these genetic variations discovered, they are really of indeterminate significance. They hint at potential problems but they certainly don't predict it for sure.

There's also experience in a number of conditions which again I think comes up within the autism spectrum, of the whole question of prenatal diagnosis particularly, but again, even diagnosed in the newborn period, for conditions where the impact of having the condition depends very much not simply upon the genes involved and maybe modifying genes, environment et cetera et cetera, but it depends who you ask.

And for a lot of things, for instance there was experience fairly early or several decades ago, starting when one could do prenatal diagnosis for certain "dwarfing conditions" where the assumption by much of the I think scientific community was that parents would avail themselves, parents who were particularly increased risk for having a child with a dwarfing condition, would avail themselves of prenatal diagnosis, or that the parents who did would do that with the idea that they had reached the decision that they would terminate a pregnancy if the pregnancy turned out to be affected.

Well, that is what some parents opted to do. There were other parents who opted, knowing that they had a significantly increased risk for having a child with a dwarfing condition, the same thing happened with some hearing conditions, because the parents themselves had those conditions, in fact their decision-making about prenatal diagnosis was their decision that they would want to make sure that their fetus had the condition which was theirs, that parents tend to want to have children who are like them, parents want to have children who are part of the same community they are part of, et cetera et cetera.

So anyway, there are a number of issues here that have some precedent, that have had some scholarly thinking about, that have had some studies that really looked to the individuals and families who are affected by these situations to see what kinds of things they are thinking about, decision-making, et cetera et cetera.

Now all that being said, the committee may still want to go forward. One of the things that Tom and I talked quickly about is you know I think what is particularly instructive for us would be to know, well, what isn't there known that would be particularly instructive, again potentially unique but at least distinctive, about autism.

There certainly are unresolved questions in these things I've talked about, but my guess is even if we do another study, they are going to be still unresolved, maybe equally unresolved.

But there may be some that haven't been looked at at all, or that are particularly important at this particular point so that one way to go would be to have perhaps some kind of a small meeting or conference where we bring in some of the folks that have been part of this earlier work for us to hear from them, gee, if we could be crisp about what are the questions we think are particularly important, whatever, that we could ask them well what do you think is known already from other situations that are applicable here?

What is known for instance in terms of prenatal diagnosis for fragile X syndrome?

That's even obviously closer. What does that tell us? Here are the things we are particularly thinking about, the community is particularly thinking about, et cetera.

Is there any research already which is on point for these or is that really where the need is? So I hope that's helpful.

Dr. Insel: Yes, I think that's very helpful orienting comments and I must say when we have talked about this, we hadn't actually focused in the subcommittee about how this is -- what has been done in other disorders and now that you mention it, we probably should have begun there to try to figure out actually what ground has been plowed already so that we didn't just begin funding studies to the same people who had already done the same studies in a closely related disorder.

Let me see what the sense of the group is about this and what we have here is a recommendation for five ancillary or dedicated studies, that's what we couldn't decide. You are suggesting that maybe before we go ahead with studies, we should take a moment and maybe more than a moment, take some time to actually find out what is out there and to bring in some of the experts to advise us about how best to do this.

Comments. Ari?

Mr. Ne'eman: So I think it seems, correct me if I'm wrong Alan, from your comments, that what we really need is a conference or convening of some kind to produce a document that is going to highlight next steps to really start a meaningful autism ELSI study.

It would seem to me though, and maybe this is one of the distinctions between short- and long-term objectives, that it would still be valuable to have an objective that looked specifically around those ELSI-related issues that we currently know there is an interest in, and we currently feel there is a need to explore, particularly as we pour a considerable amount of money and time and energy around all manners of genetic research that could have serious implications for some of these things.

So, I wonder if there might be some possibility of approaching this from both perspectives, to in the short term, prioritize getting together a meeting or convening on this topic, but in the long term really clearly communicate the need for the investment in studies of this nature, be they either ancillary or dedicated.

