U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

INTERAGENCY AUTISM COORDINATING COMMITTEE

FULL COMMITTEE CONFERENCE CALL

FRIDAY, DECEMBER 11, 2009

The conference call and webinar was held at 9:00 a.m., Thomas Insel, Chair, presiding.

PARTICIPANTS:

THOMAS R. INSEL, M.D., IACC Chair, National Institute of Mental Health

DELLA HANN, Ph.D., IACC Executive Secretary, Office of Autism Research Coordination, National Institute of Mental Health

SUSAN DANIELS, Ph.D., Office of Autism Research Coordination, National Institute of Mental Health

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

ELLEN W. BLACKWELL, M.S.W., Centers for Medicare and Medicaid Services

HENRY CLAYPOOL, U.S. Department of Health and Human Services, Office of Disability

JUDITH COOPER, Ph.D., National Institute on Deafness and Other Communication Disorders

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

PARTICIPANTS (continued):

DEBORAH HIRTZ, M.D., National Institute of Neurological Disorders and Stroke

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

JENNIFER JOHNSON, Ed.D., Administration for Children and Families

CHRISTINE McKEE, J.D.

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

CATHERINE RICE, Ph.D., National Center on Birth Defects and Developmental Disabilities

ALISON TEPPER SINGER, M.B.A., Autism Science Foundation

EDWIN TREVATHAN, M.D., M.P.H. National Center on Birth Defects and Developmental Disabilities

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

TABLE OF CONTENTS

Call to order and opening remarks
Dr. Thomas Insel......................4

Administrative Comments by
Dr. Thomas Insel......................4

Approval of November 10, 2009
IACC Full Committee Minutes 7

Review and Decisions for Updating the Strategic
Plan: Discussion and Votes
Chapter 7......................... .8
Chapter 2 30
Chapter 3 42
Chapter 4 55
Chapter 5 62
Chapter 6 81
Chapter 1 97

Closing comments 125

Adjournment 137

PROCEEDINGS

Dr. Insel: Those that are listening in we are just getting this process underway by starting roll call. This is Thomas Insel from NIH, the Chair of the IACC. I want to welcome everyone to this December 11th webinar and conference call to focus on the last part of this updating process for the research Strategic Plan. We'll start by taking a roll call. So let's go back through the list of who is on the phone call at this point.

Ed Trevathan at CDC – Cathy Rice is also on and when I need to leave for another meeting in a few minutes and she will sit in for me. Ellen Blackwell, CMS; Lyn Redwood, SafeMinds; Alison Singer, Autism Science Foundation; Peter van Dyck, HRSA; Christine McKee; Judith Cooper, NIDCD; Henry Claypool, Office of Disability; Deborah Hirtz, NINDS; Gail Houle, U.S. Department of Education.

Dr. Insel: We heard from Lee Grossman and Yvette Janvier and they will not be able to join us this morning but I want to thank the rest of you for taking the time out because it is a very busy time of the year to be able to help us on this last surge for the update of the Plan. A couple of announcements about the membership just to clarify – Susan Shurin, who was at the last couple of meetings representing NICHD, has been moved to NHLBI where she is serving as the Acting Director. She is no longer in the Child Health Institute. Alan Guttmacher, who came to the last meeting for the first time, representing Dr. Francis Collins, who is the Director at NIH, is replacing Dr. Shurin at the Child Health Institute so he’s the Acting Director. Dr. Collins has not yet appointed a replacement or nominated a replacement for his seat on the Committee but we expect that to happen certainly before the next meeting. Any other questions about roster membership? A few words about how we’re going to do this today – this is a little complicated since I can’t see you to call on people so I’m going to have to ask you to actively join in by letting us know when you have something to say and to be mindful that people are listening in and unless you identify yourselves they will not know who it is that is speaking so please start your comments by saying who you are. Also I want to remind you that you should have received by email not only a copy of the minutes and agenda but also public comments which hopefully you had a chance to look at because those are important for our discussion today. There is a final introductory comment – let me just remind you that when we met the last time we talked again about what the Plan is supposed to achieve and we turned to the original value statement when we talked about objectives that were following the acronym SMART, specific, measurable, achievable, realistic and time-bound, so today when we finish up this process looking at the objectives we want to make sure that we keep that acronym very much in perspective and we try to ensure that whatever it is we’re recommending for the research field that it follows each of those five provisions. With that as an introduction we've got quite a few things that we're going to get finished here in the next little while. Let's start with the minutes from our last meeting – these were distributed by email earlier in the week so I can accept questions or comments about the November 10th minutes from the full IACC Committee meeting.

Ms. Redwood: I noticed that on page 5 of the minutes next to the last paragraph that starts with Committee, the reference should be the 2004 Institute of Medicine report not 2007.

Dr. Insel: Alright, thank you – any other comments? Do I have a nomination to accept the minutes with that amendment?

Dr. Trevathan: Accept.

Dr. Insel: Second?

Dr. Walker: Second.

Dr. Insel: Without having to identify yourselves let's ask who approves of the minutes and who doesn't and then we can move on to all approving. (All approve.) We’re moving forward – thank you. Let’s go ahead to question 1 - we have Jennifer to take us through question 1. Anyone else for question 1? We’ll just move on to question 7 and we’ll have to return to 1 when someone is here that can take us through it. Question 7, I believe, Alison Singer, you were charged with pulling much of this together.

Ms. Singer: The idea for adding a section 7 really came out of the scientific workshop and it looked like to be we were going to be changing section 6 to focus more on issues of adults with autism spectrum disorder. There are a lot of items in section 6 that have to do with infrastructure and the workshop members also pointed out that there was infrastructure scattered throughout the other sections as well. So the suggestion was made to collect all of those infrastructure items and an additional infrastructure item that came up during the workshop and put them together into a section 7 which in keeping with the other chapter titles we organized into a question. Nowhere in the Plan had we accounted for the epidemiological work and other surveillance work. So this chapter is put together by myself, Cathy Rice, Ed Trevathan of the CDC, and Cathy and I focused on the surveillance and I really worked on just pulling out the infrastructure items in the other sections. The questions that we built this chapter around were the four bullet points of what infrastructures needed to be built to support this Plan and the second was how we can ensure that resources and data are shared to support the scientific research process. The third came up throughout the workshop which was dissemination and finding out how we can ensure it is being communicated to the public in a timely manner and finally how we can improve autism surveillance efforts. In this section we combined the What Do We Know with What Do We Need just because it’s not being focused on and with research objectives we combined those and talked about what we currently have and then we focused on the specific areas. The first thing we focused on was data sharing. I’m not sure how you want me to do this but I think everyone has it in front of them but I guess I can go through it.

Dr. Insel: Alison, if you can do that – I think everyone has seen this but we need to go over the general questions before we go into the weeds here. I have one to ask you about – we talked a little bit about workforce as an issue and it shows up I believe in one of your objectives that it’s not something that you focused on early in this chapter and is that something that we felt should be in part of this document or is that relevant to the Strategic Plan.

Ms. Blackwell: I noticed the comment on Page 4 and I think this would be an excellent space to (Inaudible)

Ms. Singer: The issue came up during the public comment portion of one of the scientific workshops and one had to do with workforce and one had to do with workforce related to research dissemination and, again, I think this is going to be one of those issues for this Strategic Plan is that we should try to focus on issues related to workforce development regarding researchers and dissemination of researchers and to make sure we talk about the need to develop a workforce for service delivery when we talk about services.

Ms. Blackwell: I totally agree with you but it might be helpful to have linkage to that on Page 8.

Dr. Insel: That was actually one place under What Do We Know that would be useful to capture in 2009 how many people are in training for autism research and whether there are specific training efforts either through federal agencies or through private foundations. I don’t know that anyone has tried to put that together. It would be interesting to capture the numbers as to who is in the autism workforce and what is the capacity to grow larger and how does the workforce that we have match with what we say we need in terms of some of the research goals of the Plan. I didn’t want to stop the discussion but that is meant to be a general recommendation that we can bring under the What Do We Know with those kinds of numbers.

Dr. van Dyck: I had a question on page 3 under surveillance. I think it would be nice to at least acknowledge the population-based survey somewhere there. It does talk about describing the population and it would be nice to have a population-based survey.

Dr. Trevathan: So you’re referring to a national survey on children’s health?

Dr. van Dyck: Right.

Dr. Trevathan: I think that is a good idea. I wonder if it would be worthwhile just specifically mentioning the national survey on children’s health not as being the whole answer regarding surveillance but as a nice collaborative across the agencies – I agree that would be a nice thing to add.

Dr. Hann: If you want to add that kind of information it would be very helpful if we could have a sentence or two describing that work or at least a reference for acquiring that information.

Dr. Trevathan: I’ll provide you a couple of sentences, Della.

Ms. Redwood: I had a quick question for Dr. van Dyck – would it be possible for the future to expand the questionnaire with regard to ASD. I noticed that there was a change from the data in 2004 and in the last draft you have the question of how many children don’t have an ASD diagnosis and there was 30 percent or so response that they no longer had a diagnosis it would be interesting to try to understand that response a little bit better so I’m wondering whether or not that questionnaire can be expanded, Dr. Van Dyck?

Dr. van Dyck: We’re considering that because we have the same interest.

Dr. Trevathan: I agree and that’s a good point, Lyn.

Dr. Insel: Are there any recommendations or changes other than the two we just heard up to the aspirational goals so that will take us through What Do We Know and What Do We Need? If there’s interest I can try to get some of the numbers on the workforce to add to this.

Ms. Redwood: I think that would be a nice addition, Dr. Insel.

Female Speaker: Talking about data-sharing, I thought it might be useful, instead of talking specifically about one grant, say the NIH-supported autism centers of excellence and recent ASD grant-related funding — I lost my train of thought — must include means for data sharing — because I think the point is just to say that data-sharing mechanisms are built into the new research.

Dr. Insel: Maybe I can clarify this. That actually isn’t the case – it’s just for the ARRA grants. The 68 million dollar effort which is so large but I think the point – and I wasn’t involved in writing this - specifying it this way is to stress that to make funding contingent upon plans in data sharing and since we've done it on such a large scale already it's time to now make sure there is a similar approach for NIH funding for autism research. Am I getting that correct? Is that the implication? Ellen, you had a comment about putting community in front of practice on line 14 and I'm not sure I understand that or is disseminated into community practice – I'm not sure what community practice means.

Ms. Blackwell: Some of the objectives, for example, there's one objective that we talk about moving in chapter 7 – on page 2 we want to be sure that we include people with autism. (Inaudible)

Ms. Redwood: About the insertion of community – if we do that we are missing medical practice and how this is to be translated into medical practice as well.

Ms. Blackwell: That's fine, Lyn.

Dr. Johnson: We need to not only improve the speed but I’m just wondering if that reference needs to be emphasized more on page 1. I don’t think it really gets to the issue that we brought up at the scientific workshop as to it always being applied by the practitioners. We need to better understand how to get the information out and it is utilized by the practitioners either in the community or the medical setting.

Dr. Insel: Can you recommend language that would improve on what we have here? It says here to improve the speed on which findings are disseminated and translated into practice.

Dr. Johnson: Do you want me to do that now or?

Dr. Insel: What is that not doing for you that you want to add?

Dr. Johnson: I think we often times use translated practice but I think that is getting to the issue of the provision of information to practitioners about the research findings and we need to understand the message for taking the research and translating that into practice.

Dr. Insel: If it makes you feel better page 4 has a whole section about it. I don’t know if you feel that it needs to moved up in the document but I read that introductory paragraph on page 1 as just keying up all the issues that are in the subsequent pages.

Dr. Johnson: That’s all that was meant to do is to have an introductory paragraph that mentions each of the upcoming sections. We could change translated into applied to.

Dr. Insel: So this is going to say ‘and rapidly’ – I like the term translated because it conveys the sense of what needs to take place.

Dr. Hann: Do we add the word ‘used’ – so we have disseminated, translated and used in practice?

