U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

INTERAGENCY AUTISM COORDINATING COMMITTEE

FULL COMMITTEE MEETING

FRIDAY, OCTOBER 23, 2009

The Committee convened at 9:00 a.m. in Conference Rooms E1/E2 in the William H. Natcher Conference Center, 45 Center Drive, National Institutes of Health, Bethesda, Maryland, Thomas Insel, Chair, presiding.

PRESENT:

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

JAMES F. BATTEY, M.D., Ph.D., National Institute on Deafness and Other Communication Disorders

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

HENRY CLAYPOOL, HHS Office on Disability

ROSALY CORREA-DE-ARAUJO, HHS Office on Disability (For Dr. Henry Claypool)

PRESENT (continued):

CHRIS DeGRAW, M.D., M.P.H., Health Resources and Services Administration (For Dr. Peter Van Dyck)

LEE GROSSMAN, Autism Society

DEBORAH HIRTZ, M.D., National Institute of Neurological Disorders and Stroke (For Dr. Walter Koroshetz)

LARKE N. HUANG, Ph.D., Substance Abuse and Mental Health Services Administration

YVETTE M. JANVIER, M.D., Children's Specialized Hospital

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

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

CHRISTINE M. McKEE, J.D., Public Member

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

CATHERINE RICE, Ph.D., Centers for Disease Control and Prevention (For Dr. Edwin Trevathan)

STEPHEN M. SHORE, Ed.D., Autism Spectrum Consulting (by teleconference)

SUSAN SHURIN, M.D., National Institute for Child Health and Development

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

TABLE OF CONTENTS

PROCEEDINGS

9:01 A.M.

Dr. Insel: Good morning everyone. It's time for us to get started. I want to welcome you to this meeting of the Interagency Autism Coordinating Committee.

I'm Tom Insel, your chair, there are some new faces around the table, and I just want to make sure we take a very quick moment to do introductions so that everyone knows who's here. Let's start to my right with Dr. Hann.

Dr. Hann: Good morning, I'm Della Hann, and I serve as the Executive Secretary for this committee.

Dr. Daniels: I'm Susan Daniels. I'm Deputy Director of Office of Autism Research Coordination in NIMH.

Ms. Blackwell: Ellen Blackwell, Centers for Medicare and Medicaid Services. I'm also the parent of a child with autism.

Dr. Shurin: I'm Susan Shurin.

I'm the Deputy Director of National Heart, Lung and Blood Institute, and I'm also the acting Director of the National Institute for Child Health and Human Development, and I'm here in that capacity.

Ms. Redwood: I'm Lyn Redwood, SafeMinds.

Dr. Lawler: I'm Cindy Lawler, Program Director at National Institute of Environmental Health Sciences, and I'm here today for our director Linda Birnbaum.

Dr. Battey: I'm Jim Battey, National Institute on Deafness and Other Communication Disorders.

Dr. Hirtz: I'm Deborah Hirtz from the National Institute of Neurological Disorders and Stroke.

Ms. Singer: I'm Alison Singer from the Autism Science Foundation. I'm also the mother of a beautiful 12-year-old daughter with autism, and I have an older brother diagnosed with autism as well.

Dr. DeGraw: Good morning, I'm Chris DeGraw representing HRSA for Dr. Van Dyck.

Ms. McKee: Christine McKee, I'm a parent of a 10-year-old girl with autism.

Dr. Rice: Hi, I'm Cathy Rice representing CDC for Ed Trevathan.

Dr. Janvier: Yvette Janvier, I'm a developmental pediatrician and board certified in developmental, behavioral pediatrics and developmental disabilities, Medical Director at Children's Specialized Hospital in Toms River.

Ms. Correa-De-Araujo: I am Rosaly Correa, I'm the Deputy Director for the Office on Disability, the Office of the Secretary.

Dr. Insel: And do we have someone with us on the phone at this point? I believe Steven Shore and Lee Grossman will be joining by phone, but it doesn't sound that either of them are here yet. Anyone else phoning in?

Very good. Let me remind you this

meeting is webcast, and it's really critical for you to use your microphones so that people can hear. We have a very full agenda this morning. Before we get started, I wanted to take just a moment to just reflect on some of the recent events since our last meeting, which was on July 15th.

I know a lot of this has been in discussion both in the community and amongst members of the committee. Much of this focused on Dr. Landis's resignation from the IACC, which was certainly unfortunate as she said it was because of an unprofessional issue.

But most of all, I thought for our purposes we should recognize that this was a violation of one of the core values we agreed to as a committee, which was a spirit of collaboration and listening to diverse views with open minds.

Story has already apologized to the committee, but I want to as Chair, apologize to Lyn who some of these comments

were directed to. And I think that we all need to take a look at this and ask whether there's a teachable moment here.

My sense is that there -- from the beginning there have been many areas where members of the committee have disagreed, but to quote David Mandell, who was at one our scientific workshops recently, we've got to make sure that there's a sense of honesty and civility that rules as we listen to some of these diverse views.

It's just got to be the case that we understand that we can participate here without fear of rejection or ridicule. And I don't think we can bend on that in any sense. This is really especially important because we're working against a background of such increasing disagreement, often strident disagreement, within the community.

I think everybody at this table knows that recently the tone in some parts of the autism community has become hostile to

this committee with name calling, with lots of personal accusations, some of them directed against individuals within the committee, including myself.

And what I'm concerned about is that so many people have lost trust in this committee, seeing us really as part of the problem and not working for the solutions that all of us need.

So it's going to be critical for us to, within the committee, maintain an open forum, a respectful dialog, absolutely fair procedures and not to become the stage on which so many of these frustrations and suspicions play out.

Dr. Shore: I don't know if anybody can hear me, but I can barely hear you.

Dr. Insel: Steven, we can hear you.

Dr. Shore: I can barely hear you. You're cutting in and out, mostly out.

Dr. Insel: Okay. We'll see if we

can get our audio engineer to help. I've just been talking about the difficulty we have communicating. So you make that concretely evident to us.

Dr. Shore: And if someone can send me an e- mail as to how to connect to -- through the internet so I can have the visuals, that would be good, too.

Dr. Insel: We will take care of that.

Dr. Shore: Thanks a lot.

Dr. Insel: Steven, is this any better?

Dr. Shore: Keep talking, I'll let you know.

Dr. Insel: Okay. Thanks. My point that I've been trying to make is that if we get to a point within the committee where there's no trust, I can guarantee you there will be no progress.

Dr. Shore: Oh, yes, I agree, fully.

Dr. Insel: Thank you. Lack of trust here means really lack of progress, and we need to really lead the community here by establishing and maintaining trust with everything that we do.

Dr. Shore: Right. You're still very, very soft, and you're about 50 percent in and 50 percent out.

Dr. Insel: Do you want to try calling back in?

Dr. Shore: Yes, let me try that. I'll call right back.

Dr. Insel: Okay. All right. We will go - - we're not going to start the regular agenda for a couple of minutes anyway, and I'll be happy to share my remarks with you individually.

Dr. Shore: I'm going to call right back.

Dr. Insel: All right. So in thinking about this over the last few days, I thought maybe it would be helpful to put some

things on the table that we really do share as kind of what we sometimes call in science going back to first principles, and, of course, a lot of that is in the plan.

And you can see in the plan where we've listed all the values. But I think there's actually, there are a few things that are not there, and I thought it would be worth noting them. I think one of the things that most of us share is a sense of frustration with where we are.

We do recognize that there's great progress, that we are spending a lot more money, and you'll hear much more about that, where a lot more science and we're seeing in the scientific world some really brilliant people who are working on cancer or hypertension or diabetes now moving in to the autism field, which is a very positive development.

But there are a lot of other numbers that are going in the wrong direction,

and those are numbers that have to do with prevalence, that have to do with cost, have to do with services, have to do with employment. So that's part of this frustration.

We also, I think, share a commitment to change. I think on the federal side that everyone around this table feels that the status quo is not acceptable and that we have to find a way to do much, much better. We have to get past our fundamental ignorance about the pathophysiology of autism, about our lack of evidence-based medical treatments and our fragmented service delivery system or sometimes that's called lack of system.

And third and finally, I think that we all share, I hope we all share a belief in the importance of science to answer the big questions here. Science has done that for other medical crises, and science should do that here. We may disagree about what science will bring the answers that we are all looking for, but I don't think we disagree

about the questions and about the importance and the power of science to answer them.

So I'd like to just remind us that we all share that, and it's worth also probably remembering that we work on a committee that has very high expectations but actually has fairly limited authority and a very limited budget. We're not a funding committee.

We don't make funding decisions. We're advisory for the Secretary of HHS, and we're coordinating. But when you're in that space, when you don't have lots of money and you don't have lots of authority, what you have to do is lead with the power of ideas.

You have to bring the intellectual power to the table, and that's going to mean ideas about strategies, some of which are in the plan, ideas about new initiatives, new ways of coordinating, and ideas about other ways of bringing people who are not in this field into the field that make a difference

for the science.

The last thing I want to say is I'm dismayed by, I don't know what else to call it except our attendance. We don't have many of the principles at this table who should be here. Now, I understand that there are always problems with attendance because people are busy and they have other things to do, but this is an important committee where we have to really have to request that the people who are on it are engaged.

There are a lot of people who want to be on this committee who don't have a seat at the table. So for those organizations and agencies that are fortunate enough to get a seat, I expect you to be here and to be engaged with the process in every which way we can. So I hope those of you who are kind enough to be representing your principal will send that message back and make sure that as we go forward, we can look to having meeting with much more broad attendance.

So I'll just summarize by saying, I think given everything that has been going on outside the meeting, I think this is the time when we need to kind of go back to remembering what we're really here for, which is for families and for people on the autism spectrum. And maybe that's the very best introduction for the first session in today's meeting which is about an opportunity for us to meet with some families and some very special people who come from this autism spectrum world. Many of you live this and are very familiar, others of you are not so familiar.

We're fortunate to have Elizabeth Emken and Peter Bell who have agreed to help organize this session for us. So I'm going to turn this over to Peter, and I'm hoping that as the day goes on, we can continue to reflect on the opportunity we have here. Peter?

Mr. Bell: Thank you, Tom, I appreciate it, and thank you to Della and your

staff for all of your help in the logistics of organizing this panel today. We really appreciate the extraordinary efforts that you went through to help bring these families here today and giving us an opportunity to share the stories of a lot of very special people that are here with us today. So this is a wonderful moment I think in the IACC history.

There's a common expression used by many in the autism community, if you met one person with autism, you have met with one person with autism. People use this phrase in an attempt to illustrate the diversity and range in which autism is expressed.

There's no question there are many faces of autism. You see them here before me today. In fact, the term autism spectrum disorder was initially introduced on the early 1990s when the criteria for PDDs were expanded to include autism, PDD-NOS, and Asperger's.

The general public's perception of autism has been shaped over the years in large

part by the media, as well as the entertainment industry. For many of us, our first exposure to autism was the 1988 film *Rain Man*.

In his Academy Award winning performance, Dustin Hoffman portrayed the unforgettable Raymond Babbit, a middle-aged autistic savant who possessed extraordinary memory and mathematical skills. Although Raymond had spent most of his life confined to a mental institution, he was blessed with a knack for counting toothpicks, memorizing the phonebook, and scoring big at blackjack. Because this popular movie depicted autism as a disorder that included special talents, to this day, many people incorrectly assume that all people with autism have some savant-like skills.

Once autism emerged as a more common medical condition in the 1990s, it was largely portrayed as a childhood disorder. As the prevalence rates grew from 1 in 10,000 to

1 in 2,500 and then 1 in 500 to 1 in 150 and now 1 in 91, most of the images reflected in the media were of very young children, mostly adorable toddlers, sometimes even infants extolling the benefits of an early diagnosis.

Although the median age of diagnosing autism in the United States remains troublingly between four and five years old, a growing cohort of children are now being identified at early ages, some as early as 15 months. These children do indeed benefit from an extremely effective range of behavioral and biomedical forms of early intervention.

Today, the face of autism is rapidly changing. The adorable toddlers of autism in the 1990s are now lanky teenagers rapidly making their way through adolescence towards an uncertain adulthood. Some describe the phenomenon as a tsunami since the official rates of autism are so much higher in this generation than they were found in previous decades.

There's an emerging recognition that the number of adults currently living with autism is on the rise and that some, if not many, of these individuals are quite capable of advocating on their own behalf. Indeed, it is encouraging to see that autism is no longer considered a condition that only affects young children. Thankfully, lifespan issues are increasingly more abundant in the strategic plan as well.

Historically the IACC has had limited access to the broad array of individuals living on the spectrum. As we know, many members of the autism community are not able to participate in these meetings due to their limited language, cognitive abilities, the challenges of sitting through long meetings, and other sensory issues.

The committee currently includes one very accomplished person diagnosed with autism, Dr. Steven Shore, who has provided wonderful insights on what it's like to live

with autism and who has made significant contributions to the IACC during his tenure. We have also heard from several members of the self advocacy community who have brought another important perspective to the committee, which has helped shaped our understanding of the issues that certain portions of the autism community face in various, often under- represented aspects of life.