Dr. Insel: So what about taking that on as a proposal that for this 2011, we plan to convene a meeting, believe it or not we are going to be starting on the update of the Strategic Plan before you know it, and take whatever comes out of that meeting to create the next objective around this topic.

Mr. Ne'eman: So I wonder if we might take the approach we took with the safety recommendation which is to say to place a short-term objective saying exactly that and then to transfer our existing objective into a long-term one.

Dr. Insel: I just don't know what it would be. That's why, in that case I think the value of having a meeting is to educate us to really focus on what the salient question would be. We wouldn't lose any time, since if it is going to be a long term objective anyway, it would give us the change to pull together the best proposal for what it is we are recommending to the field.

But I hear your sense too of concern that this not be completely ignored. It's now 5 o'clock and we, by FACA standards, have got to close the meeting down. So, I do want to see if we can take this to a vote.

But if there are any critical comments before we do that. Coleen?

Dr. Boyle: I was just going to roll them together, just to say we will do a workshop with the objective to identify the long-term goals or something like that, so we don't forget it. That's all.

Dr. Insel: Della, do you want to make that a vote on what Coleen just recommended?

Dr. Hann: Okay, so what I heard was that the committee would, or the idea of convening a workshop in 2011, right? Convening a workshop in 2011 to study the ethical -- that examines the ethical, legal and social implications of autism research as well as other disorders so that you can learn -- I can't say it right now, how it's going to look, but you know, to learn them from other disorders as well to inform the -- what issues are most salient for ASD.

Dr. Insel: With a focus on long-term objectives, informing long-term objectives for the Plan. Okay.

Dr. Koroshetz: Primarily genetics and other diagnostics, that is what we are talking about, right?

Dr. Insel: Well I think at this point that seems to be where most of the ELSI questions are, although Alan was saying he doesn't like the term ELSI but yes, it seems like genetics is probably right now -- because there are people selling genetic tests for autism, we should get that. Ari?

Mr. Ne'eman: I just want to seek Alan's opinion just on this question of whether or not what we currently have is appropriate for a long-term research objective. I do feel that while obviously we are going to be needing to be identifying additional areas, it does seem to me to be fairly clear that the language we currently have around genetics and prenatal testing is an area in which there is a need for investment. So I'd be curious if Alan feels differently or if he agrees or -- I just want to tap your expertise.

Dr. Guttmacher: I think there is probably a need for investment, but I think we will invest most wisely if we are guided by a combination of a better understanding of exactly what is out there that is relevant and also what do we think is needed, so that, the kind of conference I would imagine would have both people who are experts in ELSI research and just parenthetically, the reason why I object to the term, I don't object to the concept, but in some ways it's a nice short-hand term and it has the advantages of a short-hand term, but it also has the disadvantages of a short-hand term, is that people lump everything under ELSI.

And ethical issues are different from legal issues often, which are different from social issues and a lot of times people throw other issues in that are neither ethical, legal nor social but et cetera et cetera.

So we would have to be clear about what we are talking about a little bit, but to see I think if we see, gee that has been done so let's not invest there, though somebody if we put out an RFA might want to take our investment, let's invest more wisely in certain areas where the key questions still lie.

Dr. Insel: Let's take this to a vote because the meeting is officially over and we need to draw this to a close. So Della?

Dr. Hann: Okay. Those in favor of the workshop language, with the idea of seeking out objectives, please raise your hands.

We have one, two, three, four, five, six, seven, eight, nine, 10, 11, 12. Anyone on the phone?

Apparently not. It carries.

Dr. Insel: Okay. Thanks very much and we still need to do the introduction. We will do that January 18. Fortunately there, there are no objectives, so that is just text that we can work through and I'm sure it will be very simple for us at that point.

Happy holidays to everybody coming up and we will see you in January. Thanks for sticking with us today.

(Whereupon, at 5:07 p.m., the committee adjourned)