Dr. Insel: I think it’s redundant. I don’t know how much time we want to spend on this but can we add ‘rapidly’ as Lyn is suggesting?

Ms. Redwood: It’s not only improving speed but that which is translated into practice.

Dr. Insel: I see.

Ms. Redwood: So improve the speed to which findings are disseminated and the extent to which findings are translated into practice.

Dr. Insel: We’re back on page 2 and, Ellen, you had a comment.

Ms. Blackwell: (Inaudible)

Dr. Insel: Is the word clinical better than patient?

Ms. Blackwell: We’ve got some projects that are not clinical. I would say personal information.

Dr. Insel: So just strike out patient and just say data bases that collect information and coordinate recruitment of people with ASD and their families. And, Ellen, you also wanted to take the term patient out of line 4 – what would that read? Programs that support contribution of data for recruitment, health care, education, social services and administrative data bases.

Other comments in this What Do We Know/What Do We Need section – anything else that people want to see edited, taken out, added in, or changed?

Dr. Trevathan: I think the one addition that we would suggest – it could either be at the bottom of page 3 or top of page 4 – is a statement regarding the importance of international autism surveillance activity and epidemiologic research so we can compare across countries which we do a little bit of that here already at CDC and I know most of the folks would consider the international activity helpful. So I would be happy to send, or Cathy can send, a sentence about that.

Dr. Insel: Any comments about that? Okay, anything else up to page 4, line 16 or anything else in the document that people would like to see edited, deleted, or added?

Ms. Blackwell: In the biomarker section on page 2 and at the bottom of page 3 it could be a little more positive. (Inaudible)

Dr. Insel: Any other comments?

Dr. Johnson: On page 4 the section on communication and dissemination – just going back to what I said earlier – one of the questions I have on this section is on line 6 – translating properly and appropriately to the public – is it data that we’re translating or the research findings. To me it would be the research findings that we would want to be translating into practice.

Dr. Insel: Comments? Discussion?

Ms. Blackwell: I agree with Jennifer and on the next line we would want to say communication channels need to be strengthened and add people with autism.

Dr. Johnson: I would agree with that and just to go back to line 6 – I think it would be better if we included in that sentence findings are communicated properly and appropriately to the public so that data can be better translated into practice as appropriate. What was meant by communication channels?

Ms. Singer: We simply meant different

modes of communication.

Dr. Johnson: I’m going back to the issue that came up at the scientific workshop that I don’t know how well we understand how practitioners receive information so that they can change their practice – so I don’t know if communication channels is referring to that or not and whether this section needs to make a comment about the need to better understand dissemination science essentially and what are the best practices to getting information to the field so that practices are spaced.

Dr. Insel: Is that something, Jennifer that you can add at the very end of that paragraph as more professionals become involved in autism research there is a need for organized input to provide guidance and expertise and a comment about the need for a science around the process of dissemination.

Dr. Johnson: Yes, I can do that.

Dr. Insel: Any other comments? In terms of What Do We Know, What Do We Need what would be the science for this, Ellen?

Ms. Blackwell: We had actually talked about moving the emerging practices to (inaudible)

Dr. Insel: I have some concerns about that and what I worry about is talking about a system for emerging practices we're lowering the bar for the kinds of recommendations we would be making. There may be a greater need here to ask for replication of findings rather than whatever it is people are doing without a scientific basis.

Ms. Blackwell: (inaudible)

Dr. Insel: It's there and we can visit that in a minute.

Dr. Birnbaum: I finally made it. Dr. Lawler just mentioned to me that there was a discussion about dissemination and I thought we needed to mention that dissemination and research findings in policy given that some of the research is being supported under the Plan is more in the arena of public health and implications for prevention. That’s not usually captured – we usually think about clinical practices.

Dr. Insel: Linda or Cindy – tell us where you would insert that so we would know how that would read.

Dr. Birnbaum: It came to mind on page 1 – I was trying to chime in but we didn’t have connection – so line 14. I have one other question and I apologize since I was late getting here – page 3 under surveillance – that first paragraph needs to be updated because the report has come out showing the prevalence may be as high as one in a hundred as opposed to one in fifty.

Dr. Trevathan: I think that would be fine because by the end of next week we should also have a more detailed comprehensive surveillance report from CDC published online and then there’s the publication from earlier so I think that would be fine to add.

Dr. Insel: Thank you for bringing this up

– this is actually the main reason we're doing this so we can respond to emerging findings. Ed, can we ask you to rewrite that paragraph to reflect the 2009 Pediatrics or actually the MMWR report that's out next week?

Dr. Trevathan: Yes, we'll go ahead and send that.

Dr. Insel: We need information from both the Pediatrics paper from September/October and a paragraph that can be up-to-date on current estimates.

Dr. Birnbaum: I have another comment on page 3; line 14-17, that sentence that starts "surveillance" is incredibly awkward. It took me about four reads to understand the data that was being referred to was the surveillance data. It's just the sentence is really awkward. Breaking it into two sentences makes it much clearer what we are trying to say.

Dr. Insel: Is that true – the surveillance promoted early identification?

Dr. Trevathan: I think it would be better to say the surveillance data can be used to promote early identification of children and can improve planning for health services. The surveillance activities themselves don’t improve outcomes but I think the data can so I think that needs to be clarified – I agree.

Dr. Insel: Can we get you to rewrite that?

Dr. Trevathan: Yes.

Dr. Insel: Is there anything else?

Dr. Birnbaum: I have one more and I apologize but on page 4 – it starts on line 8 and ends on line 11 – it would be necessary to identify and address the wide range of issues related to the diagnosis, assessment, communication of autism risk as well as the social and clinical impact of diagnosis on the person’s family. That’s kind of like an added on thought and I think again it should be a separate sentence.

Dr. Johnson: I agree with the comment and I kind of wondered what that sentence was doing in the paragraph. I understand it relates to communication dissemination but it seems to be a separate concept as to what is being discussed otherwise that paragraph is more to me about replication and getting information out to the field and this is dealing more with the ethical issue so I was wondering if it could be perhaps made a separate paragraph under the topic of communication and dissemination broken down into smaller sentences to address the various issues that are being identified in that sentence.

Ms. Singer: I think we have to leave some of it there because the point of the sentence is to indicate that there are ethical issues involved in risk communications.

Dr. Birnbaum: If that’s what you’re trying to communicate make the statement something like you just said – in other words the fact that this is an ethical statement and is a little buried and it’s just all kind of linked together is where it gets confusing so I would just separate it.

Ms. Singer: I’m fine with that – I just think it is important to mention that there are ethical issues here.

Dr. Insel: So you would bring together the first part and then move into the ethical issues at the end. Della, take us through this so we see where we are at.

Dr. Hann: On Page 1 of the Chapter – we modified the opening sentence – line 10 and I have on line 13 that it would read ‘data among researchers to which findings are disseminated and the extent to which findings are put into practice and policy’. That was the only change to page 1; Page 2, line 2, line 3 inserting people with ASD including family, line 4 removing other patient, in the section under biobanking – general comment that we could modify to make it more positive – for example, tissue banks cannot satisfy the demand just so they can be expanded to meet the demand would be an example of making a more positive tone; Page 3, paragraph beginning on 4 will be updated – Ed Trevathan and CDC will provide the updated information for that paragraph. Beginning line 14 – again this will be reworded by Ed and comments by the CDC to emphasize the data and that the data will potentially improve outcomes in both children and the families. In this area too Peter van Dyck will add information with regard to the National Survey on Children’s Health. The area beginning on line 19 which extends to the next page the inclusion of the sentence provided by Ed Trevathan on the importance of international and surveillance efforts. On Page 4, line 6 findings are communicated promptly and appropriately to the public so that research findings can better translated into practice as appropriate. Then the next sentence additional attention needs to be paid to improving the communication channels between scientists, practitioners, people with ASD and their families. The next sentence we are putting a period on line 11 after the word autism and striking the end and the sentence will then be moved to follow line 15 as a separate paragraph. Line 15 will be augmented also with the sentence to be crafted on the dissemination (Alison agreed to do this.) Also here before we go to aspirational goals I believe this is where you were going to insert data on workforce.

Dr. Insel: Let me get a sense of the community if that’s what we’re including or not.

Dr. Trevathan: I think having something on workforce as you described would be really very helpful.

Dr. Insel: I can tell you we have 29 fellowships and 25 cohorts on one training ground. Are there other kinds of numbers that are comparable from other sources? Does anyone have a sense of that?

Dr. Trevathan: Peter, I was wondering if HRSA’s programs fall into this category.

Dr. van Dyck: They might.

Dr. Insel: There’s a lot of interest in expanding this field very rapidly and we’ve got a huge number of objectives and we’re probably going to double them with these provisions so somebody has to ask who is going to do the work whether we have the right number and the right kinds of people doing it. Someplace in this Plan I think you have to address the workforce issue and if we also will be supporting more training so that in 2015 we will have the right number of people we need. So I don’t know if numbers like 29 fellowships and 25 cohorts is the right number or if we know what the right number is but I would suspect that one is too low. What I was suggesting is that we try to find a place in this overview of What Do We Know and What Do We Need to at least reflect on the problem of making sure we have the capacity to do the work we’re recommending on the rest of the Plan.

Dr. van Dyck: The Combating Autism Act does provide money for the programs which are training programs at 35 universities to train physicians, nurses, physical therapists, psychosocial people, social workers, etc. to better care for children with autism and other developmental disabilities.

Dr. Insel: Can we get a number of how many of those various professionals are being trained and what you think the numbers will be based on the current investment of how many we’ll have in 2012 or whatever the timeframe is for actually getting this done? What I’m trying to get at here is using this document to provide a clear picture of what’s happening now and then to use the objectives to provide a clear set of goals – measurable and suitable goals for what we want to be able to implement into the Plan. If we can get that from you I can draft a couple of sentences about what the current training environment is like and what’s being done at NIH and having access to other information we can get some of the other funders to provide their training efforts. Hopefully we can get that together before we get you the draft final document in January.

Dr. van Dyck: What page are we talking

about right now?

Dr. Insel: It’s not in there – that’s why I brought it up – looking at what’s missing in this overview because it just struck me that we ought to use this introductory section to lay out the landscape of what we now have.

Ms. Singer: I think it’s also going to be important because so much of the ARRA funding is focused on workforce and because $68 million is ARRA funding it’s going to be important if we want to continue to see those funds after the ARRA is done so I do think we need to collect that data.

Dr. Insel: There’s a huge question — those are two-year dollars.

Ms. Singer: If we’re going to get them again after the two years we’re going to have to show data.

Dr. Insel: And what happens to all of those people who are being supported in 2011 or are we just going to go off on a cliff here and not have an increase or drop in the number of people working in this area and this is the chance to put all of that information into the Plan. Okay, are we ready to vote on these comments that take us to Page 4, line 16? Can I get a motion to accept the changes that Della has spread out? (All accepted) We will make sure you have a chance to see the final because there will be many questions as to how it will be rewritten and I will turn this back over to Alison to take us through the rest of the Chapter.

Ms. Singer: After the short goal, I crafted a section for development and support structure of surveillance systems of autism research. I want to point out some administrative points here – what's different in this section from that of the other section is because the entire section is new. The lines that appear in blue track change are actually material that was brought over from other sections and lines that appear in plain black text are sections that are new. With regard to the research opportunities this is for items that have to do with infrastructure, databases, coordination, dissemination, all to enhance autism work – so on page 5 there are 7 items that we pulled from different areas of the Plan. You want to talk about that before I go on to the short term objectives?

Dr. Insel: Let’s see if there are any comments from the Committee about the items on Page 5.

Dr. Birnbaum: I’ve got an issue again. On Page 5 the 4th bullet – I don’t understand it. It was moved from somewhere else and as a toxicologist I read this and didn’t know what was being asked for.

Dr. Rice: I think this was moved and it was linking the administrative data bases that said education data or social services information that can help provide information on service utilization...

Dr. Insel: This is the one on toxicology. Can anyone clarify what the 4th bullet means to a toxicologist?