Today, we would like to introduce you to an even broader cross section of the autism community. These individuals, although diverse, still don't capture the full diversity of those affected by autism. However, these families have taken the time to be here with us to share this common thread. They have directly been affected by autism. I want to thank each and every one of them for being here today and to share their stories with us.

As previously mentioned, for the

past decade the most common image of a person with autism has been that of a young child, typically between the ages of three and eight. Nora Fitzpatrick and Robert Stephens from Bethesda Maryland are the parents of Rory Stephens, a beautiful four-year-old girl who was diagnosed with autism about 18 months ago.

Although autism affects boys four times more often than girls, research has yet to elucidate why such a gender difference exists. Rory's mom, Ms. Fitzpatrick, will describe what it's like during the early years of a diagnosis.

Ms. Fitzpatrick: The new chapter of our lives started in the fall of 2007. Our daughters were wearing their beautiful crisp, Christmas dresses ready to take a picture for the card. Our older daughter, Grace, held a wrapped gold package and smiled right at the camera. Little Rory would not look up, avoiding us and the camera at all costs. It was at that moment that it all changed.

I remember shouting and crying that something wasn't right, despite the reassurances of our pediatrician who said Rory does not have autism. She was finally diagnosed with PDD-NOS in February of 2008. That official diagnosis came as a relief. There was finally a name to what was going on, a reason for the language delay, difficult behaviors, and avoiding meeting our eyes, but it was also the beginning of a long and painful year.

The doctor at Kennedy Krieger where we had gone for a second opinion told us that our daughter was mentally retarded and sent us on our way. Before we left, we showed the doctor a video of Rory dancing and singing along with her sister to a Wiggles song demonstrating skills she no longer had.

The doctor went white as a ghost and the med student that was with us got a nose bleed after watching the video. We were told to come back at four months at which

point the doctor would reconsider her diagnosis. With autism you don't have four months to waste.

Next, Rory was enrolled in an intensive needs class for two year olds with ASDs who showed potential. Our hard-headed little girl did not want to do the ABA work, which was the sole reason we picked this class. Rory kicked and screamed every day at the table but was a model student at circle time.

My husband and I agonized over what to do. One morning we discussed our options while Rory was playing on the floor in front of us. Rory got up, went over to her PECS board and got the card for work, then she went back and got the universal sign for no and put it over the work card.

She held them out and looked me right in the eye. At that point I was energized. Rory was smart as a whip, and she had potential, and we were going to find the

right place for her. We enlisted the help of private psychologists who all had the same conclusion, Rory had functioning autism and would flourish in the right environment.

At the same time, we became aware that Rory's teachers had discontinued their attempts at ABA without informing us they had done so. They just stopped trying and didn't tell us. Their recommendation for us was to get our daughter a dog.

They also steered us toward a class that unbeknownst to us was a life skills class. Our private psychologist said absolutely not. They wrote letters on our behalf saying Rory immediately needed 30 to 40 hours a week of intensive therapy. The county responded by arranging ABA instructors to come into our home and work with her.

Around this same time we had someone very special come into our lives, a private tutor who turned out to be Rory's Auntie Sullivan. The first day working

together, Carolyn informed Rory that she would have to say milk if she wanted her cup. Rory was having none of it, but what she didn't know is that she had met her match.

Carolyn wouldn't budge. Rory cried, screamed, dropped and kicked, and Carolyn said that's fine, but you still have to say milk. In the height of the tantrum, Rory said milk almost unwittingly and then realized she had been defeated.

From this point on, it was onward and upward. If it were up to me, all the treatments from which Rory could benefit, speech, OT, PT, and visits to developmental pediatricians would be covered by insurance. Believe me, none of them are.

It's a struggle for parents of autistic children to decide what their child needs most urgently and where their money would be best spent, when we are not the experts. We finally have a wonderful developmental pediatrician overseeing her

care, but he does not accept insurance.

As a result of this enormous expense, many families are left to struggle with major medical and educational decisions alone. And I think this is the reason so many parents seek alternative, unproven remedies for their kids.

I'm great at being Rory's mom, but I'm not a doctor, scientist, or therapist. It would be wonderful if the government sent money toward developing a program that provides parents with a clear path of what has been shown to be effective in treating children with ASDs.

My greatest hope, and what I would ask of you, is to direct federal funding to promising scientific research such as genetic studies and to other environmental factors that have not been disproven multiple times. Further studies into links that have been repeatedly disproven would only be a waste of taxpayers' money and take funding away from

research that might lead to the real cause.

This fall, Rory has started her second year in Montgomery County's CAP program, and she's blossoming. The child who just over a year ago couldn't sit at a table to do ABA now uses words all the time. During horseback riding when she didn't want to make the horse go, she told the instructor I'm busy.

She looks at us, not through us. She's a fully engaged participating member of our family no longer in her own world because of the therapy and classroom experience she's had. Rory and Grace are now fighting with each other, annoying to most parents, but music to our ears.

On a recent trip, the girls were in the backseat of the car singing Brown Bear, Brown Bear together. It was without question the greatest moment of my life. Thank you.

Mr. Bell: Thank you, Nora. Somehow I think Rory took all of that in. She

knows she's the highlight of what we just heard. Thank you.

Autism is traditionally thought of as a developmental brain disorder. As we know, the core symptoms are deficits in communication and social interaction combined with restricted and repetitive behaviors. Increasingly, however, it is recognized that autism affects many body systems, including the immune system and the gastrointestinal system among others.

Parents report a high degree of co-occurring medical conditions that often exacerbate their child's autism symptoms and significantly impact their child's quality of life. In addition to the well documented co-morbidities like seizure disorders, neuropsychiatric conditions like depression, OCD, anxiety, ADHD, individuals with autism were reported to have significant issues with motor planning, sleep disturbances, metabolic disorders, immune dysregulation and

gastrointestinal abnormalities.

We don't exactly know if these cause or are the effects of certain brain disturbances. But for many with autism, they are real and they make life difficult.

Our next panelist is Judy Chinitz from Chappaqua, New York. Her son, Alex Gorman, who is now 15, has had a long history of medical issues in addition to his autism diagnosis. Please welcome Ms. Judy Chinitz.

Ms. Chinitz: Good morning. The first major event in my son's life was a fever he developed at 48 hours old. As per the standing protocol for infants younger than three months, he was re-hospitalized and put onto IV antibiotics for five days.

When he was finally released it was with the diagnosis of quote, "Virus of unknown origin." I've always felt that this was symbolic of the rest of his life, that is, he's always been sick, origin unknown.

He was a fragile baby in many

ways, he barely slept, he wouldn't take solid foods until he was nine months old, he projectile vomited on a daily basis, he screamed for unknown reasons, sometimes for hours on end.

In his second year of life, he continued to slowly but surely deteriorate in health and then subsequently in development. At 15 months old, after yet another severe virus of unknown origin, this time a stomach bug, he stopped responding to his name.

Over the next few months he not only tuned out more and more, but he lost all the words that he'd had and finally became mute by 22 months. Two years after his second birthday he was diagnosed with autism.

His health continued to severely regress to the point where as winter approached, our pediatrician recommended a flu vaccine as she was nervous of him getting the virus in his current state of health. Immediately after the vaccine, Alex was

bedridden for eight or nine weeks with continual vomiting, diarrhea, rashes and raging fevers that would come and go all day.

Just after his third birthday our pediatrician finally sent us to an immunologist, Dr. Avraham Kadar who before going into private practice had been a fellow in the laboratory of Clinical Investigation at the NIH.

After running a series of tests, Dr. Kadar diagnosed Alex with immune suppression and dysregulation of, yet again, unknown origin, and he put him on gamma globulin IVs for -- every three weeks. We were reliant upon these IVs for seven years. They kept Alex from being bedridden, but his gastrointestinal symptoms continued to worsen.

The next five years were filled with vomit, mucus-ridden diarrhea 10 to 15 times a day, Alex screaming in more pain than I have words to describe. I took him from doctor to doctor, but none had any answers for

me.

Finally, in 2002 I found a gastroenterologist who would scope him. Now eight and a half years old, Alex had become severely self injurious and incredibly destructive. He smashed everything he could get his hands on including telephones, answering machines, remote controls, furniture, and even computers.

I had to keep my hands on him all day or something in the house would be destroyed. When I cooked, when I cleaned, and even when I went to the bathroom Alex went with me on a toddler leash.

The colonoscopy revealed that Alex had both colitis and cryptitis. On top of the IVIG he was put onto five different medications for his gut including steroids, 6MP, and Colazal. Except for helping with the destructiveness and the absolute worst of his pain, the medications did nothing.

The gastroenterolgoist explained

to me that Alex's colitis was called prednisone dependent, that is if the dose got below 20 milligrams it would flare up beyond endurance. When Alex was nine and a half years old, after a year on steroids, the gastroenterologist called me and told me he had to take Alex off the prednisone.

He had been on so much that it was dangerous. He suggested we consider a feeding tube as Alex was drastically underweight and had trouble keeping food down and was having at this point at least 20 bowel movements of mucus a day.

At that moment, one of the worst in my life, and I've had a lot, I suddenly remembered hearing about a diet that supposedly could help people with inflammatory bowel disease, it's called a specific carbohydrate diet.

The details of the diet are laid out in a book called *Breaking the Vicious Cycle* by Elaine Gottschall. I had bought the

book several years before but had never read it. At that moment I pulled it off my shelves, read the first three chapters, called the GI back, and told him I wanted to try one last diet before we put in the feeding tube.

I asked him to give me three months. He reluctantly agreed. I started Alex on the diet that night. Within six months of starting SCD, Alex was down to five or six bowel movements a day, and they were slowly becoming more and more formed.

After about six to seven months, it was down one to two bowel movements a day. He put on 10 pounds, and he was off all his gut medications. His health was so much improved that I risked taking him off the gamma globulin. Not only did I see no repercussions from that, but his health has continued to improve ever since.

I have spent the six years since attempting to understand what we know about the immune status of so many children in this

current autism epidemic and looking for ways to help my son and the many children like him.

Clinically, one of the things I do know is that removing complex carbohydrates from their diets causes major global improvements in the vast majority. As you can see, my son was just too sick to ever recover. By the time I started him on SCD he was already nine and a half years old. It was too late to save him, however, even at his age he does continue to improve in many ways.

We've gone from that toddler leash and being prisoners in my home to being able to go out and have fun, to eat out, to go on vacations and even to be here today. Over these years, I have found several more treatments that have helped, all immunologically based, including things like the antibiotic minocycline and helminthic therapy.

Essentially for children like Alex, pharmaceutical and natural treatments

that modulate the inflammatory response seem to have profound global effects. Thank you.

Mr. Bell: Thank you very much, Judy. You know what, Alex, you have an amazing mom who's done amazing things for you. And just as much as she has done some extraordinary things, you have done some extraordinary things yourself, congratulations.

In the early 1990s the prevalence of autism was about 1 in every 2,500 children. By 1998 the rate was estimated at 1 in 500, and the word epidemic started to surface. Most of us can recall how this rate eventually reached a staggering 1 in 150 when the CDC published its study for the ADDM Network in 2007.

This study examined the rate of autism in 15 states across the country among eight year olds who were born in the years of 1992 and 1994. This cohort is now 15 to 17 years old.

The next two speakers are from the older end of this cohort. Both children were born in 1992, diagnosed when they were three to four years old, and received the best medical care available at the time. And while their outcomes are very different, I view them both as enormous successes.

Our first speaker is Elizabeth Emken, mother of 17-year-old Alex Swartz. Until last month, Elizabeth was Vice President for Government Relations at Autism Speaks and has been a long time advocate for those that are affected by autism.

In fact, Elizabeth was involved in the development and passage of the Children's Health Act of 2000 and the Combating Autism Act of 2006. Since both of these acts established the IACC, you can probably argue that she had a big hand in the creation of this committee.

However for Elizabeth, an even greater accomplishment is the fact that she's

here with her son Alex, and earlier this week Elizabeth announced her candidacy for the U.S. Congressional Seat of the 11th District located in Northern California. So it gives me a lot of special mention to say Elizabeth, please join us, and Alex, up here and speak with the committee.

Ms. Emken: Thank you so much. Dr. Insel, I want to really thank you and your staff for having Alex and I back here today. I really appreciate it.

Dr. Insel: Thanks for coming.

Ms. Emken: Thanks. So I'm Elizabeth Emken and this is my son, Alex Swartz.

Mr. Swartz: Alex Swartz.

Ms. Emken: When Alex was diagnosed with autism at age four, I became first and formerly and then professionally an advocate for individuals with autism and then ultimately for all special needs children.

Gosh, until recently I was, I hate

to say it in the past tense, Vice President of Government Relations at Autism Speaks, the nation's largest science and advocacy organization devoted to this emergency, this national public health crisis that autism has become. I just recently announced my candidacy, as Peter mentioned, for Congress in the 11th Congressional District in Northern California.

Alex and I are here today to show the committee an example of a person living with autism. We all know that autism is a spectrum disorder, but at meetings like these, which are very orderly, with scheduled speakers and tented name cards, the environment is best suited for those on the spectrum who can express themselves.

Alex is on a different part of the spectrum.

Mr. Swartz: A different part of the spectrum.

Ms. Emken: And he represents a

significant number of individuals living with autism. Most individuals with autism cannot walk up to this microphone and tell you what's on their minds. Most can't talk about how they feel and discuss their hopes and dreams with you. Many couldn't be here for today for more than --

Mr. Swartz: How are you?

Ms. Emken: Almost time, almost. For more than a few minutes. Okay. He knows it's time, Alex do you want to say something? Not too loud. No, let's do your name, how about your name?

Mr. Swartz: Alex.

Ms. Emken: And what school do you go to?

Mr. Swartz: San Juan Valley High School.

Ms. Emken: That's right.

Mr. Swartz: Ladies and gentlemen --

Ms. Emken: That's right. Stand

right here why don't you, so we don't blow everybody's ears out. How about your sisters' names? Your sisters?

Mr. Swartz: Hailey and Emily.

Ms. Emken: Say it better.

Mr. Swartz: Hailey and Emily.

Ms. Emken: Right. And what about, do you have a pet? What's your pet's name.

Mr. Swartz: Sam.

Ms. Emken: Tell us about Sam.

Mr. Swartz: Pet's name.

Ms. Emken: And what kind of pet is he? Go ahead tell them.

Mr. Swartz: Cocker spaniel. Ladies and gentlemen --

Ms. Emken: Alex is a happy, happy boy, and that means so much to our family. Get back away from the microphone now. Peter was mentioning earlier about different abilities that individuals with autism have, and Alex has, we like to call it his parlor

trick, meaning no disrespect.

But it's very helpful at parties whenever we go to a house with lots of kids around who aren't on the spectrum, this is something that we do that pulls Alex right in to the group and gets him interacting with the other kids.

So, Dr. Insel, I'm going to have you be the subject of our demonstration here if you don't mind. Alex, let's go see Dr. Insel real quick. Dr. Insel.

(Off mic comments.)

Dr. Insel: October 19th.

Mr. Swartz: Alice in Wonderland.

Ms. Emken: Alice in Wonderland. Everybody should know their Disney movie, don't you think. So if you would like to know yours at the break, Alex would be happy to provide you with that information.

Mr. Swartz: That's microphone.

Ms. Emken: The microphone, I know you love it. Okay, mommy's turn, okay?

Mr. Swartz: Mommy's turn.

Ms. Emken: My turn?

Mr. Swartz: My turn.

Ms. Emken: Okay. Just for a few minutes, okay? Thanks. That's really all Alex can share with you today. He can't tell you how it is he came to be here, he can't explain his background or his education.

If he could, he would tell you that he excels in math. He is currently doing well in an Algebra I class, and he tested within 27 points of passing the California High School Exit Exam. His language comprehension skills, however, hover at around the second grade level.

He is even more limited in his conversational skills. It is unlikely that Alex will go to college or that he will get a job in the traditional sense. But we're hopeful about his future and we're optimistic about what he will be able to accomplish if he's afforded the necessary assistance.

He will likely be unable to live alone or to get married. He won't be forming a 501(c)(3) to promote his interests. Autism has left Alex profoundly disabled. Intensive behavioral therapy provided beginning when he was four years old has, however, enabled him to travel here today from California by plane and sit at this meeting for awhile. We'll see how long.

And he loves school, loves to travel, big traveler, and he misses his family when one or more of us are away, and he always insists on knowing what city we're in.

But if Alex could say this to you today, I'm confident that he would ask you for help in curing his autism. Curing his autism. I spent many years on the Board of Directors of Cure Autism Now, and I was fortunate enough to be afforded the opportunity to build the government relations department at Autism Speaks before my recent departure.

I do believe that autism is a

disorder that should be cured, an affliction that robs individuals of their ability to lead a productive life. It robs most of them of their ability to address you here today. It robs them of their liberty and their ability to pursue their own happiness.

Autism for the vast majority of those that struggle with it everyday is the difference between a life of independence and of life-long dependence. We should not accept autism as a naturally occurring variant of the human condition, unless we have unequivocal proof that autism is in fact a naturally occurring variant of the human condition.

And as of today, we do not have the foundation of knowledge to make that claim. Therefore, as a parent of a significantly impaired young man with autism, I implore the IACC to aggressively, aggressively pursue causation mechanisms, including potential environmental impacts on genetically susceptible individuals, effective

treatments including psychopharmalogical intervention and aim for nothing less than a cure for autism and return to normal functioning.

Thank you again so much for your attention and thank you for your good work.

Mr. Swartz: Goodbye. Ladies and gentlemen.

Mr. Bell: We have a date for french fries today at lunch, so thank you, Elizabeth and Alex. We can only imagine what it's like to travel across country to be here for this meeting, and I'm sure we all share what a moment this has been for you to be here to address the members of the committee but also the autism community at large who's here in this room as well as who may be watching us on video.

Our next speaker, like Alex, was born in 1992 and was diagnosed with autism in 1995. But as you will see and hear, his trajectory was very different from Alex's.

Today, Jason Ross no longer meets the criteria for autism. He's recovered.

As recently reported, it is believed that between 10 and 20 percent of those diagnosed with autism can recover or at least lose their diagnosis. More research is warranted to better understand this phenomenon, but now there definitely exists greater recognition that the course of autism is not necessarily stagnant.

Although Jason's mom, Nancy Ross, is here with him today, Jason will be speaking on his own behalf. Jason Ross, please join us at the podium.

Mr. Ross: Okay. Fantastic. First things first, I would just like to apologize for the photo. I think I'm a lot more attractive in person.

Sorry, I just want to get everyone to laugh because I think -- my mom's over there, Nancy Ross, and I'm always the guy who's trying to make her laugh because I

believe that, well, you know, part of me just wants to make her happy and another part of me just thinks laughter's good for people.

So I always like to start anything important in my life, whether it be a really important college interview or a huge meeting like this, I like to give a little chuckle or a laugh out just to begin.

So let me start. Hi, I'm Jason Ross and I'm here to tell you my story. Before I do that I want to comment on what I heard this morning from the families here who are touched by autism. I applaud them, I applaud their courage, their bravery, and I wish them only the best.

My story has similarities to the other stories that we've heard because I, too, was touched by autism. Today I'd like to cover two areas. I'd like to cover my years with autism and what it's like to be on the other side of autism.

I know my history because for the

last two plus years I've read through hundreds of journal entries, medical reports and I've asked my mom tons of questions.

In short, I was diagnosed at the age of three and a half in July of 1995. My diagnosis was apparently late, but my mom had fears and concerns from when I was 17 months old all the way up through my first diagnosis.

My first diagnosis was by a developmental pediatrician who said I had infantile autism. Shortly after, the Yale Child Study Center diagnosed me with PDD. I was evaluated and monitored by Dr. Michael Powers and Dr. Deborah Fine in December 1995. They confirmed my PDD diagnosis.

I quote, "Last summer, Jason was extensively evaluated. He received a diagnosis of infantile autism from a developmental pediatrician and a diagnosis of pervasive developmental disorder from the Yale Child Study Center. The evaluations noted many features of the autistic spectrum."

"Language was not used communicatively, speech was echolalic, eye contact was fleeting, play was not purposeful, prior OT evaluations found delays in fine and gross motor development, poor balance, and difficulty processing sensory inputs."

She went on to say quote, "Jason still meets the criteria for PDD although he has made significant gains in language and social interaction since the summer." I had Yale Child Study Center and Dr. Michael Powers as my primary help for the next several years.

Here's the abbreviated story of the type of therapy I had. Between the ages of three and a half to five and a half, I had the full regimen. The ring leader was my mom, then I had a general therapist, a few speech therapists, a physical therapist, a gross motor therapist, a fine motor therapist, and two occupational therapists from Hartford Hospital for children, plus my nanny was trained.

This was the early days of treating autism, and we lived in a rural community in Northwest Connecticut, so there wasn't a lot of resources like there are today.

Apparently there was one book, Let Me Hear Your Voice, by Catherine Maurice that described ABA therapy. The first year was spent doing a home baked version of ABA and a ton of speech and everything else was layered after that.

When I first started to study my journals that accounted my ABA therapy, it was very frightening for me. I was torn between a profound sense of disbelief and sadness. It was clear that my family and I were subjected to an unwelcome journey, there was consistent panic about my future, years of intensive remedial work, handlers and therapy that covered every aspect of my existence.

Words jumped off the page from these journals describing my physical,

emotional and cognitive state, clumsy, non-responsive and uncoordinated. Whether it was learning to work with a speech therapist to say my own name, having my fingers clutching triangle shaped pencils, learning to look into someone's eyes, or simply learning to open a door, my life was defined by therapy, repetition, discipline and rehearsals. Nothing in my life was spontaneous.

Some of you may wonder if I had any other medical problems of note, and the answer to that is no. You may also question whether all my therapies worked, apparently not.

There were experiments with changing my diet, cutting out processed food and sugar, and it seems that they didn't do anything. Also, there was an art to getting the right therapist to help me, so there was apparently a lot of recruiting, hiring and firing of folks in order to find the right mix

of people to help me.

Although my mom played a huge role, I also realize that I played an integral part in my metamorphosis. As I read through the journal entries, it is evident that even though I was very young, I demonstrated an intrinsic doggedness, a determination noted again and again. It was the willingness to endure and eventually excel through a grueling daily regiment, a regiment that lasted for about 16 hours a day, seven days a week.

Some may wonder whether there was a big breakthrough. Apparently there wasn't. It was a slow grind, more like inch by inch. Two years were spent with the entire contingent. By first grade, I was able to go into a regular class with an aide, and that's when to the surprise of many I learned to write. And by write I mean the physical act of writing and read.

Reading was probably the key because it unlocked so much for me because

once I could read I could really put meaning behind words in a book and it held my attention. And after that, I just buried myself in the world of books. I still have a profound love of literature. We just read Hamlet and I just can't get enough of it. Writing was a slow process, but it, too, was well worth it.

Now I'd like to talk to you about me today and what it's like to be on the other side of this diagnosis and of autism in general. First, I'd like to say that the process of discovering myself was and continues to be intense and sometimes painful. It has taken me several years to absorb its full meaning, and I'm sure that there is more that I will continue to learn and understand as I am trying to do today.

Today on the other side of autism, I feel strangely lucky to have had the experience as it gives me a distinctive view of the world. I say I beat autism, but it's

part of my history. There are things about me that are clearly straight from my autistic days, my discipline, my endless willingness to try new things, my love of reading and writing, and my feeling of having lived a past life.

I will always know that my childhood wasn't typical, not innocent. In fact, it was full of worry, it was full of work, it was full of charts, it was full of entries.

So today, on one hand I feel really lucky. I'm a senior with all the happiness and hopes that you see many other senior guys talk about. I'm happy because I go to a great school, got a great family life, got good friends, I'm a great playwright, I'm the co- captain of the cross country team, I drive my own 11-year-old Volvo.

I'm facing down the final and hopefully the best year of high school. I'm hoping to go to a great college like

Georgetown someday, hoping to get the best girlfriend, hoping to get the best job, but most importantly the reason I'm here today is I hope that I can make some type of impact on the world as I get older.

So I have this history, and I'm a history buff, and I know that history defines and shapes people. In my case, my history with autism defined and continues to define my reality. I have to help others who have autism. Maybe autism will be better understood in a few years or maybe it will just take the rest of my life, but I don't care because it's a part of me.

So that's my story and let me end with this message. For me, "autism recovery," in quotes, was possible. We know more about it than when I went through it, but it's still not enough. I can't tell you why my therapy worked, and I'm very sure the same therapy that worked for me may not work for somebody else. Unfortunately, a lot of autism is still

a mystery.

All I want to say is before I hand the mic back over, I just hope -- I don't want to give it to you falsely, but I just want to give some people here, especially the people sitting on that panel, because you guys are the people who really can work the machine and advocate on our behalf, I just wanted to give you all a little bit of hope today. That's it.

Mr. Bell: Jason, you give everyone in this room and everyone who watched that speech, not just a little hope, you give us a lot of hope. As the dad of a young man who's not terribly different in age, I look at you and I have a profound sense of respect for what you've accomplished, but it also helps me look at my own son in a very different way.

And I thank you for that personally, and I'm sure many other people in this room also thank you. And, Nancy, thank you for sharing Jason and his story. It takes

a lot of courage, I know. So thank you both.

Fortunately, increased attention is now being devoted to the topic of adults living with autism. Today, we are fortunate to have two individuals with us representing this growing segment of the community.

Our first speaker, Adam Berman, was first diagnosed at 18 months with PDD. His doctors told his parents that he was severely retarded, however, with intensive early intervention and other therapies Adam made significant progress and graduated from high school with his peers.