Dr. van Dyck: I think if we don’t know what it means, it shouldn’t be in there!

Dr. Birnbaum: The call is for the use of existing resources and the need for additional resources in toxicology to help understand mechanisms and possible prevention from environmental causes for example – that makes sense but I don’t think that is what it is saying here.

Dr. Insel: What you just described is already elsewhere in the Plan in another section so, Linda, just guessing here – I assume this is about infrastructure for toxicology and as a toxicologist at NIEHS who could help...

Dr. Birnbaum: No, for example, banks of tissues, specimen banks, clinical banks, availability of research facilities – that’s the kinds of things that I think of as resources – toxicology infrastructure resources unless we’re talking about additional training.

Dr. Insel: Can I recommend that unless

somebody knows that there’s a specific resource that we’re trying to see as a research opportunity that we strike this if it’s not adding information? We do have other sections to talk about databases and repositories.

Dr. Birnbaum: Cindy is saying she is wondering if this is in reference to GEI but I think we reference that elsewhere.

Dr. Insel: As I look at this again the previous bullet talks about clinical biological information and existing examples of high risk siblings but there’s no place here in terms of research resources that mentions existing samples which we have 11,000 DNA samples for example that might be a research opportunity for someone but it’s not mentioned in this from what I can tell. It just says use of existing clinical and biological resources to provide infrastructure for studying...

Dr. Birnbaum: That would be fine.

Ms. Redwood: I just had a quick question about this. Does NIEHS have resources for investigating synergy between toxicants?

Dr. Birnbaum: We are talking about the development of programs in that area but we don’t have the explicit resources to do it but we are talking about potentially developing a program for developing some approaches.

Ms. Redwood: Is that something we could add into that bullet? Would that be something important to mention?

Dr. Birnbaum: Well the topic for this area is related to the infrastructure. It does talk about forms of environmental risks so if we wanted to put something in that talks about environmental factors may be implicative or something like that – that’s a statement we could make.

Dr. Insel: This is a section of research opportunities. What do we have in hand that we can describe as a resource that people can use? Creating can certainly go under the objectives but this section should try and capture what currently exists.

Dr. Birnbaum: I think we’re talking about banks of different kinds. I think that’s what we’re getting at here.

Dr. Insel: So should we have a bullet here that again gives the number that talks about the autism tissue program that has a hundred brains, a repository that has 18,000 samples and up to 27,000, the international consortium of additional samples – these are all resources that people should know about rather than what we currently have which is vague and unclear to someone who would be in the field. Maybe we need a bullet that summarizes the current state of biological specimens that are available in December of 2009.

Dr. Birnbaum: I think that would be a better approach. These could be available for asking environmental questions. What we don’t have for environmental risk is good measures of why people’s exposures – we may have bio specimens but that doesn’t tell us what might have been their exposure earlier.

Dr. Insel: I wonder if that would actually relate to the next bullet which is the current population based studies where we have information on environmental risks that could be expanded. There are other studies that can become an opportunity.

Dr. Birnbaum: I totally agree with you. I really like the next bullet. I thought it was clear and very important and we could just expand it – say supplementary funding to the NIH National Children’s Studies and other longitudinal cohorts or something like that.

Dr. Insel: I think again if these are research opportunities then what you want to describe is what’s there that could be used – it wouldn’t be funding it would be the population based studies and maybe again in terms of helping the field we could provide a short list of what the National Children’s Study is actually the last in that line there are several others that are equivalent in that size and much further along.

Dr. Hann: I remain a little bit confused about what the Committee is asking for in modifying the bullet.

Dr. Birnbaum: We’re talking about maybe taking it out or listing some of the existing resources that might be available for the exploration of environmental risks.

Ms. Singer: What I heard was that bullet 4 was confusing but what was missing was an acknowledgement of existing database resources that could be used since this is the section on research opportunities.

Dr. Insel: What I had intended was to change bullet 4 to list the repositories that we now have so that we’ll have some place in the document that describes what’s available for anyone that wants to access that. They could be used for lots of things so I’m not sure you would want to constrain how we would use them. I think what you want to do here is to provide information about what’s been collected. I would list the current tissue banks that we know about, the current DNA banks that we know about which is the PGC and NIMH collection and any other banks that people can tell us about.

Dr. Hann: You could say use of existing clinical and biological resources such as and then list but that makes it sound like it’s not the entire universe.

Dr. Insel: And the subsequent bullet issue was to focus on the existing studies that could be again a foundation for additional research. We have a problem with the verbs all the way through here because these are more non-research opportunities but there’s action upon the opportunities which is what you want to have in the objectives so it seems to me that you want to state these as what exists out there that can be used for the objectives.

Ms. Singer: It would be best to use the exact same sub-headings in this chapter and I tried to do that to be consistent if not appropriate.

Dr. Insel: Or do some of the wordsmithing on this so at least the language is such that we use this section to provide the reader in the community with what the resources are that could be used in infrastructure.

Ms. Singer: So maybe we make it just research resources instead of opportunities.

Ms. Blackwell: I have a question about the 3rd bullet. When I read this I wonder if it is exactly in terms of the long term outcome or could it be in mortality.

Ms. Singer: I think what we meant to say is the outcomes of being diagnosed and not diagnosis as an outcome.

Dr. Insel: Is there anything else that we're leaving out as a major research resource that we should be thinking about? This includes the state of the state for purpose of looking at policies.

Dr. Birnbaum: I just have one question about the issue of major resources. For research resources one thing we need not only is samples from people without autism but we need animal models. We talk at one point about stem cells and that kind of opportunity of the development of stem cells from some of these banks but there are certain things that animal models would be very useful for. Is that something we should mention?

Dr. Insel: We cover that in some of the other parts of the Plan.

Dr. Birnbaum: I don’t know if it belongs here or not but I want to be sure that we don’t kind of let it slip.

Dr. Insel: What’s the sense of the group?

Dr. Birnbaum: There are animal models for treatment but not for environmental causes.

Dr. Insel: So you’re thinking of the mouse repository or what would be the infrastructure here?

Dr. Birnbaum: Development of availability of generically defined or you might just say development of infrastructure needs would be the availability of animal models for investigator use or something like that in order to study environmental triggers.

Dr. Insel: The word development – the verb says to me that is an objective and not a current research resource. We do have the mouse project, the rat libraries...

Dr. Birnbaum: Maybe we just want to refer to them.

Dr. Insel: That's a great idea to have a bullet that summarizes some of the animal research resources that have already been developed and we'll have to think about how to frame that but we should capture that because it does come up elsewhere. Anything else missing or anything else that you think should be moved?

Dr. Hann: Here's what I've heard – Page 4, line 18 to now say research resources as opposed to research opportunities; Page 5, 3rd bullet which begins on line 6 going down to line 9 delete the word diagnostic and replace it with health; the bullet that begins on line 10 will be rewritten to use of existing clinical and biological research resources such as and a listing of the various repositories would be provided there; the next bullet will be rewritten as well talking about the available longitudinal studies that could be used to examine environmental factors and diagnosis; the other two bullets were not modified and then we just talked about adding a bullet on the available resources for animal models.

Dr. Insel: Let me just add to your comments, Della that it seems the wording here needs to be shifted a bit to make it apparent that these are existing resources and in that regard it may be that the first two bullets can be merged because they may be talking about the same thing. And the next to the last one should just clarify that there are surveillance efforts that are tracking trends and those are our resources that can be used. Any other comments about this? Let’s get a motion. (All favor). We’ll move on to Page 6 at this point – short term objectives, Alison...

Ms. Singer: The objectives here that are in plain black text are new and the ones that are in track changes. The ones that are in black have not yet been discussed by this Committee so we need to go through them and really talk about whether they should be here at all – some were from the outcome of the workshop and some came from public comments made at the IACC meetings. The first one – current mechanisms to support the contribution of data for the National Database for Autism Research - That came from a presentation that we had at two IACC meetings ago – there's really no mechanism yet or incentive for other researchers who are receiving funding from other resources. We had discussed at that time that it might be beneficial to offer our supplemental funding to those researchers so that they could put that data into NDAR. That's the idea behind that objective.

Dr. Insel: Comments or questions?

Ms. Redwood: I have a question about including the IAN network in there. Is that a second database or a private database? I’m just curious whether we should be making the recommendation for private databases. There are several other data bases in the community.

Dr. Huerta: Let me just offer that the architecture of NDAR allows us to connect up with any major data resource and I’m not on the Committee but we might make this simply more generic and connect NDAR with other major data resources.

Ms. Redwood: I think that might be better.

Dr. Insel: In the spirit of what we said in the introduction to the Plan about having smart objectives that would be specific and measurable and achievable, can we make an objective to say link to do it...

Ms. Singer: The reason I used create mechanisms there is because what I think it is going to come down to is actually have a funding mechanism whereby there’s supplemental funding attached to grants that specifically supports having the researchers putting their data into

NDAR.

Dr. Huerta: There are two ways to add value to NDAR – one is to contribute data directly which that first part of the sentence refers to and then the second is for NDAR to lend existing data resources into a different activity but both of together those would provide users of NDAR access to more data. It could be create mechanisms to specifically support contribution of data activity to NDAR and to link NDAR with other existing data resources.

Dr. Insel: Comments?

Ms. Redwood: I think that sounds like a nice addition.

Ms. Singer: I think the reason we put it in there specifically was a sense to concern that was brought up at the workshop about recruitment participants across the board and in studies.

Dr. Insel: But it also could include many others. I’m still struggling with the verbiage of the sentence but if we’re trying to have a date for something and have a cost associated with it, it just seems that we agree to the mechanism here right now and be done with this one and what you really want to do is achieve the linkage and we should specify what we mean by that.

Ms. Singer: We could take provide funding to read researchers to support the contribution data.

Dr. Insel: Alison, if we had a way of making sure that data we’re contributing that we could have all our investigators providing their data without any additional costs and that being actually better or just as good?

Ms. Singer: What we raised at the meeting was the reason they don’t do it is because they don’t get money to do it. They estimated it at approximately $5,000 per grant for data loaded into NDAR and to me that seemed considering how much money they get an additional $5,000 makes the data more acceptable. Does that make sense?

Dr. Insel: Exactly. So what I’m pushing you to do is to make the final goal – what we’re asking for here the mechanism, not to get to the goals. If we were to say, for instance, 90% of all research would be linked to NDAR or something like that. I’m just concerned that we’re being too easy or soft on what it is we really want here because we want everything, not just the aces, we want just not the ARRA funding but we want support and hopefully not just by NIH but a whole community. We want them all to come into this repository and I’m just concerned that the language we have in here won’t accomplish that. Mike – do you want to suggest how best to specify this?

Dr. Huerta: The wording would solely support the contribution of data to NDAR and the linkage of significant ASD data resources to NDAR with the goal of having NDAR serve as the portal to all ASD research data.

Ms. Singer: What if you just said create mechanisms for 90% of research data to be contributed to NDAR? Combine your outcome.

Dr. Huerta: I think we should have outcomes that are actually something that we can control so if we’re talking about all ASD research, public and private, we can seemingly control the public part of that. We can’t control the privately funded data piece.

Ms. Singer: Why? You could offer funding mechanism of $5,000 – I mean we’re getting in the weeds here – but you could offer a funding mechanism of $5,000 to the researchers.

Dr. Hann: Just to jump in and try to come up with some wording – to create mechanisms such that 90% of ASD research data is either contributed to the National Data Base for Autism Research or that it is linked in some matter.

Dr. Huerta: I would say that 90% of data would be very hard to measure.

Dr. Insel: Mike, is there some reason that it is not 100% - are there some projects that you don’t want?

Dr. Huerta: This is someone that is funded to do research and even if they submit those data to an agreed data base – even if we are linked to agree there is no guarantee that we would have access to those data if Autism Speaks wants us to have access. My point here is basically we don’t have control over some of the research projects. Right now we are probably at 5% or something like that so 90 is a big number.

Dr. Insel: Della, we’ll wrestle on the wording for this.