He then attended the University of Maryland and graduated in three years. He currently works as a special education paraprofessional while attending graduate school at George Washington University where he's working on a degree in acquired brain injury and transitional services.

Eighty percent of his tuition is being covered by a fellowship. Recently, Adam

lobbied for autism insurance reform in his home state of Maryland. Adam's parents, Jeff and Diane Berman, are here with us today in support of their son, and they couldn't, I'm sure, be more proud. And Adam is going to speak on his own behalf. Adam?

Mr. Berman: Hello, my name is Adam Berman, and I would like to address everybody here, members of the panel and the audience, not just as a person with autism, but also as a paraprofessional and a graduate student studying special education and brain injury.

With all that I've gone through, I've learned a lot, but I think one of the most important things is that interacting with people is a very dynamic process, and with my autism, I've found it very hard to be a part of this dynamic process at the beginning. But as I go through my life, it becomes a little bit easier each time.

So how did I become used to this

dynamic environment that's so hard for a lot of people with autism to cope with? Well, to start, early intervention was very important. I had ABA therapy 40 hours a week, and part of that was circle time as well. Circle time isn't the academic sort of treatment, it's more like a let's get together with your peers and do some activities like singing and reading.

Initially when I was at MPAC, Montgomery Primary Achievement Center, where my early intervention was, I really didn't like circle time. I'd run around and refuse to go into the circle time, and I'd have the teacher assistants carry be back and put me on that chair and tell me you better sit.

Eventually, I became used to it and became able to cope with dealing with my peers and the singing and the reading and things of that nature. I was mainstreamed in first grade where, again, I would have to cope with more of a dynamic nature of society and

being with peers.

Being mainstreamed was very difficult initially because I had to deal a lot with meeting new people, dealing with a crowded classroom, totally different environment which was very hard to deal with.

I had a lot of therapy, I had speech therapy, I had -- I went to the guidance counselor a lot. I had a lot of issues. I was very anxious as a child with dealing with my peers. I'd often cry over a lot of things. I'd cry if I felt slightly rejected, I'd cry over a bad grade, and by bad I mean C or lower.

So I had a lot of times where I went to the guidance office. That was very helpful. I had a reading coach. I even had somebody teach me how to tie my shoes in second grade because the teachers got sick of helping me. I had a little issue with motor skill so they had to address that. So I had to learn how to tie my shoes in second grade

when a lot of kids might have done it at three years before that.

I was mainstreamed in elementary school, however, I felt my abilities were short changed when I was in the fourth and fifth grade where I was placed in a lower math class than a lot of my peers because of my autism despite my scores on mathematics tests that indicated that I was very capable of performing at a high level for mathematics.

I was placed into -- there were four levels, four classes of math, and I was placed on the third one, on the third lowest. There was a high one, a higher and a kind of low and then the lowest. I was placed on the third one of that list, and I felt short changed because I saw most of my peers were in higher ones, and I'm like what the heck am I doing here.

It wasn't until a very astute teacher noticed that my test scores indicated that I did not belong there. She asked me

later in the week if I wanted to do extra work during lunch and recess to study for about six weeks and take another achievement test to make sure.

I gladly accepted knowing that I could achieve much more. After that experience for six weeks, I went up to math class and received As. I graduated with elementary school looking forward to the whole challenges of new math and higher math.

And I went to middle school, and I would say that was particularly hard, the middle school because the building -- it's very little differences that you notice, but like it was old and gray, and I really didn't like it.

So I think might have had an impact as well as the transitioning from one period to the next, I really didn't like that. So it was a lot of footwork in getting used to a new environment which was very difficult. And also the special education services

weren't good at the initial middle school, so my parents sacrificed a lot to move to a new area where the middle school provided better special education services.

So my parents were out there a lot for me and they looked out. And I was pretty upset about the move first because the couple of friends that I did have, that I had to work so hard to make at my old place, I had to move and try to make new ones. I was a little upset about it at the time, but I understand what they did now, and I'm thankful for it.

In high school, I, again, I was -- the transition into high school as a freshman was very difficult. I tried out for the football team, I played on the football team, but I thought I was going to start on the team. Of course I didn't because I didn't have any years of experience and I was kind of goofy running. I had a little difficult running, I'm pretty slow running.

I don't know if that has to do

with the autism or not, but it's a little difficult. And I was in geometry as a freshman, and I had a difficult time with another fine motor skill, we were doing something with a compass and a protractor, and it was really difficult and I got a D on that whole unit, and I was really upset with myself.

So freshman year was very hard. Football did help. I felt like I was being with my peers and getting something useful, exercise especially. But what really made high school a very unique experience and very worthwhile was something called Montgomery Exceptional Leaders Program where I learned how to speak. And this is where I started to learn how to be dynamic with people, with audiences, to know how to be flexible with speaking because I can't just be in my own world, I have to connect with my audience.

I did it for two and a half years, and I learned at first I had to use cards and

things like that and be a little nervous. I read and my speech wouldn't change that much. But as I went through, I learned how to speak from a more holistic point, from a more dynamic point and learned to look at people in the eye, learned to make certain jokes that might connect with the audience better than others, like saying underwear jokes at a professional setting wouldn't work well where as it would work well with an elementary school setting.

And I spoke to various places in high school, including my board of education, which was very rewarding because I told them how -- what worked and what didn't, I told them about early intervention and the therapies I went through and how available guidance counselors were for me and what was needed to be done and things like that.

And this is part, when I went to college I felt the most short-changed because there were a lot of issues with transitioning

to college. Granted, I had a lot of issues transitioning from elementary to middle and middle to high school, but high school to college was probably the most difficult.

My whole freshman year, I didn't get a lot of advisement on what to do. At first I thought I wanted to be a veterinarian so I took a lot of chemistry and boy was I wrong. A lot of work. That and I had to be in a dorm that looked like my old, old middle school. So it was very depressing, gray, no air conditioning, there was heating though. It was dirty and -- I don't want to think about it.

Yes, that, and there's wasn't a lot -- on top of the lack of academic help with transition, there wasn't social transition because I was naive enough to believe that trying to join a Greek organization fraternity would be beneficial despite it not playing to any sort of my strengths.

Of course I didn't get a bid, but I think that was for the best in the end because I hear a lot of people now kind of complain that it didn't help much. But at the time I was really disappointed and felt like I was worthless and I'd sit outside by myself for a good half hour after I heard that I didn't crying about it.

So what did I do after that, is I tried to start a group kind of like my high school group where I would have people speak to the community. I got it started, but it didn't work out as well as I thought it did, but I hope somebody there at Maryland right now is trying to get that started up again.

So anyway, after I graduated in three years -- how I graduated in three years was I did a lot of winter and summer courses because I realized that I picked the wrong major so I'm going to need to catch up with my new major of psychology so I had to do that.

Then I realized, I'm getting sick

of all this college stuff, the workings of college, all the obsessiveness with drinking and all that stuff and going -- living in a dorm so I decided to, let's try and get out of here early and see if I can do something more that I want working with children with special needs and autism.

Also during my senior year, I worked with -- I worked at my old pre-school MPAC for about a year and a half and I taught -- and I was a practitioner of applied behavioral analysis at the school. And I felt that was very rewarding and that's where I find myself today, being a paraprofessional and in grad school at George Washington University in acquired brain injury.

Given all that I complain about my college and all the social events I had to turn out to, I realized that it was for the best and that learning how to be part of society was very helpful for me.

Granted, I still have some issues

dealing with people, but I've become better at it slowly so I can anticipate how to be appropriate with people, not perfect because I'll still not look people in the eye, but enough to control my own volume, things like that.

My parents always would complain about me being too loud. I still am often, they'll tell me voice modulation disorder extremely obnoxious, it's an acronym we created, VDO. So I still need a little help with that.

But I feel that as a person working with children with autism and other special needs and a person with autism himself, I feel that we need to be placed in a least restrictive environment in a sense where we can be placed into a group of people where we can learn to interact with each other and learn what's okay and what's not.

Because things like social skills therapy, while they're pretty helpful doesn't

give you the whole feel of what it's really like because you might learn something in social skills training, but you might not be able to correctly apply it in a real world setting.

So I would say that least restrictive environment, this doesn't just refer to school, this refers to activities. My parents would often make me do activities, some that I didn't like, but I realize now what they were trying to do and they were trying to place me in this least restrictive environment and get me to be social with other people and learn the rules of the game as people like to call society.

Also, I would say transitional services and a better emphasis, not just on a job per se, job would be very nice with transitional services, it's a good start. But I would say even if you're looking to go into community based -- dealing with people in college or even trying to go to do new

activities, it transitions to those from a kid to an adult would be very useful as well.

Because, I mean, I couldn't -- I had a lot of trouble guiding myself because I really didn't have the insight to know what would be good for me and what wouldn't, in the sense that I thought joining a fraternity would be the best idea and it really wasn't.

So something, a guiding hand with transitional services to deal with work and social issues would be beneficial so that people with autism can learn the rules of society and the game, as I would like to call it, in the best possible environment. So I thank you.

Mr. Bell: As I was going through security this morning I saw Adam in line, he was on his own, he had driven here and parked in the visitors lot and I actually think he probably did the -- figured it out the easiest of all of us on how to get into the NIH. So congratulations Adam.

Our second adult representative and our final panelist this morning is going to be Troy Cunningham and his mom Sondra. Troy is 38 years old and was born at a time when autism was considered a rare disorder and sadly, it was also a time when some still accepted the notion that bad parenting was a cause of the disorder.

Although much progress has been made, as you will hear the Cunningham family continue to face real challenges in helping their son. Troy is here with Sondra, Sondra is the Executive Director for the Local Autism Society chapter here in Washington, D.C. and we're happy to have them here to show us the older end of the spectrum.

Ms. Cunningham: Good morning. As Peter said, this is Troy. Troy is 38, I'm going to see if he can say hello. Can you say hello? Okay. And I don't think he's going to want to stand the whole time.

Okay. As Peter said when Troy was

born in 1971 I believe it was 1 in 10,000 person who had been diagnosed with autism. Also important, Troy was in the group of babies, the last babies born in what was Freedman's Hospital.

He spent about five days in an incubator because of some problems at birth. But from that time on, he seemed to develop into a normal child.

We thought he was developing well, everybody thought he was oh so pretty, you know, such a big pretty baby and I would be embarrassed sometime because people say old is he, and I would give them his age and they would say, oh he's so big. And I guess about 18, he was about 18 months and I had some friends who worked at Sander Spring Friend's School in Olney, Maryland.

And they got to asking about Troy, why he wasn't talking, they thought maybe he had a hearing problem. So I said no, but anyway I got to thinking about it so I called

immediately to Gallaudet, to the Kendall's School and we went in for a hearing test. Troy's hearing was fine.

So then I went to his pediatrician, Dr. Crawford, who's now deceased, he said oh, nothing wrong with that boy, he's a big old handsome boy. You know, he said boys develop later than girls. So we said, okay.

And then one day I saw a commercial, I was home during the summer break because I worked in the public school system for about 34 years until June of 2002, about autism. And so I said well maybe that's what it is.

So then I called, I had a friend at Howard University in the child development center, so I called, we got an appointment and they looked and took questions and did this, did that, but no answers. But she did send us to the Linwood Center in Ellicott City, Maryland where Troy was evaluated and was

diagnosed with infantile autism.

Okay. So we said, oh, okay. They have a school there and this was `74 I guess, three years, two years old, I don't know how, time - - I'm so old now myself. But anyways, I thought the school was $900, you know, come to find out it was $9,000.

I said oh my goodness. But anyway, we finally ended up at Georgetown University's Child Development Center for further evaluations. And Troy was eventually accepted at the Easter Seals Society's school.

He stayed there until he was five and the Director of Special Education for the District of Columbia had observed him at that particular facility.

So I remember him making a request for him to be put in a special school, some kind of way he got to go to the American Foundation for Autistic Children, which was located in Chevy Chase at the time.

And he stayed there until I think

he must have been about seven. The school's license was abruptly discontinued or the contract was canceled with the District. So around eight, I believe, he started at St. Johns Child Development center. It's now St. Johns Community Services.

He stayed there until age 22 and finally when his promotion in June of that 22nd year, because they let him stay until June that September he started in the adult day program at St. Johns, the rehabilitation program.

And St. Johns had already decided that they were not going to warehouse their clients in a room where they just sat around. So they went out into the community, they were actually, I guess volunteers.

He worked in the kitchen area where they had meals, fixing trays, they pulled trash at Mazda Gallery, cleaned toys at the hospital for sick children, prepared things for mailing. So he stayed there until

October of 2002.

And the only reason he is not still a part of that program, Troy -- I was told he had a seizure at the day program, but he didn't fall. So they sent him to the hospital in an ambulance with no one from the program to Greater Southeast, it was Greater Southeast then.

I don't drive a car, so I had to get on the bus, two busses in fact, go to the hospital. And when I got to the hospital, there was no record of Troy in the hospital. So I made some more calls and then finally I yelled through the triage window, do they have somebody back there named Troy Cunningham.