Dr. Cindy Lawler: I’m just wondering whether the short term objective – most research is like on a 4- or 5-year timeframe – whether we’re really going to capture the majority of studies already underway or whether this would be a long term objective.

Dr. Huerta: If you’re talking about existing projects the subjects have been consented already.

Dr. Lawler: Maybe we can change the wording to make that clear.

Dr. Huerta: There are really no limits as to what can be done with existing projects.

Dr. Insel: Mike, if there were ARRA supplement for existing projects what would have to be done in 2010? Is it feasible?

Dr. Lawler: The 90% may not be feasible.

Dr. Huerta: The other thing is we’re not going to be getting the data – they have to collect the data first. We’re talking about many months and many years in some cases and if the incentive is for us to do extra work they weren’t planning to do to begin with then that’s not a huge incentive so for folks that want to show your data with us the money is kind of necessary but if folks are not interested in data then it’s something that doesn’t have any interest in the existing projects. We can build that into the language.

Dr. Insel: The rest of these are from other sections.

Ms. Singer: Number 2 is from Section 6. Number 3 was also brought over from another

Section – Section 6.

Dr. Insel: Can those three be blended in some way?

Ms. Singer: I think 2 and 3 may be able to be blended but based on the conversation that took place at the workshop there were many researchers that were present that said they would be happy to contribute their data specifically to NDAR if they just had that specific extra money. I don’t think we want to lose that because we’ve been talking about NDAR for the last five years and now we have an opportunity to put something in the Plan to try to rectify what is identified as a major hurdle so I would hate to see that get swallowed up.

Dr. Insel: So you want to keep that as a separate and high priority bullet with a short timeframe. What about the other two?

Dr. Birnbaum: I thought we were talking about 2 and 3?

Dr. Insel: Right, so the question is can they be blended into a single objective. Should we keep moving?

Ms. Singer: Okay Number 4 I’m going to defer to Cathy.

Dr. Rice: This was mainly speaking of surveillance data but other public data sets that could be utilized – for instance, the National Survey of Children’s Health, the National Health Survey do an excellent job as a model of taking these large data sets and making them available to the public. So this was really saying accelerating the use of the data sets as well if there are other data sets that could be developed into a data set, to accelerate that and the other portion was in terms of translating a current estimate of problems into a web tool where individuals could put in their local area and give an estimate of the range of problems to be expected in their area.

Dr. Insel: Cathy I don’t understand what a public data set is.

Dr. Rice: There’s a whole range of is it open access like the survey data are like restricted use as in something like the agreed data set is that a researcher can apply for a specific use so there’s a whole level in terms of being able to be used beyond just the individual set of those data.

Dr. Birnbaum: Cathy when you explained what you meant by this bullet it was fairly clear but the bullet isn’t clear at all. So I think the bullet needs to be rewritten to say what you want to say. Is that clear? In other words when we read this we really had to know what you were trying to get at – I mean you’re now talking about surveillance data and when I hear data sets it could be lots of things. So I think it needs to be rewritten to say what you want it to say.

Dr. Rice: I think the question for the Committee is should this be expanded beyond surveillance data sets in terms of from where I was coming from I was thinking particularly of the opportunity to move the surveillance data sets forward but are there additional data sets out there like the example that I mentioned that could be translated into whether it’s full open access to the data or restricted use for research. I think this definitely needs to be clarified to include those different levels but my question to the Committee is do you want to focus on surveillance or do you see the need to accelerate having other data sets available.

Dr. Lawler: I’m just wondering how those other data sets might be disseminated through NDAR. It seems that for most of the other kinds of data sets that I’m thinking about NDAR would be the ready mechanism for doing that.

Dr. Rice: I think for some data sets in the case of surveillance are those that require technical support if it’s used as a restricted access for researchers that may be more challenging to have it totally through NDAR but even getting it to NDAR has been a challenge for many programs that don’t have the capacity to do that translation and put it into NDAR. So it’s more of the capacity building and infrastructure to make that connection there.

Dr. Insel: Other comments from the Committee? Is there something that people want to include or think it’s a problem or does it make sense? There are two different things here, Cathy, right? We’re talking about the tool and that sounds like it is quite different from a restricted access data set.

Dr. Rice: They both go into expanding the use of data to the general public and to researchers but with different mechanisms for doing that.

Dr. Insel: How would you quantify this? How would you know when you’re doing it what the measures are here?

Dr. Rice: It could be possible to say having at least one data set that wasn’t previously public use to become public use.

Dr. Insel: How about just focusing on public estimator tool and making that a target the first three years so that people could know about it.

Dr. Rice: I would be glad to work on writing that if that’s what the Committee would like.

Dr. Insel: Again this is the infrastructure section so we’re looking at research finding but we’re looking at the resource that somebody is going to create and make available and that sounds like something you could wrap your arms around and can be achieved in a period of time like 2 years. Other comments or thoughts about this? We will move on to the next one which is the international network of biobanks.

Ms. Singer: The area in blue highlighting came from previously approved language in last draft, the second sentence is in blue but not highlighted came from question 2 and was approved as part of question 2 but then moved into this section. The idea here was to expand the network to include skin fibroblasts – that was a new technology that had emerged since the draft of the Strategic Plan.

Dr. Insel: Any comments or questions from the Committee about this? Many of us were at a retreat yesterday where this was one of the main topics around the state-of-the-art right now for induced stem cells and whether we’re at a point where we should have a national or a local repository for these. Interesting conversation in terms of the experts of the field that were not there in 2009, there are still lots of questions about the fidelity of cells across different sites and across different passages but the idea of thinking fibroblasts might make a lot of sense. The way this is worded is where science is right now. Linda – you were at that meeting as well. You might have some other thoughts.

Dr. Birnbaum: I think it was pretty clear that the induced stem cells were not identical to embryonic stem cells and we’re not positive what that exactly is going to mean. Isn’t that what you thought, Tom?

Dr. Insel: I think it’s very exciting. It’s more likely to be next year’s Nobel Prize but it’s still not clear how these cells can be used but it is very clear they are not embryonic stem cells. This bullet I wouldn’t change and I think it is only the question of whether it needs to be reworded. Okay, let’s go on.

Ms. Singer: Okay for the next two I’m going to ask Cathy to read them.

Dr. Rice: This is hopefully self-explanatory but taking again that we have several years of surveillance data on a particular cross-sectional age of 8 years of age, it would be helpful to move on to look at younger and older ages in addition to the peak prevalence age that we’re looking at – the index age of age 8. Although we do have an evaluation study to inform prevalence estimates by doing direct screening to indicate who is missed because there’s always a question of are there other individuals out in the community that aren’t being picked up by surveillance efforts as well as taking the data. For instance there have been several papers that have been published, for example, one on parental age that was utilizing the surveillance data. These data could be used to look at population levels that may be affected as well as indicate risks.

Dr. Insel: Do you want to put a date on this?

Dr. Rice: The challenge here is although this is in short term objectives this would be more of a long term as well and so in terms of specificity we could certainly identify numbers of studies to be done and then in the timeframe I would say this was more of a five- year goal so that still belongs in short term but to move to a long term would be a Committee decision.

Dr. Insel: I think what would help the Committee most would be if you would prioritize. Tell us what you think would be the most important to do in the first two years or let's say by 2012 and then we could move the rest of it to long term. I heard from the discussions of the Panel from the previous meetings we’ve had that there’s real interest in seeing these things get done and making them high priority. I just don’t know from the CDC’s perspective of how you would stage them and if you could help us with that maybe that would be the best way to break it up.

Dr. Rice: I will do that. The next objective is really – we, in particular and I know Autism Speaks has also been trying to facilitate research and surveillance efforts around the world but we get quite a bit of requests from folks that are not part of our ongoing surveillance network but would like to collect data and use the systems that they have and enhance those to collect better data in their local area to understand who is affected with autism. This is really providing a network to help collect data and are trying to help form our data and to have the infrastructure to provide those resources.

Dr. Trevathan: Let me sort of add simply to your eloquent description – one of the issues in that bullet is simply that the way that CDC funding comes is a large number of very categorical funding lines. We do not have the resources to do rapid response to requests for technical assistance to help people do prevalence estimates or analyze data outside of our sites because our autism prevalence surveillance funding is specific for atom. So this is really to allow us to do what people expect CDC to do is to respond to requests for technical assistance in these areas.

Dr. Insel: I'm a little confused, Ed – that doesn't sound like a network as much as a rapid response team.

Dr. Trevathan: It's an infrastructure.

Dr. Insel: So it's sort of an EIS for autism – is that…

Dr. Trevathan: No, EIS is a specific training program so EIS does not support autisms specifically. EIS is a training program.

Dr. Insel: I'm just thinking of a specific example – we get a report that there is a very high rate of autism among Somalis in Minneapolis or in some part of Minnesota – is this bullet in some way going to give us the infrastructure to respond to that rapidly?

Dr. Trevathan: Yes, that’s an example of the type. I think there might be some specific issues with that example that may not apply. We have to be asked by state and local authorities in other countries to go in and help but we do need more infrastructure resources – it’s really internal personnel to be able to respond to those requests.

Dr. Insel: So I guess the word that is hanging me up here is network which I think of as kind of a consortium.

Dr. Trevathan: I would say that you could just provide the infrastructure. That’s primarily personnel infrastructure.

Dr. Rice: I think the original idea was to combine both so for the great example that you mentioned. Minnesota’s Department of Health had contacted us because they were interested in establishing an ongoing surveillance system and we provided some information but it was a challenge to be able to go in and really, without implementing the full model that we have as our standard of surveillance, we could give them some information but in terms of their infrastructure helping provide the support and materials to have an ongoing system there were limits on that. So when the Somali concern came up they, one, didn't have a surveillance system in place so we did come in and provide the more specific technical assistance at that time but they needed another level of in depth. I see this as those levels of having the network to have people proactively able to collect the data that they need to inform ongoing issues and that also alerts people that when there is an emerging concern of a particular subgroup and then to be able to act more rapidly as Ed was talking about on a particular population or a particular concern that comes out of that.

Dr. Insel: So maybe you can help us with the wording – if you could just think of those examples they are of interest to the IACC and to the field to identify geographic cluster and to identify opportunities like that for the research agenda and to be able to move rapidly would be important. So if the two of you from CDC could just wrestle the words a little bit and give us a timeframe by which it would be set up that would be great.

Dr. Trevathan: We can do that and we're actually doing that while we're talking. We've already sent some stuff to Della.

Dr. Insel: Okay sounds good. Let's keep going here – what's the next one?

Ms. Singer: The next one was create funding mechanisms that encourage clinical findings – this came out of the workshop. Some of the comments were that there should be some sort of mechanism to speed the replication studies or something that is specifically focused on replication.

Dr. Johnson: I guess one question I would have related to that is if it’s rapid replication wouldn’t it have to be a separation to determine the quality of the research before you want to go and replicate it or would it be part of the replication of the research findings.

Dr. Insel: Alison, did you hear the question?

Ms. Singer: Yeah, that’s a good point – it could be either or both. I think the issue here was that there was some concern from the parent community and also the scientific community with regard to new findings particularly really interesting findings, but the need for them to be replicated before they could be translated into community practice.

Dr. Insel: Isn’t that something to build into the Chapter 4 around treatments?

Ms. Singer: This came out of the treatment panel.

Dr. Insel: So what is the infrastructure here other than money?

Ms. Singer: It could easily be moved into section 4.

Dr. Lawler: I think it’s also risk factor research too. If we have a risk factor that could lead to prevention effort it’s really important to try to get that finding replicated quickly and the existing mechanisms are so slow to do that and then someone else come in with a new application and get it reviewed. We really need to be able to move forward quickly on interesting and important hits that we get for in the risk factor domain and not just for treatment research.

Dr. Insel: So, Cindy, what would be the infrastructure that you would put in place for that?

Dr. Lawler: I think that would require some additional discussion because there’s review consideration – I think in the clinical arena we talked about having a network set aside for potentially very quickly a study to test for the kinds of things that risk factors are in sort of a consortium of existing epidemiological studies that are looking at risk factors that could have sort of easily add on or do secondary data analysis of a novel finding that wouldn’t require a new application and going forward for review.