So they did and he kept pointing at his shoulder. We later discovered the shoulder had been fractured and for several months, from October to February 2003 he was in therapy, two or three days a week. His shoulder is not, still does not have full range of motion.

From there he went to PSI, he stayed there for a couple years. Today Troy is employed, in fact he's missing a day's work, he works at the Value Village Thrift Store in Landover City, Maryland. He's been there since late May of 2009.

Prior to that, he worked at the Giant where he restocked things that we leave, you know, we pick up and then we decide we don't want them, we put it back on a shelf. So he did that, he did that quite well.

Troy, he really enjoyed the job because he knows he loves going to the Giant and I try to always leave him and his father at home because my basket has all these extra things. And because he knows certain things. He likes the Hi-C's, when he gets home, he likes a Hi- C's and a bag of chips. So he knows where those things are and where to get them in the store.

He also can remind me if I need napkins or paper towels and he can actually

read the signs. He can't verbalize it, but he knows how to read. I used to have to hold his hand when I went shopping, there used to be a Lane Bryant store at 10th and E and he would pull all the tags off the clothes and put them in his pockets.

And he had so many and he cut out the -- pull out the yellow pages, household finance and the Mercedes Benz ads and he would put them in his pockets. So finally I got him a bookbag for that purpose.

But Troy still lives at home with us. We, just in the last week or so, asked the District of Columbia, Department of Disability Services if we can have some, I guess, assisted living quarters for Troy and several others who are in our chapter here in the District.

We were at the bottom of the list, because they said there was no emergency, but what we were trying to avoid was having an emergency and having our children going to any

of the group homes in the district. And you may have read about two just last week.

We don't want him to be in a group home where -- people who have the power of speech can have him doing, and most of our children doing whatever. So we wanted to be a place where we know the provider and that we can go and check on our children because there are so many in the District who still live at home and need this service.

So hopefully, we'll know something very shortly. We have selected a very nice home, there will be three individual, three young men, they're all about the same age. I think one is about 40, the other two, the other young men is the same age as Troy and they've known each other for the past 30 plus years.

Also they will have a companion there, a program director and somebody to be there during the day. We'd just like to ask the committee to let those who have the money

and the wherewithal to -- there are so many adults living with autism that are not even registered anyplace because of misdiagnosis and those who were placed in institutions years ago.

So we need to do, I guess, an adult find for those adults who are living with autism. And autism need, we need a lifespan care. You know, there's no, you know, it's nothing something that you have a shortened lifespan, we need care across the continuum of life.

And really, that's -- and I got this quote from somebody, I think Dr. Schopler. Dr. Schopler said, "A nation has three choices, do what's right, that means providing appropriate services, do as little as we can get by with, which would be custodial care, do what Hitler did, dig a big ditch."

"But as parents, families and professionals, do we have the will to do the

first. If so, we must build on what we already have, which is more than any nation in the world and continue to work for what is right, labor into the night if necessary," end quote.

Thank you and I'm really just been so moved by the testimony of all the panel members and particularly the young man, two Alexs' and Adam. You really give me hope and I wish some of the other members of my chapter could have been here to witness this. Thank you very much.

Mr. Bell: I'm sure you all will join me in thanking these families for being here today for sharing their stories with us in a very profound and honest and open way. I want to say a very quick thank you to Ann Givens, who's our Local executive director who helped identify some of these families who could come here today and obviously all the others that traveled from afar.

I started our panel today talking

about the differences that our community has and I think what we've found here are a lot of commonalities and similarities. The love and commitment that these families have for their children is unquestionable.

When you get a diagnosis for autism for your child, your world changes forever. And everyone of these families that are here with us today and every one of the families that are touched by autism have gone through the same experiences.

And I don't envy this committee because of the responsibility that you all have to make a difference for this community. And this is a community that has suffered for a long, long time, has made great strides over the years and we're, I believe, at the cusp of making profound changes in the future for those that are effected by autism.

And so, as we all kind of take a deep breath and hopefully have a better recognition of the diversity and the breadth

that the spectrum holds. I hope that we all can come together on a common front and make those profound changes that this community needs.

We need to heal, we need to move forward and we need to make a difference for the futures of our children that are affected and touched by autism.

We hopefully have a couple minutes to do a few questions, but before I do that I want to share a quote that my wife and I have recently used as we go through the transition years for my son.

And it's a quote from Goethe, who is a German poet and philosopher and it is as follows, "If you treat a man as he is, he will remain as he is. But if you treat him as if he were what he were capable of becoming, he will be all that he can be." And I hope you all can share that same philosophy as we look at the futures for our loved ones that have autism.

So without any further adieu, are there any questions for the families here? These people, everyone has been so wonderful, I know how challenging it can be to be here, but thank you, all of you that are here. Peter?

Dr. Insel: Listen, I know that people --

Dr. Shore: This is Steven Shore, can you hear me?

Dr. Insel: Yes, just a moment Steven we'll queue you in here in just a sec. I wanted to say briefly that we're mindful of, this is not the easiest place for some of you to be sitting. And so we don't want to take a lot more of your time.

But if we can take a few minutes for additional questions and conversation, I think the IACC would really appreciate it. Steven?

Dr. Shore: Yes, a couple of things. One is that as a person on the autism

spectrum and I guess as a member of greater humanity, which we all are, I really appreciate seeing parents and people with autism coming to the IACC and explaining how things are and explaining how things can be.

The other thing is that I'm wondering if there's a way that I can get connected online to the visuals so that I can see what's going on in addition to hearing, because that will probably become more important especially when there's a PowerPoint presentation.

Dr. Insel: We will certainly take care of that and you'll need to give us some feedback if it's not working.

Dr. Shore: Okay. I guess sending the information to my e-mail that would be great.

Dr. Insel: Right. So let me open this up for the committee. Maybe if I can -- well Ellen, since you were the one who has -- go ahead.

Ms. Blackwell: I just had a comment. My son Robert has something that he likes to say that I'll share with you. Robert says, "Autistic fantastic." So thank you so much for giving us an autistic fantastic day.

Dr. Insel: That's great. Let me sort of see if I can do this well on behalf of the committee. I'm not sure I can, but I think what we have heard from you, which has been so inspiring and so important, is that we talk a lot about the heterogeneity of the spectrum, and Peter you began with that and mentioned how often we're very focused on those people who can come here and actually talk for themselves.

I think you've given us a much better picture of the broadest part of the spectrum, again, mindful that no one person represents more than a fraction of that. But what's been so interesting is that when we talk about it, we tend to talk mostly about the diversity of needs.

What you've shown us is really also the diversity of gifts, that each one of these people has something very special that they can do. And whether it's the ability to identify the Disney songs or to do some pretty interesting math or whatever it happens to be that someone finds their way to it.

And that, for this committee, is just as important as being so focused on the disabilities, which is so much of what we have grappled with. And I think for all of us, that is going to be important to remember from this presentation and a real inspiration as we go forward.

The other thing that I'd like to close with is just to emphasize Peter's comments that while each of the people on the spectrum who have shared their experience with us today have clearly been challenged.

They have also been incredibly fortunate to have families that are so loving and so committed and so resourceful, it's just

extraordinary how often people who need exactly that kind of love and support have ended up finding it in places where maybe nobody even knew it was there before.

And that, as well, I think for every one of us is a great source of inspiration and hope. And so, thank you on behalf of the entire committee. Some of you have gone to great difficulties getting here and not the least of which is getting through NIH security.

So we appreciate your ability to navigate that as well as airports and trains and everything else that you needed to do to share this with us. With that -- Stephen?

Mr. Grossman: No, this is Lee Grossman.

Dr. Insel: Lee? Yes, go ahead.

Mr. Grossman: Sorry that I can't be with you today, there's some circumstances that came up that has me on planes, trains and cars all over the country today so I'm calling

from an airport right now. But if you don't mind, I would like to ask the panel a question, I also want to thank them for their participation. Is there still time for that?

Dr. Insel: We've got just a minute, because we're about 20 minutes over schedule.

Mr. Grossman: Okay. Well then they're going to have to decide who should answer this. But I would really like to hear from the panel or from a couple individuals what they believe is the most important message that they would like the IACC to walk away with in terms of what they're trying to get across to us.

Dr. Insel: Anybody want to take a swing at that pitch? Judy?

Ms. Chinitz: I want to make sure that everybody in this room understands that there is a contingent of children out there that are incredibly physically sick.

Okay, and even before Alex was

diagnosed, when I was calling his pediatrician and taking him to the doctor continually, I kept telling her he's acting this way because he's sick, before I knew what acting this way even meant.

And I have a degree in special education, I didn't recognize what was wrong with my son, because the special education I had, you know, in school, I had been taught that children with autism were that way from birth. My son was not that way from birth. He was fragile and he was sick, but he was not autistic.

So if there's one thing that I want to emphasize is that now I got another degree in nutrition, I work with kids all the time, you can make children get better by treating the physical illness. Of course the kids that I'm seeing are a like group, they're people who are coming to me because they are sick.

So while I know that there are

many children out there who don't manifest clearly signs of physical illness, there also are a tremendous, tremendous number of them who do.

Mr. Grossman: I think that was great. Thank you.

Dr. Insel: Thank you. I think unless there's any other comment or any other message from the panel, let's give them all -- oh go ahead Adam.

Mr. Berman: Hello. I would say that a very important thing to keep in mind is we've had, through all of idea and the idea of least restrictive environment, I feel that for people with autism and anybody in general, but especially for people with autism, that least restrictive environment, not just in schools, but in society itself.

Whether it be having a job coach with them at a job or being in a job by themselves or having somebody there to monitor them when they're doing an activity with their

peers or them going out with their peers themselves, that providing that environment is extremely important to people with autism to learn to be with others and to learn the game and the rules of the game I would like to say.

Dr. Insel: Adam, we're going to give you the last word. Thank you very much and let's have the -- get a round of applause. And Peter our gratitude for you and others for putting this together. We're going to take a 10 minute break, we'll be back at 10:50.

(Whereupon, the above-entitled matter went off the record at 10:38 a.m. and resumed at 10:55 a.m.)

Dr. Insel: We want to -- we're a bit behind schedule, but for good reasons and I want to make sure that we move into the next item on our agenda, which is a presentation that was developed with Ellen Blackwell. So I'm going to turn this over to Ellen to introduce.

Ms. Blackwell: Hi, Lee are you

still on the phone?

Mr. Grossman: Yes, I am. I had to take it off mute.

Ms. Blackwell: Okay. Thanks. I just wanted to mention that Tony Charman is here today from the University of London. The services subcommittee presented to the IACC the topic of applied behavioral analysis-based treatments.

Certainly an important issue for families across the United States and also much debate in states regarding private insurance coverage. So Tony initially was slated to speak with Ted Carr from the Stony Brook University, who unfortunately was killed in a car accident over the summer.

So we really appreciate Tony being here today coming all the way from London to talk to us about applied behavioral analysis-based treatment. And Tony, I'm going to turn it over to you.

Dr. Charman: Thanks Ellen. And

thank you for inviting me to come and speak about intervention. It's a real privilege to be speaking after so many family members have been telling us about their experiences of autism.

Now, I wanted to think very carefully about what -- I thought it might be helpful to sort of cover in the session today, and I'm also going to go fairly rapidly because I think there are lots of good summaries and lots of you will know lots about the intervention literature to try and get some of the points across in terms of two sort of themes really; what do we know and what do we need.

Those are the sorts of things that I'm trying to encapsulate in the talk. I'm particularly talking as someone who works within the intervention field, not especially in fact within the ABA field. I have done some work in that area, but I also do intervention work on social communication

approaches that are somewhat different in their sort of focus.

And I wanted to think about the state of where we got to. So just before we start, I think it's important to say what my potential conflicts of interest are here. My government and charitable funding agencies, I have no financial interests to declare relevant to the talk.

And we know a lot about what ABA is, so here's a sort of summary slide, I'm not going to really walk you through this. There are sort of well recognized elements about the techniques that are used that come from psychological theories about behavior that's emerged after the second World War within the mainstreams like psychology field, nothing to do with autism and they're just a particular psychological theory about how to influence behavior.

And we know that what's usually characterized as ABA or sometimes now called

EIBI, early intensive behavioral intervention, is usually intensive, at least 20, 24 hours often in many programs that have been described 30 plus hours, usually commence in preschool at a fairly young age, often begins at home moves into the school.

The skills worked on follow developmental sequences. The programs are programmatic, they cover all skill to means and work very much as a program, which is both a strength, but certainly in terms of researching ABA actually potentially a limitation.

Parents should be involved as co-therapists and one of the problems about both describing ABA practice, but also understanding the research evidence-base is the bottom point, that actually over time we were talking about a rather changing practice.

And now-a-days, lots of ABA programs include aspects of the TEACCH program, PECS, I'm going to mention the

picture exchange communication system, verbal behavior, more social and child oriented practices such as pivotal response training.

So what is the evidence-base and I'm going to just show you some recent reviews in what are called meta-analysis. They're sort of statistical reviews of reviews of the scientific literature.

It's by far the most studied intervention. That doesn't in any mean that necessarily it is the most evidence-based, although it also is true that it is the most evidence-base.

But it's by far the most studied intervention with hundreds, but I suspect thousands of single case or case series reported. And then I'm going beyond individual cases where ABA, a practice, you know, is extremely well evidence-based.

One of the things that people have been doing ever since the first Lovaas studies from UCLA is trying to do more group-based,

either case control or randomized trials. Now these are seen important because in a sense, the results are likely to be more generalizable than individual case studies.

Individual case studies tailor the particular programs to the needs of that child and demonstrate benefits for that individual child and that individual approach has to be taken for every individual child.

But if I wanted to talk within, let's say, a more sort of medicalized sort of model of what's a good evidence-base and is a program well evidence-base, one usually looks towards more group-based approaches to see whether in general terms, one particular intervention benefits children more than treatment as usual or another intervention.

So there are something like 10 to 12 what we call case control sort of studies where there are groups of children who might or might not be reasonably matched and one group of children are in some form of ABA

program, usually the other group is either in a less intensive or more often a not very well described eclectic sort of program of a mixture of services, but only two randomized control trials.

Now one of the things as a scientist is there is a particular value to randomized control trials and in the trials literature, we talk about that as the trials being the best protection against bias.

And some of those people think, well what's wrong with these things called case control studies where you have these groups who are sort of matched on various variables and you follow them over time to see whether they differ in outcome.

And what randomization gives you is there may be things that you haven't measured, the children, the therapy or their family characteristics, that you haven't measured that you don't know if the groups are matched on that actually is affecting

differential outcome. Randomization is the best way of protecting against biased.

And then the point of the bottom is, is just what I sort of said before that, you know, ABA was, you know, not an approach that was developed specifically for children with autism. It's a program that came from basic psychological theories about how to change behavior and began to be applied for children with autism from the 1960's onwards.

So it happens to be that in the past 18 months there have been five systematic reviews of the ABA EIBI field. And here, they're here. I'm going to just put a quote up from each of these reviews. Two of these include this thing I just referred to called meta- analysis, which is sort of a statistical sort of pooling of information from different studies.

So in a sense you should be well placed to be really, really clear about what the evidence sort of base is. That's actually

not going to be the case and I'm just going to go through in chronological order of when these different reviews were published.

So here's the first one, published towards - - published in the beginning of 2008 and I'll read the quote for people who haven't gotten the pictures online or haven't got the text.

"In closing, early intervention for children with autism is currently a politically and scientifically complex topic."

"Positive effects of early intervention programs," and this is primarily talking about ABA, but not solely talking about ABA programs, "have been demonstrated in both short-term and long-term studies, but initial reports of dramatic changes and excellent outcomes in a large minority of children receiving a specific treatment have been reported in few studies thus far."

So that's sort of moderately positive. Here's a review that I did with

Patricia Howlin, specifically of the EIBI literature published in the beginning of 2009. One of our summary statement is, "This review provides evidence for the effectiveness of EIBI for some, but not all preschool children with autism."

That's reasonably positive. Here's another review and the summary line here is, "While this review suggests that Lovaas," is particularly focused, they're calling ABA programs Lovaas approach here, "may improve some core symptoms of ASD compared to special education, these findings are based on pooling of a few, methodologically weak studies with few participants and relatively short-term follow-up."

"As no definitive behavioral or developmental intervention improves all symptoms for all individuals with ASD, it is recommended that clinical management be guided by individual needs and availability of

resources."

This is another review from this year and it says, "Currently," it includes a meta- analysis, "Currently, there is inadequate evidence that an ABI," applied behavioral intervention they call it here, "has better outcomes than standard care for children with autism. Appropriately powered clinical trials with broader outcomes are required."

And then the most recent and probably the most positive review again includes the single meta-analysis, "These effect sizes," that's on IQ and adaptive behavior, "are generally considered to be large and moderate respectively."

"Our results support the clinical implication that at present, and in the absence of other intervention with established efficacy, Early Intensive Behavioral Intervention should be an intervention of choice for children with autism."

So as a scientist, in a sense it's interesting to think about why these systematic reviews by people from the science field are coming up with what seem like different conclusions. I think actually the conclusions are not as different as they seem when you look in detail at the studies and at these reviews.

And I, you know, spend an awful lot of time with the scientific literature trying to make sense of it. And I've gone through various reasons including some issues on the people within part of the U.K. are asking us to give views on, have gone through these reviews in enormous detail.

They have some similarities. They all use the same search strategies, so they're basically drawing on the same literature, so that can't be the reason behind why they seem to come up with the different conclusions. They have different criteria for inclusion.

So one of the things about this

particular technique called meta-analysis is that there's a sort of first root of meta-analysis, you only meta-analyze trials and the meta-analyses in these reviews actually in a sense probably should never have been done because we don't have enough trials in the ABA EIBI filed to do a meta-analysis on.

That sort of criticism or a limitation in terms of the evidence-base thus far, it just means that it's evidence-based and still building and people shouldn't be applying sort of a methodologies that we haven't yet got the information to make sense of.

It's also true that the way that the reviews have summarized trials is they use different metrics of what they count as a positive effect, what they count as a good outcome.

And the reviews include different sort of studies, some focused only on ABA or

EIBI literature, some look more generally at early intervention more broadly defined, including a whole bunch of other sort of social communication approaches I'm going to mention somewhat towards the end.

Not as a contrast particularly to ABA because those studies haven't been done, but as a way of thinking about how the science field can help sort of move the evidence-base forward.

And then this last point is critical. In a sense it's a rather banal point, but it really is hugely important to understand why there's controversy about how solid or profound or how moderate and potentially variable the evidence-base for ABA or EIBI is.

The higher you set the threshold for what you're going to count as good evidence, the less evidence gets in. And it's true in the developmental disabilities field in general. We haven't been good enough, at

running good enough studies to provide the answers that families should be able to call on us as a scientific community for our answers to.

And that's sort of, for me, a huge sort of source of frustration. I think what's happened for many decades and probably the last decade is people spent too long arguing about what they thought about the initial promising, but also somewhat flawed early studies on the ABA and not doing new, better designed good enough studies.

Now I know it's true that in studies funded over the past decade, over the past five years in particularly by NIH and by charities such as Autism Speaks, but a lot better trials are going on.

And I know from the strategic plan that we should be having more better trials going on. But as a scientist, one has to say that we haven't been doing a good enough work so that we can give the right recommendations

to families.

Other important studies that -- factors that vary between studies. Well there's all sorts of things that differ in terms of, for instance, in the ones that aren't -- the families of the children that aren't getting ABA, what are they getting?

It's often very poorly described, we often don't know the quality of what's being delivered and it's very hard to work out sometimes what ABA is being compared to.

This issue about implementation or in the trials literature what we call fidelity of implementation is very, very, variable. It's very important to describe what's being done within a study because if you don't know what's being done and what's being delivered, you don't know what's really making a difference.

And that's one of the limitations I've eluded to in terms of programmatic interventions are good because autism is a

multi-factorial complex condition, programs need to be individualized for any particular child and their family.

But it's also true that programmatic interventions, you know, make it hard to describe what's actually being delivered because a whole bunch of different stuff is being delivered and it's being delivered in different ways for different children.

And I'll pick out just some examples from the non-ABA intervention literature where I think in a sense the non-programmatic interventions that had a more specific focus allow us to do some of that working out what's going on and what's making a difference.

The outcomes, and the way that that reporting can be different, the analysis is different and then this last point I'll come back to, I think it's another critical thing for understanding the evidence-base is

people sometimes focus on what happens at the group level, which group is doing better at outcome.

But I think it's really important to focus on the individual child data too. If you're running trials, you do report the group evidence first, but in terms of understanding the variability of effectiveness of ABA but other interventions for children with autism, you need to think about the individual as well as the group. And I'll come back and give a specific example of that.

Just to say, one thing that's interesting reviewing the literature over the past 30 to 40 years, and this is sort of in terms of frequency, but also historically what was being reported as outcome, the Lovaas study and the initial studies all focused on IQ.

Then sort of began to look at adaptive behavior, often score placement that's a bit of a strange sort of outcome

because there was so many local factors within the system and within the family that are going to affect choices about school placement.

Increasingly, studies are looking at the latitude that to me seem quite important. Are these interventions improving language and communication abilities and are these interventions impacting on, I'll call it here, autism severity, could call it social ability.

And those latter things, social and communication abilities seem pretty core to me along side managing behavior as appropriate targets for intervention.

And just the final point is, I've eluded to already, is that actually increasingly approaches that combining aspects or sort of more pragmatic and social communication approaches with behavioral techniques are being developed.

And there, in a sense, whether

you're talking about a behavioral technique or a social pragmatic technique, I think the water gets a bit muddy. In some ways it's no bad thing, but it's hard to research.

So what are we to conclude from this evidence? Well, you know, we certainly know that ABA EIBI approaches are based on sound psychology theory and evidence in terms of the approach, behavioral techniques work at what they do. It's not the same as saying, behavioral programs work, but it's certainly saying it's a good place to be starting.

It's also true, and I'm not wanting to specify this any more than this sort of fairly colloquial summary, in most, but not all studies, ABA EIBI does produce at a group level, that's my particular point, positive outcomes for children with autism, I key that in for some children with autism.

However, and this is the important sort of rejoinder, at the level of the individual child in every single study, and

certainly when one runs one's own studies, you see the data increasingly people are reporting individual child data, level of the individual child.

In every study that I've seen the data of, some children make substantial progress, including interestingly in the comparison groups who aren't receiving ABA. Other children make less progress and some children make very little progress at all.

And each of those points, who makes good progress, who makes okay progress, and who makes little or no progress are all really important.

So the idea that ABA should be recommended for every child is clearly sort of something that one can't conclude, but that doesn't mean that ABA, you know, in a sense any intervention wouldn't be recommended for any child.

Because the research evidence-base, you know, isn't universal in

terms of saying every child benefits and because there are lots of limitations to what we do know about how the programs work and who benefits from these sorts of programs, the clinical decision needs to be made at the local level about the characteristics of the child, the wishes of the family and then thinking about what the most suitable intervention package should be for that child.

Some of the questions we don't have answers to. For which children is ABA most effective? The one consistent finding when this is being looked at is the brighter children, children with -- you start with a higher IQ tend to make most progress. But that's not telling us about ABA, that's telling us probably about a continuity over development.

And then a sort of critical point that in a sense this might seem a bit controversial, but I've really though this issue through, I didn't think it is, is there

evidence that early delivered interventions produce additional benefits.

The first point would be developmental theory leads us to expect this be the case. People do cite a couple of studies that are used to support this claim, but they don't really separate out what I call developmental effects from treatment effects.

And this is not a tool to argue, not a tool to argue, because I'm a developmental psychologist, that early delivered intervention is likely to have produced better outcomes for many children. It's just that we're in the controlled way, for instance within a trial, there's no clear evidence that that's the case. There's no study that I know that's set up to answer that.

And in a sense, we know enough now about how beneficial many sorts of interventions are for children with autism, I don't know how you could set a trial up to

measure that question.

It's also true that there are lots of things we don't know about in terms of comparative trials. What about ABA EIBI versus other sorts of approaches, either focused ones or programmatic ones? What about how many hours are needed?

What about what are the particular elements of any program that are affected because it's always true that if you're running services you want to know what the elements that work are because you could be spending resource on other things with those children or other children that you're caring for within your community.

That's just a general tenet within sort of health service practice that you only want to be doing the things that are actually helping and not just doing more because you think it's a good idea.

So also true, and I'm not going to dwell on this, I'm slightly aware that time is

moving on and I'm moving sort of fairly quickly because I do want to leave time for discussion, we'd like to know more about some of the complicating things.

So these are the technical terms, moderating, mediating factors. That's really who benefits and how does it work. That's really what scientists are interested in, developmentalists particularly because we're looking at autism a developmental condition.

So understanding more about who benefits and how that intervention benefits a particular child or group of children is developmentally in a sense very satisfying. It's really answering important developmental questions.

So for instance within the ABA field, people really haven't begun to ask those questions. And again, that's more difficult because it's a programmatic approach that includes lots of elements and it's harder to build what we call mediating analysis into

programmatic trials.

Then there are a couple of studies, I'm going to mention one in a moment, one is comparing, the Yoder & Stone comparing PECS to Responsive Prelinguistic Milieu therapy and sort of social interaction sort of therapy. And what I'm going to mention is the Connie Kasari one looking at joint attention and pretend clay.

And those are the only two studies that are probably testing moderating effects that which children benefit. Because there is a line of argument and it's rather technical, you can only test moderators within a trial.

So I'm just going to sort of go to another literature that I'm involved in that I know about that's really not about total programs, it's more about sort of specific sort of focused approaches. I'm just going to show you where I think there are some sort of good examples of the way that the field is moving forward.