Dr. Insel: So if you’re thinking about new grant mechanisms I would recommend that we leave that for the 3.0 version of this Plan because I just don’t see how we’re going to be able to make that actual, measurable, and accountable before January 19th. I’m just balking that infrastructure is a mechanism. I think it could be but at this point I think there are so many other needs around to passively do the research. I’m less worried, I guess, about the urgency of having rapid replication but we don’t have the original findings in front of us yet. I am asking the Committee whether this is one that we want to put the time and energy into now or this is something that might be back to where it came from or we talked about next year when it comes time to think about the findings that we have in 2010 and 2011.

Ms. Redwood: I noticed several times and I think we need to create some activity now. (Inaudible) I think we do need a separate process in place to be able to rapidly move forward and I hate to see it delegated to the version 3.0 because I think it is crucial.

Dr. Insel: Let me just clarify – if someone has a discovery in 2010 what’s the impediment to find the replication of that.

Dr. Lawler: I think it would depend on what studies that would accommodate adding a new environmental component and/or doing secondary data analysis or maybe some work up front for the harmonizing protocol.

Dr. Insel: Can we mute phones so we can all hear each other?

Dr. Lawler: I think there is some additional upfront work that would be important to make sure that those kinds of replication studies were possible and that could range from making sure that sort of the data collection protocol if they’re in existing studies harmonize and sort of would allow the kind of adding another environmental component or going back into a new data set and even knowledge of exactly what is being collected and tracking the kinds of risk factors looked at in different studies is really important and that could speed the ability so that if an interesting finding came up we would know where to go, what the capacity was, if we could do it at one site, whether we needed additional sites and so on. So I think there is some upfront work to put us in a good position to act quickly if we wanted to replicate a finding.

Dr. Insel: There’s the CNV finding in March of 2007 and it was replicated 4 times in 9 months. It’s hard for me to see where the impediments are for major findings to get replicated. Everybody jumps on them right away other than lack of funding. I don’t think the problem is mechanism – I think the problem is having transformed findings and when you look at not only the social variance people are actually doing this. Of all the things that we may need to focus on from where I'm sitting it sounds like this is the problem is more not having the initial findings than the need to have a mechanism to allow replication.

Dr. Lawler: You're talking a different set of problems when you're looking at replication of those kinds of findings. It's going to be much more difficult to do.

Dr. Hann: Part of the reason for the genetic findings is that we do have repositories now, people have access to the data and they can use it in a variety of different ways building on a resource that's been put into the field and as well as networking which has also been a strong thing in the genetic arena and if that is not happening to the level that people are wanting then that's the kind of infrastructure that needs to be set up. It's what we already have in here which are these kinds of repositories, etc. and then the programmatic efforts of networking across scientists.

Dr. Lawler: I agree with that but I think there’s a need for special emphasis review to look at some of these critical findings. I think that genetic studies are rapidly generated. There’s a lot of important research out there that has not been replicated so I think there is a need for special emphasis.

Dr. Insel: It’s often difficult to know when something isn’t replicated, whether people have tried and failed to find it and then decide to not to publish or maybe can’t get published negative data and sometimes whether there’s just a lack of resources. That’s why I was asking what the impediment is – whether the impediment is a mechanism for funding or the impediment is as Della is suggesting – the actual access to resources – having repositories, having networks and the case that you described, having tissue available. Is that the appropriate fix to having different kinds of mechanisms? I think that we need to keep moving on. I think there’s interest in keeping this in some form but we will run out of time so let’s move on through this.

Ms. Singer: The next is to evaluate the ethical and legal considerations of projects which enable the sharing of data for research purposes. I don’t remember who submitted this one. I don’t recall the background on this.

Dr. Insel: Anyone on the phone that has energy behind this? Is this one that we can remove?

Ms. Singer: The next one was to convene a workshop to advance our understanding of subtypes and treatment personalization.

Dr. Birnbaum: I don’t think that this belongs here – not that there’s anything wrong with convening a workshop but I don’t think this is where it belongs.

Ms. Singer: I think this one came from the discussion at the scientific workshop about the personalization of medicine and NIH’s movement towards personalization combined with public comment focused on a lack of agreement in the community as to what the core symptoms were that were being targeted for treatment and whether we could provide additional quality to the scientific community by having a conference where those issues were discussed and what we were able to do at the scientific workshop.

Dr. Lawler: I think it is a great initiative but, I agree, I don’t think it belongs here. It should go to the Treatment section.

Dr. Insel: I thought in reading it that it could be one of the short term objectives in Chapter 4 to bring people together. Any other comments about that? Moving on to the next one...

Ms. Singer: The next one was from Ellen – conduct follow up in young adulthood to understand transition experiences in current life. Ellen you can go through the next two.

Ms. Blackwell: Actually I wasn’t quite sure – I was looking at the portion of the discussion we had in Chapter 6.

Dr. Insel: Can we delete that top bullet on page 8? Okay, just go on to the next one.

Ms. Blackwell: (Inaudible)

Dr. Johnson: One question I have is that we’re talking about the research work, right? It might be helpful to say in the first part of the sentence whether its workforce research training and I agree with the part about interdisciplinary and any work in this area is done to promote research work.

Dr. Insel: Again do we want to put timeframes in here? How many people do we want to have in training?

Dr. Johnson: I think you mentioned earlier that there is data on the current number of people so maybe use that as a baseline.

Dr. Insel: Can we get a sense from the Committee about whether this should be increased 50%, double, or what’s the sense you have?

Dr. Johnson: I think if you’re talking about increasing the number of research scientists I think you need to know how long it takes to develop a researcher so I would suggest keeping the number somewhat low because, again, it’s going to take time to develop a researcher. I think that has to be taken into consideration.

Dr. Insel: Anyone on the Committee want to weigh in on how to make this quantifiable? Okay, let’s move on.

Ms. Singer: The next one actually came up from David Mandell’s presentation with regard to including something about dissemination of the actual application for funding.

Dr. Insel: Questions or comments from the group?

Dr. Johnson: This one revolved around the questions about better dissemination and application of research findings. As I stated before I think we just to strengthen this bullet and address our needs to better understand how research findings are better applied in practice - and how it increases the likelihood that they will be adopted.

Dr. Lawler: It’s not just practice – it’s sort of policy and public awareness with respect to risk factor issues. It’s not just dissemination to clinicians and issues surrounding treatment options – it’s really a broader need to responsibly communicate findings to a range of audiences depending upon the focus of the research grants.

Dr. Insel: How should we handle this for basic science proposals for somebody that wants to develop the structure of a symmetric protein that’s been implicated in ASD?

Dr. Johnson: I wonder if it’s necessary to the responsibility of the researcher to figure out the dissemination or if it’s another entity that works on how you take that research finding and take it to the target whether it’s the policy maker or whether it’s somebody in public health or it’s a practice measure in the field.

And that’s why I questioned having something that’s part of a plan for a research study and if it’s the responsibility of the researcher or if it’s the responsibility of some other entity to translate the research and figure out the best methods for that translation.

Dr. Insel: Are there any thoughts about this? Anybody want to give us how you measure and what the timeframe might be?

Dr. Birnbaum: I think it really depends – I would like to say that in basic research you should be exempt but we all know that there are samples that individuals are doing. They have a high impact finding and get interviewed at the end of it and then the first question is what does this mean for an individual affected with autism. Does this mean that it was cause by x, y or z? Does this mean I should change x, y or z? What does it mean and does having a responsible dissemination plan is there some upfront thought about the implications of resource. It will be – even the basic findings

– they are going to be translated for better or worse more or less effectively.

Dr. Insel: So you think a basic scientist who has been working on cancer would be brought into the autism field – would this be a plus or a minus knowing that you only have 12 pages on the application for describing a dissemination plan?

Dr. Birnbaum: I don’t know. I agree that in some cases it would be a plus because it allows you to ask for some support for the kind of dissemination efforts that might be appropriate – it’s more of an epidemiology study for an example. Again, I hesitate to just assume that we don’t need to think about it for the basic science finding.

Dr. Insel: I guess I’m asking what an investigator would leave out to be able to include a paragraph on dissemination which may be required for grants and any other part of medicine that would be specific to autism. I’m just trying to make sure the Committee thinks about the consequences. We just said we would increase the workforce and now we’re asking them to do something they don’t have to do – doing cancer research or heart disease research.

Dr. Birnbaum: At least in our field talking about environmental issues and some things which are very contentious we often require people to do that because we know that if they find something with chemicals – like something on the news today, BPA – they’re going to get calls and they’re going to say does this mean I need to throw out my baby bottles. I’m not sure it’s inappropriate. I don’t think we need a detailed plan but maybe like a statement that will alert the project officer and work with them to develop an appropriate strategy or something like that because I think with the visibility of autism research and the concern in the community this would be a very proactive thing for us to do.

Dr. Johnson: I think one of the things that other fields do to assist with dissemination of research to practice is clearing house– and I don’t know if that is appropriate here – but if it would be appropriate in terms of infrastructure support to have something like a clearing house.

Dr. Birnbaum: If somebody is going to go to a meeting and they’re going to give a talk and the press are going to pick up on it and it may not even be final results at that point. I think when you’re dealing with stuff that is very topical it helps to know how to be sure that the right people are going to know about it.

Dr. Insel: What happens with an investigator who doesn’t want to do this? Would you exclude a scientist who says she’s not interested in disseminating the structure of scientific publication?

Dr. Birnbaum: Nobody is talking about disseminating the information other than the scientific publication.

Dr. Insel: How do you do it for an

unsolicited grant? How do you put in a requirement for a specific area of research that doesn’t exist across other areas of research? What are the unintended consequences of doing something like that?

Dr. Lawler: I hear you, Tom. Maybe we need to think about it some more. Maybe there are other ways to do it – you can put out something like interested in this. I guess you’re just thinking about basic science and I guess the answer is if they’re not even thinking about a relationship to autism and they ask about it there’s nothing we can do about that. But if someone writes a grant where they talk about the impact of their findings and they have an understanding of autism those people should be willing and ready and educated to know how to disseminate. One of the recommendations that came out of the Autism Risk Communication Workshop that a lot of the NIH Institute supported last October was the need for some sort of web based tool box that would provide tools and resources for researchers to kind of understand what might be useful when they think about how to responsibly disseminate the research so that may be part of what’s needed here especially for researchers who are unfamiliar with that piece.

Dr. Insel: Cindy, you used the term toolbox and to me that’s infrastructure. That’s a creative resource that would be used by the whole community and it seems to me that would be a little more to the point of what we are trying to do in this Chapter.

Dr. Lawler: Right – one piece of that tool box you could build into a dissemination piece or a research project but the tool box itself would be much broader. There are a wide range of activities that you could vision being discussed or links or resources as part of the tool box.

Dr. Insel: Linda or Jennifer – does that help in this regard or is that not sufficient?

Dr. Birnbaum: I think what Cindy is saying is appropriate and I’m fine with that.

Dr. Johnson: The only thing I wanted to mention is in terms of practitioners – I’m talking about teachers in the field. I think we might want to consider the dissemination vehicle that they’re used to using and whether the tool box is going to include those kinds of people who obviously we want to target in terms of understanding the research findings in their practice.

Dr. Insel: So in thinking about the tool box which would have broad application. Okay, let’s move on because we’re going to be running out of time here. The next bullet is on the top 20 – Research Advances.

Ms. Singer: This is already required by law under the Autism Act and I included it because it was submitted.

Dr. Insel: Do people feel okay about just using the Advances to do this instead of creating a separate list.

Dr. Birnbaum: I think it’s appropriate

that this should be done by the Committee.

Ms. Blackwell: (Inaudible)

Ms. Birnbaum: I support that because some of us have different visions about this and everyone should have an opportunity to put input into that.