And I think -- I don't think these are easily translatable in terms of informing ABA research, but I think it's really important to keep an open mind where the whole field of intervention trials in autism is moving forward both including those that are studying ABA, but also those that are studying different sorts of approaches.

There's no sense -- they never set up to be comparisons to ABA, but in looking at, particularly social communication focused interventions. So I'm just going to show you and not run through the detail because I haven't got time.

It's possible to run randomized controlled trials. So there are many more trials, randomized control trials in the social communication literature than there are in the ABA literature. There are two in the ABA literature. Maybe it's harder to run trials in programmatic approaches.

We can test effective elements,

what bits actually do work, do particular focused bits bring additional benefit. I'm very interested in the idea of not always just testing the big programs and the 35 hours a week, but are there things you can do to add in something with a specific prediction to produce specific effects.

Really, really informative and you can run trials to do that. And then one thing that certainly the groups that I work with have become incredibly sort of focused on is that you use trials to test theories about mechanisms and wheeling towards a very medical model of running trials.

And that's certainly for publically funded trials in the U.K. you have to do this. You will not get a trial funded, you don't put all your bucks on one outcome because you don't want people to be running trials and saying, oh look we found a difference.

There's sort of money within the

research community in the U.K. that we can't afford to run trials where you haven't pre-specified the thing that you know you're going to change and the trial stands or falls in a general sense in terms of being things that are positive or negative outcome by whether you change the primary predicted outcome or not.

That doesn't mean you can't learn from secondary outcomes, just mean your trial didn't work. That's a sort of very conservative approach, but it's one that comes from a country with little money.

This is a colleague, who's name you'll see in a moment, Jonathan Green, he's leading a trial involved in -- here's a theoretical paper from last year now about and this is sort of -- this is my niche moment really, so I'm sort of a bit obsessed sort of mechanisms and theories within the developmental context. And trials are a wonderful way to test developmental mechanisms

and developmental theories.

And this is the way in which we build this idea that we have theories about what treatments might do. We understand the mechanisms and we understand the impact of those mechanisms and we predict outcomes that we think we'll follow on from that the intervention is supposed to be delivering.

So just a sort of summary slide, I'm not going to walk you through what these studies are. I'm very happy to be e-mailed, you can Google my name and you'll find me very quickly and send you these papers and point you to this literature.

But here are four trials that are randomized control trials that look at parent training approaches. The ends aren't fantastic, but they're at least as good as most of the two trials that have been run in the ABA literature so far, but I understand larger trials are ongoing.

And here are three other trials

with somewhat larger sample sizes that are looking at different sorts of other communication sort of approaches. And it's not that I'm arguing at all that only RCTs matter, it's just that a mature evidence-base will include some randomized trials and allow us to draw some general conclusions as well as specific conclusions.

So just to give a few examples, this is Connie Kasari's group from UCLA. This is the adding in a specific element trial. So there are 58 preschoolers, they randomized about 23 in each group to three different groups. One focuses on JA, joint attention skills, one focuses on pretend play and one's a sort of non-treated group except that the magic of this study is all the children are in 30 hours a week ABA nurseries.

So you're adding in a very specific focused 30 minutes a week -- 30 minutes a day daily for six weeks. That's 30, 30 minute sessions added in focusing on

things, and joint attention and pretend play are of interest development because they're things both in normal development and in children with autism that build language and communication skills. So we think we know what we're adding in.

Twelve months later how are those groups doing? So the first graph is a language age, they're doing about six months better than the group who didn't get those special elements, that had a very particular focus on pragmatic ways of encouraging early social communication skills.

And the second is a frequency of initiations and interactions within in experiment and again, the groups are doing better. I suspect, I'm not at all to criticize this trial, I love this trial it's a really great example. I mean I'm wowed by how fantastic the benefit 12 months later is.

I suspect if we ran this again, the benefits would be just much less worse

because life doesn't get this good often as a trial list. But I think it's just the example is not about use this treatment, it's that you can test whether additional things, even quite modest additional things that you have a theory about bring additional benefits.

Here's a study that I was involved in, so this is looking at the picture exchange communication system and this was what we call a pragmatic randomized trial where we randomize classrooms. So the kids are all in these non-verbal, relatively or well very impaired 6 to 10 year olds with autism in the special school system in the U.K.

We weren't looking at what the special school system was doing, we're saying if we randomly add in training and consultation, which was run by the Pyramid Group in the U.K. on PECS doesn't make a different to specifically communication outcomes, because that's what we thought PECS should be doing.

It's a rather complex sort of flow chart, but it just shows you how we got our groups and randomized them and we had two stages of treatment. And I don't have a great way of presenting this sort of data, so there are these graphs that are hard to read, but just read this sort of bottom line.

So we looked at three -- we developed a new observational outcome measure because we didn't think for these very impaired non- verbal children we had a good measure of what we thought would change. We just said, how often per minute do these kids initiate an interaction.

And the count is there, it's a rather complicated graph, sorry for that, but basically we find a significant effect following the PECS intervention.

How often in this -- in a sense is the most proximal measure of outcome was our secondary, not our primary outcome, but are they using the PECS symbols more, which they

really should be after the training and we get a very large effect. Yes, they are using the PECS symbols more.

And then we ask the sort of distal third- level outcome, are they speaking more. And in our trial they weren't. So that's sort of one example of taking a school system we weren't - - changing what's going on within the classroom except in regard to the particular practice of using PECS in the way it should be used with consultation.

And you find, yes they're using the PECS more. That's important, because you've got a treatment that says we're going to train these teachers to get the kids to use PECS properly and in our experience PECS isn't always used properly, they should be using the PECS symbols more, yes they were.

Does that change anything else about the child as a communicator? Yes, it did. They were making more initiations. Now I think initiations regarding impaired

children with autism are a promising thing. Did it lead to better speech? No, it didn't, at least over the time line of our trial.

Then this is another sort of example, is finishing soon, so this is a pilot trial published a few years ago about a parent training approach.

And this is an example, this is from Jonathan Green's group about having a particular theory about changing the way that parents are interacting with their preschool children with autism and expecting that to have changes in their social behavior and in their communication behavior.

The mechanism is changing the parents to change the interaction to change the child. So it's a developmental theoretically based parent training approach. So I'm not going to go into the detail, I can point you to the paper, but here's the adapting parental communication sort of therapy.

It lasts for 12 months, not especially intensive. In the current trial we're running, I'll show you in a moment, we're doing this for fortnightly for half a day and then monthly for six months and then six months.

So it's a 12 month health service based treatment and these are the sorts of things that parents are trained in, in terms of adapting their communication styles. This is not a unique program, there are many other programs that are like this. Again, it's not supposed to be everything the child gets.

These kids are in preschool getting other services, services in the U.K. are very variable so the other services are not always great I can tell you. Some are good, some are okay, some are pretty poor.

So outcomes, so it's again, the way it's presented is not easy to read, but on the left is an ADOS which is a severity measure, on the right is a parent report of

number of words said on a particular instrument.

And without wanting to sort of point you through it, what we find in the treated -- what they find in the treated group is over a 12 month period, some reduction in ADOS symptom severity over 12 months and some improvement in vocabulary in the parent training group and not in the treatment as usual group.

And we've been running this trial, we'll be reporting next year we hope, which is a large randomized control trial of this preschool autism communication treatments we now call it, which is this parent training, 12 month delivered NHS embedded, this National Health Service embedded treatment.

And there's a multi-site, three site trial with a large N, N of 152 with a predicted primary outcome and a number of secondary outcomes. And we hope to report it some point early next year.

So just to sort of wrap up, two slides. So the first is the what do we know. And there is an emerging and increasing evidence for behavioral and social communication approaches and, you know, I think one starting point for me, I guess most people will agree, but it's not always being well put forward in the field I think, what should early intervention focus on.

Now to me, these go in order, managing behavior, enhancing social interaction and enhancing communication. Treatments involving parents, both educating empower them at a time in which they're seeking guidance and need to know more and need to learn about autism. And I think most good treatment programs do involve parents.

But effectiveness is very variable in every study, in every trial. So some children in every program make great gains, other less so, some very little.

Early intervention, what do we

need? And the first point is an important one because I think sort of just somewhere I'm wanting to sort of make the point, I think what's not been helpful is that people don't always engage in the debate about what the evidence for what works in what I would call a fair minded way.

And that's what I've come here today to try and do, to be fair minded about the evidence for ABA. Fair minded approach to evaluating the evidence is important. It's also true that sometimes there are good, promising interventions that people from outside one particular field don't know about and don't understand the literature very well.

We need to do a better job of talking to each other about how the intervention field in a broader sense is growing. And it's really only very recently that people within the different communities that say this sort of pragmatic social communication cycle linguistic sort of

approach that some of us have taken with the ABA sort of type approach, they started communicating well with each other.

We do need more large-scale randomized control trials. They're not the only form of evidence, but they're the most unbiased source of evidence and that's important if we want to do the best job for the families out there in the community. You need to get the good advice and the good programs delivered and developed for them.

We need to identify more about the effective elements of interventions, because when you have a big, large package and you don't really know which bits are doing the work for you, you could be doing other things. That's a tenet again in the medical field.

You know, in a sense, one part of intervention either by time or by money or by burden is potentially excluding other things that might help. We need evidence of how interventions might work differently in

different settings. Training parents, working in preschool, working in the home.

We need to recognize that not one size fits all. We really need to start identifying not just what works at the group level given that we know the individual outcome is highly variable in every study that I've seen the data of, we need to know what works for him and then we can begin to appropriately individually tailor programs and services for children of families.

And we need to work from where we are, but move forward both with the evidence-base but also for developing appropriately trained, professionals and services because quite rightly, and in a sense, lots of the sort of progress I think that's beginning to happen over the past 10 years in the intervention field actually has been driven not by our scientists, but by parents out there clamoring and saying, it's not -- just not good enough that we don't know

what the evidence is.

And I think us scientists and the funding community have at last woken up to their message and we're trying to do that piece of work, albeit it we're playing a big game of catch up. Thanks very much.

Dr. Insel: Thank you Tom. We have some time for questions and discussion. Alison?

Ms. Singer: When you're doing an intervention -- oh sorry. When you're doing an intervention trial like this how do you control for the skill of the provider? Because it seems to me that we see that children, the same child may make progress with one provider, but not with another one. So how do you control for that?

Dr. Charman: Well I mean, all I can -- the only example where we tried to measure that well is in our ongoing study. And we're able to do that because there are -- the N in our study is 152 so roughly half

those families about 75 let's say in our PACT treatment and there are only six therapists of the three sits, across -- two at each site who are working with those families.

So we have ratings of treatment fidelity and there are analysis, but the numbers gain here won't last through this in a powerful way and they're obviously all sorts of reasons within the trial team to do this in a fairly anonymized way.

There are ways in which we can look at side effects and therapist effects and we have enough ratings of enough sessions by blinded raters that you can, when you have large enough trials, and ours isn't large enough, you can have models where you can include that within the analysis.

So if you go to other fields, we know quite a lot about that so I feel that I used to know a lot about when I was doing my training in clinical psychology, but I don't really keep up with it, but one understands

enough about how you do this, is that therapist effects in cognitive behavioral therapy are really important.

You know, you really do have to consider therapist-level effects when you're thinking about talking about therapies like CBT. It's incredibly difficult to do, you know, within a very systematic way because you just need a size of trial to have enough measures of enough therapists to really then disentangle what it is about the ones who are implementing in a way that's more effective versus the others who are not.

So you're asking hard questions that won't be answered very quickly Alison.

Dr. Insel: Can I just follow up on that Tony. One that we struggle with often in the world of other forms of behavioral therapies is that, what we have a research base on doesn't map on to what happens in the community.

I don't know what the experience

is in the U.K. with this, but the question often gets asked later so how do you know there's any fidelity with what it is the evidence-base has been telling you when you take it out on the road and you have not 150 or 100 people but you have 100,000 that you're looking for.

Dr. Charman: Yes. Well, Tom, I mean, you know, you know the literature, you know, in regards to sort of this in, you know, many fields. I mean, sort of you know, ones sort of good example where this has really gone a long way is in the sort of Carolyn Webster- Stratton approach to children with early behavioral sort of problems.

And, you know, her sort of group in Seattle has spent decades building an evidence-base and running, in a sense, wonderful community effectiveness trials.

And there's a great one run within the school system presumably out in Washington State, I can't remember, I see it must be

published I think earlier this year, where in a sense they did one of the biggest sort of community effectiveness implementations with hundreds of children and scores of therapists.

And I remember, because I was writing an editorial for a journal on this thinking this is about as good as you can get, but of course actually, they had specially trained grad students as the therapists, which isn't quite like having locally hired practitioners of whatever sort they would be actually doing the sort of delivery.

So, even that's not a true, true effectiveness even though it was sort of community delivered effectiveness sort of study. So, you know, in the U.K., we just don't have sort of good examples of this, but, you know, it's just such a general challenge.