Ms. Singer: Alison was saying that we're already doing a similar advance each year that's linked to the Strategic Plan and that's required by law and we send that in from the entire IACC to review that. The question is whether to do something other than that but – Autism Speaks does a top 10 – is there value in doing something similar to the top 20 beyond our Summary of Advances?

Dr. Birnbaum: Would that mean it was written in more lay language or talking about implications or both?

Dr. Rice: I think that means more lay language than what the top 10 indicates in Autism Speaks that Tom mentioned. I think this is covered by the Summary of Research Advances and the only way that I can see that it can be included is if a goal was added to set a date. For instance this year’s came out in August of 2009 for 2008 so it would be nice if that could be accelerated and redone earlier in the year. Easier said than done but I think that’s what would push this forward to be a useful document for the community and other researchers to have an earlier date.

Dr. Insel: So if we were to use the Summary of Advances to accelerate can we drop this item and move on? Any concerns about that?

Dr. Birnbaum: I’m okay with that but I think sometimes like a simple list like that comes out in Time Magazine – the top 10 people of the year or whatever – that hits hard and people use it.

Ms. Singer: I think the IACC can really determine how to do the Summary of Advances which are required by law. I’m just not sure it needs to be included in this Plan.

Dr. Insel: Okay – do we have a long term objective?

Ms. Singer: We have a long term objective because there was a long term objective in the existing Plan. My recommendation is to combine the short term and long term objectives in the Infrastructure section. This long term objective which previously was in 2 that talked about establishing the network of bio banks and then the other objective was to maintain them. I think if we combine long and short term objectives in this section we can just say establish and maintain.

Dr. Insel. Alison, it looks like that we can get to this much later. It doesn’t say anything about phenotype information. Is that understood or should there be a word that indicates phenotyping which is a critical piece for any biobanking.

Ms. Singer: I think it’s meant to include the phenotyping data.

Dr. Insel: Actually you’re right – it’s there and we don’t need to change it. So you will merge those two. Any questions about that? Let’s go through and see what we’ve got and see if we can finish up this Chapter.

Dr. Hann: First of all I’ve heard that we’re going to merge short term and long term so that beginning on page 6 line 3 would say short term and long term objectives. The first bullet would be reworded to something along the lines to create mechanisms such that 90% of research projects in ASD are contributed directly to NDAR or linked to NDAR through existing data bases by 2012. People are open to modifying the date and we can do that.

Dr. Insel: We need to have language in here that is really useable and really quickly – and if it can’t work until 2012 then we’ve got to find some other source to do that and if NDAR is not going to be it we’ll figure out another way but the Committee is telling us that they want this to happen yesterday. They want to have a central place where all the data from all the different sources related to autism to be accessible.

Dr. Trevathan: First of all we can’t force people to do this. And we’re looking largely at studies that will have to be done prospectively and people may not want to do that.

Dr. Insel: Why don’t we work out language that says that 90% of new projects will be dumping into NDAR and NDAR will link to existing projects to produce their data? We can do the ARRA supplement in 2010. You will help us with the wording so that the main thing is that it’s going to get done.

Dr. Hann: There were no changes to the second bullet. There were no changes to the third bullet. The fourth bullet on accelerate; Cathy Rice has agreed to do a redoing of that one – people with interest of a web tool potentially for the prevalence estimator. The next bullet is being merged with the very final bullet and it simply will be Establish and maintain an international network and that will occur over 5 years and the rest of the wording stands. On Page 7 the bullet that begins on line 6 – this also needs to be reworded with one component of it being short term essentially with a 2-year time span and the other part of it being long term essentially up to 5 years. The next bullet which begins on line 12 again Cathy Rice has agreed to help reword so that it will be kept. The bullet that begins on line 14 it was unclear to me what was happening with that bullet. This is the one on replication. We can come back and discuss that in a moment. Line 16 it was voted to get rid of that bullet. Line 18 – this bullet will actually be moved to Chapter 4. On page 8 the first bullet is deleted now. The second one is line 3 – essentially what I have is that it needs to be worked on to include information that we are going to gather about the current training of researchers and to also become an interdisciplinary for research scientists. The next bullet, number 5, I came up with a potential rewording to essentially develop a web-based tool box to assist researchers in developing their skills for effective dissemination or research findings to interested communities including families, people with ASD and practitioners. We've done away with the bullet about the top 20 Summary of Advances and then the final bullet was already merged with the prior one.

Dr. Insel: And to go back to line 14, the discussion we had here I think was most people on the Committee want to attain this in the way it is currently stated but add the word rapid to replication.

Dr. Hann: Is there a date?

Dr. Insel: Anybody want to weigh in on a date for line 14 and 15? I guess that's a job for OARC. Are there any comments about this Summary from Della?

Dr. Lawler: With regard to the date – how is as soon as possible?

Dr. Insel: Okay – so we'll rapidly put in place replication mechanisms. Any other questions, comments, anything else? Do we have a motion? (All in favor) Okay – we’re moving on to Chapter 1 or back to Chapter 1 and we’ll turn this over to Jennifer to take us through the red line down on page 5.

Dr. Johnson: The panel had discussions about the focus on this Chapter and whether it should be focused on early childhood issues across the age span and at the last IACC meeting we decided that the Chapter would be focused on early childhood. I also wanted to remind you that some of our feedback talked about issues related to the needs of people who come from cultural populations and also the issues of co-occurring conditions so those are some of the things that you’re going to see in the changes that we are going to discuss. Right below the red line – line 4, page 5 – you will see an additional bullet that addresses the ethnic origin population. Are there any comments or questions about that one?

Dr. Birnbaum: I just have one question on the second bullet. I was wondering whether we should say understanding...

Dr. Insel: I’m sorry, Linda, let’s just do the first one. Are there any issues with that?

Ms. Blackwell: I have a quick question. Is it just ethnic minorities or is it ethnic populations?

Dr. Johnson: I think it should be minority population.

Dr. Insel: So we’ll strike the word ethnic. Anything else on the first bullet? Moving on to the second bullet.

Dr. Birnbaum: I just wanted to add how diagnosis leads to intervention.

Dr. Insel: Did the panel see this as an important link or was it more finding a way to map the gaps between diagnosis and intervention?

Dr. Johnson: The issue is that often times we don’t necessarily know what happens after diagnosis and the extent to which services align with the findings from the assessment. So if both access and essentially the quality of services provide the needs and assessment of the child.

Dr. Insel: Anything that happens across diagnosis – when, where, how and whether, right?

Dr. Johnson: The question is whether it belongs in this Chapter and we kept it in there because one question that was raised and it could go on to services because we are talking about services at this point in time but there is a relationship between diagnosis and this services piece.

Dr. Insel: We could say research opportunity and you could argue that it should be here and be described as this whole space investigation and what happens following diagnosis. I’m not sure this bullet covers all of that but it’s a really important research question and we don’t know how much has to do with access and how much is – well, there’s a whole range of things that limits interventions post diagnosis. I wonder if it can be worded just so that the communities would see where the opportunity is here. The way it is stated it is now clear to me as an opportunity but I'll leave it to you to think about the best wording. Can we move on to the short term objectives?

Ms. Blackwell: I have one quick question about the aspirational goal.

Dr. Insel: I think we did that already so I'd rather not backtrack at this point. We can if we get finished in time but let's get moving so that we get everything finished.

Dr. Johnson: The next is line 11 and basically more specificity is recommended and looking at the research it can be done around training and diagnostic tools. Looking at types of training tools in terms of more broad based developmental screening tools versus more specifically related to autism and also to characteristics of autism disorders. You see that there are some age populations that are broken down in the sub-bullet list and, again, at the time when we were receiving feedback from the Committee by the panel we were talking about age issues but because we focused this Chapter on childhood we might want to eliminate those suggestions in terms of adolescents and adults.

Dr. Insel: Do you need any of that? You’ve already said our diversity in terms of age to economic status, etc. and general functioning. Couldn’t you just take out all of those sub-bullets?

Dr. Johnson: Yes, that would be good.

Dr. Birnbaum: I would support that because if you leave it in you’re missing some of the key age essentially. A three month infant may have very different susceptibility than a twelve month infant so I think just leaving all that out is good.

Dr. Hirtz: Can I go back to line 12 – I think the term broad band is not what’s used – it’s more screening tools for developmental disorders.

Dr. Daniels: At the last meeting you brought up that instead of broadband you wanted the term general.

Dr. Hirtz: Yeah, that’s better. Broad

band is just not a good term.

Dr. Insel: Anything else from Page 5? Moving on to Page 6, line 2.

Dr. Johnson: This one is getting into the dissemination and training that we had discussed previously. Again the focus is on populations of people who are culturally diverse and looking at their access to public services.

Dr. Insel: What would we do in what period of time at what cost to get this finished?

Dr. Johnson: One of the reasons is why children from diverse backgrounds tend not to be diagnosed at an earlier age than other children. Investigating whether that is part of it or do we need to look at training programs to understand how to train people to be more culturally competent and working with families – it could be a list of issues so maybe the research objective is looking at what are the reasons for the delay. Could it be access delay?

Dr. Insel: Again, we're going to want to keep this in the achievable and time bound form. If you're describing the problem as a health disparities problem let's say research to eliminate health disparities for people on the spectrum or to reduce health disparities by 50% by 2012 or 2014 to make it quantifiable. I think from David's work which is a little bit out of date but we do have pretty good numbers for what we call the disparities index – it's the difference between access and quality of care in different minority populations. So if you know it is a one year eight month flag to get that diagnosis you can set a mark by using 50% of this and 3 years as a goal for the Strategic Plan. That's kind of where I'm going because I want to make sure that we have goals that really are measurable, achievable and accountable. I'm afraid when we say that we want effectible approaches we'll never know when we've done that unless we hold ourselves to a particular standard. Is it not clear or what does the group think? Jennifer, this really isn’t a question for you – it’s for the whole Committee. Anybody still there? Guys – this is our chance to be bold. I think if we’re not going to do it here nobody else is going to do it. So if it’s not us, who is it going to be and if we don’t do it now when are we going to do it? We’ve got to really set ourselves a bar that we can be proud of and that means putting out something that we’re going to care about – putting it in real numbers and holding ourselves accountable for those.

Dr. Birnbaum: Tom, could you repeat your suggestion for the new wording?

Dr. Insel: I haven’t written this out but I’m trying to put it in terms of reducing health disparities and putting it into a number. I don’t know because it’s up to the Committee because I don’t know how far you want to reach – whether you want to reduce them 20%, 50% or 100% but we have numbers already that indicate what disparities there are based on ethnic and racial identification. So what I’m saying is give me a time and give me a goal that we can achieve so, as an example, reduce health disparities for ASD by 50% by 2012 or 2013 and in this case this is based on diagnosis and early access.

Unannounced: Would it be appropriate to reduce and if we’re going to be bold that’s what we need to do.

Dr. Insel: What does this Committee want to set itself to and….

Dr. Birnbaum: This is a short term objective. We’d like to eliminate disparities – short term is two or three years and it’s not going to happen.

Ms. Blackwell: What if we said significantly reduce?

Dr. Insel: What is significant?

Ms. Blackwell: I don’t know but at least it gives us a reason.

Dr. Hann: Another thing to think about too is the research that demonstrates the reduction in health disparities because to actually see the reduction requires a whole other service system environment that’s not being researched. We’ve done this for other topics here at NIH when we’re doing goal setting and basically you have to have the research that you can demonstrate that sort of reduction because then you can actually take the implementation of that in other forms of research and other spheres of service delivery.

Dr. Insel: Right – this is the value of information process which what we do at NIH – we do a research project which shows that we can implement and reduce and what you do is you take that to policy makers and explain that’s what needs to be done and to be able to get the same results. The implementation of that is a different task and we provide the information and that’s why we call it the value of information because we use the taxpayer dollars to make sure that there’s a compelling case to be made. So, Della, could you frame this up where it would be time valuable and would be achievable.

Dr. Hann: Here’s the wording that I was considering so take that as an offer. Research that shows a 50% reduction in health disparities and children and families accessing care or diagnosis (or whatever you want there) by 2013.

Dr. Trevathan: I was unable to speak up before because there was a glitch in the system and I think you can hear me now. One suggestion I have here is very obviously eliminating racial and ethnic disparities in early diagnosis, for example, is an infrastructure issue for our health system or lack of a health system which is obviously a bit beyond what maybe we can do just within the IACC. It’s sort of a marker of health disparities generally in some of these populations. I agree with being bold but I don’t really think at this point we have the data systems that allow us to accurately measure and track this in a timely way. Seems like this is a way that cuts across missions of CDC, CMS, HRSA – there’s a few of us. I wonder if we need to, at the same time be bold, but also be realistic and maybe for starters what we need to do is get all these various groups together that we know play an important role in the measurement and implementation and develop a strategy. I don’t think we have a strategy now for addressing this and that is likely to be affected and if you guys disagree but I wonder if we want to just take a step back and bring people together for strategy of how to reduce these health disparities and then how to measure our progress over time.

Dr. Guttmacher: Do we yet really understand all of the reasons for the disparities? Some of them but not all of them including setting a short term by 2012 to fully identify the causes of disparities in terms of autism.

Dr. Insel: Maybe creating a disparities index for different aspects of ASD from diagnostics to treatment, but that’s something that could be done quickly.

Ms. Blackwell: I think we need to be real careful about the wording of that about what people access in care and education services or be thinking a lot of what we're talking about here.

Dr. Insel: We need to move on. I'm going to turn this back over to Della in a moment to come up with language but I think everybody is saying this needs to be a short term goal. I hear the Committee vacillating about the extent of what you want to reach in the short term but everybody wants to keep this within the means of research so we'll wrestle some language together over the next few minutes. Let's keep going.

Dr. Johnson: On line 5 this objective is looking at the outcomes. You're going to see something similar to what we just talked about the relationship between diagnosis and early intervention services. The second sub-bullet addresses the issue regarding co-occurring methods, medical conditions and ASD characteristics and how that affects diagnosis over time. The third one is looking at essentially the developmental trajectories and outcomes for certain populations.

Dr. Insel: What does that third bullet mean?

Dr. Johnson: What the panel discussed is whether there are differences for children who are essentially at high risk for ASD to other populations of children with ASD. I believe it was to look at the comparison between high risk samples to children in the general population.

Dr. Insel: So there should be the word comparison after samples?

Dr. Johnson: Yes, I believe so but we should probably go back to the notes to confirm that.

Dr. Insel: Other issues here on this particular bullet? Can you give us a timeframe and some way of quantifying the deliverable?

Dr. Johnson: One question that I have because we’re focused on early childhood in early diagnosis is whether we need to have a sub-bullet in there that looks at the relationship between co-occurring medical conditions and ASD characteristics because it was referenced in terms of what happens over time. As the child gets older what happens in terms of the changing conditions including the changing characteristics of ASD.

Dr. Insel: Committee – everybody still with us? Jennifer is asking us about the second sub-bullet.

Ms. Blackwell: Jennifer, would it help if you put an example with regard to severity of ASD characteristics.

Dr. Johnson: I guess what I'm wondering is whether we should have essentially what is a life span issue included in a Chapter that's really focused on early diagnosis. We have other Chapters about adult issues now and so I don't know if it fits better in there to have what happens over time and how during the life span characteristics change and how that relates to co-occurring conditions. Since this Chapter really focuses on early identification and research I’m just wondering if it’s now appropriate to put it here in this Chapter.

Dr. Insel: What would we lose here if we took out this entire bullet? What would be the discovery or science that would not happen?

Dr. Johnson: The issue that was of concern is being able to understanding the co-occurring conditions and how they would relate it to ASD and also the difficulty in differentiating over time the ASD co-occurring conditions. I guess what would be lost is a better understanding of the variation in ASD and the relationship of that variation in co-occurring conditions.

Ms. Singer: We talk about that in section 2.

Dr. Johnson: Again maybe it would be more appropriate to have it in another Chapter rather than this Chapter since this Chapter is focused on the early diagnosis.

Dr. Trevathan: It sounds like a great thing to do but it doesn’t seem to belong here perhaps. I would say it could be taken out and not lose anything.

Ms. Blackwell: I don’t have Chapter 2 with me – I have Chapter 6 and I don’t see where it addresses this in Chapter 6. So you’re saying that this was referenced in Chapter 2?

Ms. Singer: I’ll pull up Chapter 2 and I can read it to you.

Dr. Insel: Again to make this quantifiable do you want to put in a number on here and a timeframe? Like 3 studies – is that the sort of thing that the panel was looking for?

Dr. Johnson: I think so – yes.

Dr. Insel: While we’re waiting for Alison – any other comments about these two bullets?

Ms. Redwood: Some of these co-occurring medical conditions may occur prior to the diagnosis of autism – for example, speech and language delay. If you look at it from that perspective then it would be important in early diagnosis in this Chapter as well.

Dr. Insel: So it should include seizure disorders.

Ms. Blackwell: I see in Chapter 2 that is a long term objective but it talks about a large-scale multi-disciplinary project and that people with ASD change over time compared to people with typical autism but that’s the closest thing I see in 2 and they don’t say exactly the same thing.

Ms. Singer: On page 8 in Chapter 2 there’s a short term objective on line 15.

Dr. Insel: So the question is where to put it. Is that the issue?

Ms. Redwood: I think they are two separate issues. One is that it is appropriate there but I think it could be included here and help us pinpoint things that could be diagnosed earlier.

Dr. Insel: I read this in a different way I suppose. I think maybe Lyn and I read it the same way. This was about identifying changes in development prior to the manifestations of autism. Perhaps if it’s not clear to us it won’t be clear to anybody else. I wonder if what it is really is being recommended here.

Ms. Singer: I think the way you just stated it is good. It’s different than what’s in Chapter 2.

Dr. Insel: What we’re struggling with is the recognition that the behavioral manifestations may be out staged in a process that we’re trying to find other ways to detect. I don’t know if that’s actually in here or not but that’s the kind of search that we’re already supporting and hoping to do a lot more of. There are several projects like that with high risk samples that are genetic.

Ms. Singer: Can we restate this objective which I actually took to be something completely different than that and to indicate what you and Lyn just said?

Dr. Insel: It would be altering diagnosis based on these other factors that we don’t currently have enough information to do but we would hope we wouldn’t have to wait until there’s a language or behavioral problem and we would be able to make a diagnosis much earlier.

If that is not implicit in this I wonder if we should make it.

Ms. Redwood: Could we change it from co-occurring to precipitating?

Dr. Insel: What I’m trying to get at is I’m not sure even if these are co-occurring medical conditions. What I’m trying to understand is where in this Plan do we call for the kind of research that looks at the biological changes in an infant before there are manifest behavioral changes. Our current diagnostic approach is by definition is late – that is it only happens when there is manifest behavior and that may be a late stage.

Dr. Johnson: Isn’t a lot of this rolled into the first long term objective of bio markers at risk? I think the whole definition of co-occurring condition is back on page 5 in a bullet on line 11 in terms of keeping out other conditions relating to autism or are they a different condition. This was really looking at after the diagnosis what happens across the life span.

Dr. Insel: Do we need that here?

Dr. Johnson: Again since we decided to focus the Chapter on early identification it doesn’t belong here because it’s a life span issue and it sounds like it is elsewhere.

Dr. Insel: So what if we were to just eliminate this bullet entirely and focus on that first long term objective which describes explicitly the need for pre-clinical diagnosis.

Dr. Johnson: Yes, I would agree with that.

Dr. Insel: What does the rest of the Committee think about that? Alright – we’ll move on to the long term objectives.

Dr. Birnbaum: The first bullet – I’m not sure what its saying. The English or the grammar really needs some work.

Dr. Insel: How about if we just say identify behavioral and biological – it could be factors or markers.

Dr. Birnbaum: I think you’re getting close.

Dr. Insel: That accurately identifies one or more subtypes in children at risk. If we said behavioral and biological signatures – would that work?

Dr. Birnbaum: I don’t understand why you can’t just say markers – that way they can be biomarkers, they can be thought of as clinical markers, they can be thought of as behavioral markers...

Dr. Hann: Here’s what I heard – identify behavioral and biological markers that separately or in combination accurately identify before age 2.

Dr. Birnbaum: I think that’s fine.

Dr. Insel: What’s the rest of the group feel? Alright – moving on to the second bullet under long term objectives on page 6.

Ms. Singer: What does continuous dimensions mean?

Dr. Johnson: That was language in the Chapter originally.

Dr. Birnbaum: I think it refers to the

value added to capture quantitative differences.

Dr. Insel: Right I think this speaks to dimensional approaches – it is how someone is doing on this particular domain.

Dr. Trevathan: Could one example be, for example, Constantino’s work in social scales – is that sort of what people are thinking of?

Dr. Insel: Yes, precisely – that was one that was developed to be a continuous dimension that could also serve as a quantitative trait.

Ms. Blackwell: Could I make a suggestion that instead of just saying parent we say and/or families.

Dr. Birnbaum: Somewhere else we said parent or guardian.

Dr. Trevathan: I wonder if what is intended is something like a measure of social continuous variables in the population like social language of maybe a couple of those examples could be given so we actually know what’s intended by continuous dimensions which I wasn’t sure either.

Dr. Insel: I think we should know what this actually means before we put it out there.

Dr. Trevathan: That’s why I was asking what it was.

Ms. Singer: I think what we were trying to get at here was are there clinical diagnosis that can inform treatment response. I don’t know that we should take it out.

Dr. Insel: I didn’t think it was recommended kicking it out. I think we just want to put a parenthetical in with some examples.

Dr. Trevathan: I’m not suggesting it needs to be limited to language or social – I’m just thinking what are the continuous variables.

Dr. Insel: We can have OARC go back to the original 2008 conversation and find out whether there were some examples provided and if not they can try to get some from program and we can put those in parenthetically. The only new language here is including determining the prevalence of factors associated with changes and features. Is that helpful or do you guys track that?

Dr. Johnson: I think that is getting at the issue of determining if there were changes in the features of ASD over time. I guess I have to raise the issue that we decided to focus this Chapter on early identification and this is just really dealing with issues across the life span.

Dr. Insel: So you want to just remove it or leave it at the original language?

Dr. Johnson: We’re talking about what happens after diagnosis and across the life span and the question is does it belong in another Chapter.

Ms. Singer: There could be changes in core features in children.

Dr. Johnson: Before or after diagnosis is the question.

Dr. Trevathan: I’m a little bit concerned about using the term prevalence when we’re talking about monitoring these continuous variables in the population. We’re really nowhere close to measure degrees of social of the of the population and I don’t really know when we’re going to be there. People are really talking about these are in clinical studies rather than the general population so you could use the term frequency rather than prevalence and that could then not be so specific to the general population and you could use that term in clinical studies.

Dr. Insel: Is the sense of the Committee that this additional clause in here about changes in core features is useful or not needed?

Dr. Trevathan: I don’t think it’s useful.

Dr. Birnbaum: I think it’s useful.

Dr. Trevathan: What core features are you talking about again so that we are all on the same page?

Ms. Singer: That’s why we had the workshop to agree on the core features. I think we may not need to have this in Section 1. The way it is written is to respond to prevention.

Dr. Insel: That’s what Jennifer is telling us – this was put in when we were talking about diagnosis across the life span.

Dr. Johnson: And now I agree that it can come out – this section is really covered in section 4.

Dr. Insel: There seems to be a lot of disagreement on this so first, can you give us your name and I can get the numbers that way – to include the language as stated – Linda, I do; Lyn, I do; and to remove – Ed, Ellen, Jennifer, Deborah, Christine - and Tom – I think it’s gone.

Dr. Hann: Just to clarify – we are deleting that phrase or in its entirety?

Dr. Insel: Deleting the original phrase that was put in – we’re going back to the original. Final bullet – page 7 – Jennifer, do you want to give us a sense of this.

Dr. Johnson: Essentially this research objective is getting at a better understanding of particular signs and symptoms of ASD.

Dr. Insel: So it sounds like we were just there and we decided that we don’t want that in this Chapter because this is about the early part of diagnosis. What was the sense from the panel?

Dr. Johnson: Our panel was having a conversation and this was a life span chapter.

Dr. Insel: So what’s the Committee want to do with this – leave or lose? Does anybody feel that this is really important to include it?

Dr. Trevathan: I think we can lose it.

Dr. Insel: Ok, unless I hear anybody arguing differently it’s gone. There’s an additional issue we need to bring to your attention which is also in the long term objectives. There’s an objective that’s been deleted it shows up in the box on the side of page 6 – five measures of behavioral or biological heterogeneity in children or adults with ASD. This was in there and now it’s no longer in there.

Ms. Redwood: Any explanation for why it was deleted?

Dr. Johnson: It was deleted because the panel was recommending changes to the other objectives and they felt like that was being addressed by the changes.

Ms. Redwood: Is that really happening based on what we decided?

Dr. Johnson: I think so.

Dr. Insel: Is there anywhere else in this diagnostic chapter where we focus on the heterogeneity? Is this captured in another chapter?

Ms. Redwood: I don’t think so but I wouldn’t know but I think it would be important to include.

Dr. Birnbaum: I would argue that it needs to be somewhere.

Ms. Singer: In looking at Chapter 2 and I think we included something similar.

Dr. Insel: I don’t see it in 2. Can I make a recommendation because we’re running out of time? We can put this back in its original place and if it turns out its truly redundant with something else that we've added then we can drop it later. (All agree) Della, it's up to you to get us over the finish line here.

Ms. Blackwell: I have one very quick comment about the aspirational goal.

Dr. Insel: Let's get this part done and then we might have some time at the end. We'll get back to it in a moment.

Dr. Hann: Here's what I've heard – beginning on page 5, line 4 – striking the word ethnic; line 6 – we need to consider a reword about how diagnosis essentially informs or can inform intervention but I think OARC was asked to try to figure out how to reword that; the next set of changes begin on line 12 where we will strike the use of the word broad band and use the word general instead; and the items that are listed beginning on line 16 through 20 as well as line 1 on the next page are all being deleted; and something identifying at least five factors that contribute to health disparities in children and families accessing screening and diagnosis in community based and clinical studies by 2012. The next section which began on line 5 has been deleted. Does anyone have any objections or issues with what I’ve gone through so far? Okay, long term objectives – line 11 has been reworded to identify behavioral and biological markers that in separation or in combination and then it continues as currently worded. Moving down to line 17 – replacing parents with the word families; line 18 – the new phrase that was added that’s in blue is being deleted. We’ll also reinsert the objective that’s sitting over on the grey box on page 6 and keep it as an objective. We’re deleting the final objective that was listed on page 7.

Dr. Insel: Questions about that proposal? Motion to accept. (All in favor) Ellen, talk to us about the aspirational goal.

Ms. Blackwell: I seem to recall that we

had a lot of discussion about this, Jennifer, but it kind of struck me about the four characteristics. I think it would be better if you just said the four ASD characteristics.

Dr. Insel: Ellen, I thought that the point of this was to find biological characteristics that would emerge before the behavioral characteristics and so behavioral was specifically put in there to clarify that’s where we are now and the aspirational goal would be to understand autism at many different levels and not simply a behavioral level.

Ms. Blackwell: Okay – I was just asking for some clarification.

Dr. Insel: Della – you had some issues…

Dr. Hann: I have some general points to clarify with the Committee so my office can proceed in preparing the final draft for your review in January of the entire Plan. One thing I would like to hear from the Committee is that there are some new objectives that have been added to the Plan – if you all are comfortable

OARC can work with program officials as well as CDC and I believe there’s some in Chapter 6 and/or 7 and that we would work with program officials in those places to develop recommendations for the budget but I need your okay to do that. Then we can bring that information back to you in January. (All agree)

Ms. Singer: Della, can you also, in preparation for the final review, have a few people that read through the entire document for purpose of internal consistency. We talk about the chapter by chapter approach and I think it would be helpful to have a couple of people read through it.

Dr. Hann: I have no problem with that. Who would like to do that?

Ms. Singer: I’m happy to do it and I think a couple of people should.

Ms. Redwood: I would be happy to.

Dr. Insel: This came up at the last meeting and it shows up every time we do this and it’s a problem by trying to write this by

Committee so it does need a unifying voice at the end of the day.

Dr. Hann: Let me just clarify that a unifying voice would also be changing adjectives and things like that. It would not be to add substantial new content, correct?

Ms. Singer: If we have areas where we have examples and making sure everything is formatted but not to add or subtract to make cosmetic changes so that it looks like it was written by one person and not by six different teams.

Dr. Hann: I just wanted to make sure I understood.

Dr. Johnson: I do wonder though if we need to do an analysis that looks at the objective to make sure that there’s a certain level of consistency between them and there isn’t an overlap between the objectives.

Dr. Insel: We may need to do that before we get to numbers from program. I have the same concern and it’s because we have done this over time and we’ve had kind of a silent approach.

This raises the question of how we want to do this next year and I'm not going to open that up right now but at one of the upcoming meetings we have to think about what could be a more efficient approach for the next update which could start somewhere after January 19th.

Dr. Birnbaum: I hate to go back but there was one bullet that was done the last time – research opportunities, Chapter 1, page 4, lines 17 to 18 – but I'd like to just bring up for a second – this one says ASD sub-populations associated by behavioral markers are an early indication of ASD and early opportunities for appropriate early intervention. First of all I really don't think we need that word. Hopefully that's a given that intervention should be appropriate but the other think early indications not only lead opportunities for actual prevention of development into the entire spectrum of the disorder so I was just wondering if we wanted to say something that early diagnosis or identification.

Dr. Insel: You know Linda all of us have words and terms in here that we would love to change but I’m afraid if we start this we’ll never finish it. But there’s always next year. We have a few other issues that we do want to address before we break. Go ahead Della.

Dr. Hann: We have found in working with this document particularly when it comes time to do portfolio analysis it is very helpful to be able to order and number the objectives. We have not ever done that before and I wanted to get the Committee’s impressions about whether they consider that to be okay. For example for Chapter 1 what we would do in the objectives is just number them – so you would have 1, 2, 3, 4, 5, etc. within that Chapter. It just makes it easier for us to communicate and work with you, the Committee, in terms of a portfolio analysis.

Dr. Insel: Any thoughts or concerns? We don’t want it to look like we’re setting a priority with this but on the other hand we need to have some transparent way to link objectives to outcomes.

Dr. Birnbaum: Instead of using 1, 2, 3, 4, use a, b, c, d – that has less of a numerical implication to it.

Dr. Insel: Any other issues, suggestions or concerns about that? I have just a couple of things to bring up with all of you. One is just a point of information for anyone interested we spent a lot of time today talking about registries and repositories – there is a meeting in January called the Boot Camp and it’s scheduled for January 10th here in Bethesda being supported by the Genetic Alliance. I don’t know if this was of interest to the people on the Committee but it occurred to us in talking about where we were going at the IACC – public members were interested enough in this to send someone from the Committee and report back to us at our next meeting. This is around all kinds of repositories.

Ms. Singer: January 10th is a Sunday.

Dr. Insel: It says 3 p.m. to 9 p.m. on

January 10th. I think they're doing it then because the next couple of days is a meeting called the Rare Disease Research meeting and that's all about registries and repositories so I think this was meant to proceed that. I'm not saying that anybody needs to go but just to bring it to your attention that if there are things here that are connected to the IACC that we are happy to help people become involved in them. If anybody wants to know more about this you can contact Della or Susan and they can get you the information. Again, not connected to the Strategic Plan, NFAR is coming up on May 20th and 22nd and we've been talking about having an IACC presence there for this year. It's too late to do any sort of symposium but last year we were asked to talk about the Strategic Plan and intentionally this year get on the agenda again to talk about progress so I wanted to make sure you know about this as an opportunity and we can talk a little bit more about it as time goes on. I do think this is a chance we should try to take advantage of – it’s one time that we can get many of the people who implement the Strategic Plan in one place to tell them what it is we’re hoping to get done.

Dr. Birnbaum: Tom, I think it would be great if we could have a booth there but obviously that costs money but it would certainly increase some visibility.

Dr. Insel: I think what would be great would be to have people on the Committee actually support the booth, be at the meeting, and be able to talk to the investigators as representatives of the IACC. If anyone is interested in doing this we would be very interested and help you participate and again, that’s in Philadelphia on 20th and 22nd of May 2010. Last thing I wanted to mention was our next meeting is on the 19th of January and I think we’ve had an opportunity to work on all of these projects on these supplementary meetings, but I was also hoping to take that as an opportunity to hear about some breaking science that would be of interest or the areas that came up at the last meeting which was genetics or any other topics which you would like to hear.

Dr. Trevathan: I think genetics would be a very important topic – it might be great.

Ms. Singer: I agree epigenetics would be a very important topic but I think another important topic would be the stem cells and what that new technology is and how we can apply it in autism research.

Dr. Birnbaum: It may be a little bit premature due to most of the talk we heard yesterday.

Dr. Insel: It’s likely that anybody that comes in to talk about epigenetics can certainly talk both issues. I wanted to make sure that we were at least up to speed on the area that’s really breaking very quickly and that’s relevant to so many aspects of autism that’s not yet being represented by the autism research community.

Ms. Redwood: I also think it would be

important at one of the later meetings to talk about treatment.

Dr. Insel: Any other ideas of scientific or talks that you would like to hear? Okay, other issues from the Committee, comments or questions?

Dr. Johnson: I just wanted to say something about Chapter 1 – this is based on our decision at the last IACC at a meeting where we decided to focus Chapter 1 on early diagnosis and I thought it might be beneficial to include some research around the importance of early identification and the importance of access to early intervention services because that’s not really reflected in the Chapter now. We don’t really have reference to that kind of research. I wanted to find out if the Committee would be comfortable with that addition to Chapter 1 because, again, it’s important to the issue of early diagnosis of ASD.

Ms. Blackwell: I would support that.

Dr. Insel: Any other response to Jennifer?

Do you want to put something together, Jennifer?

Dr. Johnson: I would be happy to do that – yes.

Dr. Insel: One other issue that’s on the agenda here is just thinking into the future a little beyond the January meeting is getting the Planning Subcommittee together in February and we can get back to you about dates and times but in thinking about getting an early jump on this process we’d like to have an opportunity really just to talk about the update process and for this Subcommittee to figure out the best way to do this in 2010. We will get back in touch about dates but I wanted you to know that’s on our agenda. What else from the Committee?

Dr. Johnson: I mentioned earlier that I was not actually on the Planning Committee but I ended up facilitating the panel so I was just kind of curious as to whether you want me to be part of this discussion and I guess we could talk about this offline too, but I was just curious.

Dr. Insel: I think you became an honorary member when you became a member of the panel so you’ve done all of the work so when we come back around February we’ll make sure you’re part of that. Anything else from the Committee? I want to emphasize again that since we don’t have public comment at this meeting because we’re doing it by phone we have distributed the comments to everybody in writing and I encourage everybody to take a close look at what’s been distributed. They went out in an email last evening. Unless there is anything else from our Committee let me thank all of you for hanging in to get this update done. It’s been a few extra meetings and a lot of time and line by line sweat but I’m hopeful that the final product will be worth the effort. I wish all of you a very happy holiday and….

Ms. Redwood: Please refresh my memory – are we responding to these comments because I think it is important that we do so because people spend a considerable amount of time on these comments and I think we need to respond to these in some way.

Dr. Insel: As a policy issue we have not responded either in writing or orally at the meetings partly because of time constraints at the meetings but why don't we put this on the agenda in January and discuss whether the Committee wants to change the way we either integrate the public comments or the way we respond to them.

Ms. Redwood: Thank you.

Dr. Insel: Okay – happy holidays everyone – we are now adjourned – thank you.