I mean, let me give you a different sort of example, and it's not particularly that I have a particular affiliation to PECS beyond the fact that I

think it can be incredibly powerful for some children with autism who have very limited language skills to have a basic communication mode.

The reason we got motivated to run our randomized control trial was it just -- it was practice was going on, and it's maybe true, lots of environments in the U.S. as well, loads of schools were using PECS and we thought, well hold on there's some promising case series, but we haven't seen any really well conducted studies, let's just run one.

Now it happens that Paul Yoder and Wendy Stone were also, and we didn't know this, running another RCT, quite unusual, somewhat differently delivered.

And so our first thing was to go and find schools who we thought, let's find some PECS- naive schools who basically haven't been trained in PECS because we want to get people who are starting off at the same level, and then we'll get them trained through the

pyramid and scheme and whatever.

We went to all the schools around the south England, they all said, oh we've got staff who are trained in PECS and we thought, we got all this funding we can't find any PECS-naive schools, so we sat in the classrooms and what was saw was poor PECS practice.

So, you know, in a sense these weren't PECS- naive schools, they were PECS who before the trial, before the training had been using PECS poorly. And schools who are doing the training, begun to learn to use PECS well.

We had one group who followed up for another length of time who didn't get the consultation and in that small group, the treatment effects fell out. So when you don't have someone there who's got the expertise, this is our interpretation, who's got the expertise who's monitoring your implementation, the fidelity, go to back to

Alison's question, then maybe the treatment effects fall off.

So that general question about how you move from university run trials with specially trained therapists to more general community services is a challenge in every intervention field and a very significant one I think for the autism field too. So there's no easy answers to that, but the work needs to be done.

Dr. Insel: I don't want to draw this out too much, but there's a real problem with phase. I mean, we know that there's increasing demands, we have a very limited workforce. In the U.K., if someone decides that they do ABA, is there any accreditation -- what keeps anyone from putting out a shingle and saying I'm an ABA therapist?

There's certainly a way that you can't begin to write prescriptions for medication, you can't begin to do surgery in this country, but for psychotherapies like

this, we have a different bar set up for accreditation. What about in the U.K.?

Dr. Charman: Well the people within the ABA field who are providing the better ABA programs, they're not widespread in the U.K. all call themselves board certified therapists. But that doesn't mean that someone can't set up some sort of program whether it's ABA or something else for exactly the reasons, if they aren't a board certified sort of therapist.

Because as you say, you know, for, you know, professions such as mine as a psychologist, you can't call yourself certainly a clinical, a charted psychologist without meeting some health professions, counsel sort of regulations.

And there's been, you know, but within the more generic sort of therapy fields, you know, that's not sort of true either. I mean, the point that you're, you know, the point you're also raising is one of

the ones where in a sense one has to be pragmatic and it's difficult to know what advice to give.

Because even though I'm being genuinely encouraging about what we do know and genuinely encouraging about the work that I understand is going on and where we might be in five or 10 years time, as you say, the demand and the need for services is there right now. It was there right now five, 10 years ago.

And the numbers of children now being diagnosed at a young age that we all know about, then, you know, the demand outstrips supply. And, you know, that means that sort of individual clinicians and communities need to make their, you know, decisions about what to provide and how to try and make sure it's as best evidence-base as it can be.

But what I would say, and I'm sorry for repeating it for third time, but I

do think that puts an onus on all of us, policy makers, scientists and practitioners, and you know, in communicating with each other and with parents to be fair-minded about the evidence-base.

Certainly, you know, I really find it very hard when people tell me that there's only one approach which is an evidence-base, because that just doesn't seem a fair-minded way of understanding the literature. It really is about doing the best that we can for the community and taking each of our responsibilities.

But the challenge that Tom is highlighting means we can't wait, as we all know, for 10 or 20 years to work out exactly what's going to work for each child. We have to move with where we are and it's tough.

Dr. Insel: Other questions or comments? Deb, you have -- Deb Hirtz, did I --

Dr. Hirtz: Just related to what

you have said, which is given the constraints that we have, the time and money and our ability to do many, many very large randomized control trials, what alternatives can we look at to get the information in shorter amount of time.

Can we figure out other ways that we can get maybe close to the quality of information that we would get from large randomized control trials if we somehow organize the kind of data that we can collect observationally, even though that's not traditionally the gold standard of testing? But, you know, I think you just sort of led into that with saying perhaps there are.

Dr. Charman: I do think it's important to think about, and I think a recognition of this is there in the strategic plan. I was on the intervention scientific workgroup I think in January 2008, so it was nice for me to come back and hear about how much progress is being made.

But I think, you know, you do need to be disseminating the evidence-base that we know and make sure that's done in a fair-minded way. We do need to be using some of the sort of examples I sort of showed you of, in a sense with lighter touch sort of, you know, studies that maybe are, you know, always the big fully randomized everything, the big 35 hours a week program.

But just are there things that we know that can be added in to what happens in preschool environments to children with autism that we think make a difference and understand why they do. And yes, you want to be running some big trials too because they give you a particular power to answer particular sort of questions.

And you need to be moving forward with all of those things and with training at the same time. I mean, it's frustrating that we can't do that knowing -- taking all the boxes and knowing what all the answers are,

but we need to be doing all of those things sort of, you know, all at once. It's hugely challenging in a country that I come from too.

Dr. Insel: Other questions, comments?

Mr. Grossman: Hello?

Dr. Insel: Yes, go ahead.

Mr. Grossman: Hi this is Lee Grossman. Thank you for your excellent talk. I have about two questions. The first one is do you believe that there is any effect that ABA or early intervention behavioral interventions won't have across the lifespan?

And the second question I have is what else other than ABA should be included in an early intervention program that you find effective? And I'm about to get on a plan so I'm going to put the phone on mute.

Dr. Charman: Thanks Lee. So just a very quickly sort one, not answer, but at least respond to those two sort of questions. In a sort of formal technical sense, we don't

-- we can't measure the impacts of early intervention, ABA programs, you know, any intervention across the lifespan, because in a sense those sorts of long term studies haven't been done.

However, one might expect that when you can show more relatively short term benefits that at least hold promise for continuing benefits across the lifespan, but you know, that does depend on, you know, continuing sort of studies sort of being done.

And in a sense, you know, some of what you're asking the second sort of question I think is probably already going on that people are beginning to include more specifically sort of social interactional, social communication aspects of intervention approaches, therapists working with children as in the Connie Kasari study, parents working with children as in the study that we are running, that, you know, will be of benefit as well, you know.

Because, you know, it's certainly true that sort of in a sense, you know, if you understand behavioral theory or at least as I understand as a psychologist, there are things that, you know, that the behavioral techniques themselves in a sense can't do, because, you know, social interaction, social understanding comes through so, you know, comes from social interaction and social understanding experience.

And, you know, when you incorporate social communication approaches within a behavioral framework, you know, I guess that's a sensible thing to do and I think increasingly people are.

So, you know, I mentioned Sally Rogers, you know, promising but as yet, you know, not fully tested and program that combines aspects to the Denver model with ABA with pivotal response training called the Early Start Denver Model, PRT is incorporated in lots of behavioral sort of programs.

And certainly when I go around and see some of the groups here in the U.S. when I'm visiting and see people doing work with parents and doing work in preschools and kindergartens, I see people who are introducing sort of, you know, very purposefully social communication approaches into other frameworks and they're sort of very needed and very sort of necessary.

But, you know, I just wish that we were further along. It's always very humbling to come and just, you know, talk to an audience where actually a lot of what I'm saying is that we need to understand what we know, but we also need to understand what we need. And I wish that we knew more and needed less.

Dr. Insel: I'm very concerned about the time. I know Chris and Kathy both had questions, but I think we better move along. And Tony, if you can stay around a bit perhaps you'll be able to chat with some of

the committee members during our later break.

Dr. Charman: I'm here for the whole day.

Dr. Insel: Terrific. Thanks very much and thanks for coming over to help us with a really important topic.

So we are far enough behind in our schedule that what I'd like to ask is that we shift around a bit and we move the presentation on NDAR to the afternoon. Mike, if that's okay, we'll do this right after lunch.

As well as if you're willing, Ellen and Lee to do the services update, can we delay that until after lunch because we have promised to have public comment at 11:45, I'm want to stay close to that schedule. We have 15 minutes set aside for public comment, we have three people who have signed up to talk to us and I wanted to move right to that now so that we can break close to noon.

So let me ask the first person for

public comment to join us, that's Paula Durbin-Westby.

Okay. I should make one more comment while Paula is joining us, I received in a few of the previous presentation from Tony the National Autism Center has just put out the National Standards Project, which is a four- year study trying to look at the evidence-base for behavioral interventions.

Susan Wilczynski who ran that project is with us someplace, Susan? If you could raise your hand. This is now available on the web so for anybody who wants to get a much more granular look at the specific interventions that are part of the ABA package and many others that Tony talked about, this is a very deep and interesting summary of what actually exists in the literature representing the work of scores of people over the last four years. It's now available online.

So I won't take any more time, go ahead Paula.

Ms. Durbin-Westby: Hi, I'm Paula Durbin- Westby. Thank you for permitting me to address this meeting of the Interagency Autism Coordinating Committee. I'm representing the Autistic Self Advocacy Network.

I appreciate having had the opportunity to represent ASAN at the recent scientific workshop. The meeting offered many opportunities to make changes as the strategic plan is updated for 2010.

Inclusion of an objective to study ethical issues related to the assessment and communication of genetic, environmental and clinical risks for autism was one of the recommendations from panel one, which is the panel I participated in.

This objective is good, but it does not go far enough in that it only addresses assessment and communication of risk. It does not address other ethical issues, which we believe to be important.

Therefore we strongly urge an objective that would address ethical, legal and social issues related to all aspects of research, not just the communication of risk, although that is a critical area given recent developments in identifying prenatal risk factors.

Another area for concern about ethics is early intervention, as interventions are initiated at earlier and earlier ages. Ideas about what early interventions will work are generally based on assumptions of non-autistic people about what the reasons for autistic behaviors might be with little to no input from autistic adults who can inform and guide that research.

A concerted effort is being made to increase acquisition of biological materials such as skin, fibroblasts, brains and other tissue types. There's an ethical concern with collecting biological samples from young children who are not capable of

giving permission.

Potentially, children might not want to contribute biological material if one of the purposes would be for developing a prenatal test aimed at selecting people like themselves out of the gene pool.

All though there are many reasons for collection of biological materials, this concern must be addressed. People on the autism spectrum who can't communicate and people with other disabilities such as Down's syndrome and their families have advocated against and continue to advocate against such an aim.

In general, recommendations of many of the panelists to include adults in many of the sections of the strategic plan are a step in the right direction, although the IACC does not fund research, presumably it has some influence on research priorities or it would not bother to come up with budget recommendations.

Here are some figures from the 2009 strategic plan, recommended budget for diagnosis and assessment $133 million, for biology and risk factor research $179 million, for causes and prevention $216,400,000, treatment and intervention gets $190 million.

For where can I turn for services, where indeed? Not to the IACC recommended budget, which suggests a grand total of $25 million. If research were really funded at the levels recommended by the IACC, that question becomes even more anxiety provoking for autistics and our families.

We will certainly need to turn to avenues other than the IACC for answers to questions about needed services and support. Research into causes, biomarkers, prevention, et cetera will not help people who are alive today and need evidence-base information about services and support.

Recent research and initiatives in the United Kingdom can provide a model for

services oriented research and also research into adult issues. The National Health Service has released a study of autistic adults indicating that prevalence of autism in adults in the U.K. is similar to the recent figure here of 1 in 91 children.

Interestingly, the NHS report avoids alarmist rhetoric and talks about an epidemic of autism. In addition, initiatives in the U.K. such as "Don't Write Me Off" employment campaign and the "Supporting People with Autism Through Adulthood" campaign can make a real difference in the life of autistics, especially young people who are transitioning out of school settings and adults.

Sadly, the United States is falling behind on crucial issues related to services and lifespan issues and is failing autistic adults, families and communities.

Currently, the strategic plan does not address communication differences and

disabilities at all except for a brief mention. This is a surprising omission since one of the criteria for an autism diagnosis is a communication disability.

Although panel four on treatments and interventions mentioned communication as an emerging tool, specific mention of communication research should be incorporated into the 2010 strategic plan. Thank you.

Dr. Insel: Thank you. We also have Ms. Teresa Wrangham.

Ms. Wrangham: Good afternoon. My name is Teresa Wrangham, I'm president of SafeMinds, I'm also the mother to a 19-year-old young adult woman recovering from autism, Rachel. She traveled here a year and a half ago to address the IACC and asked this committee questions, questions for which we still don't have answers.

Today she couldn't be here because she's in college, something that when she was diagnosed at six and a half years old and had

regressed from vaccine injury and we were close to losing her speech, she couldn't have been here because she wouldn't have been able to tell you what she wanted.

What she told you a year and a half ago was is that she'd like to know why her body works differently, why hyperbaric oxygen therapy had increased her verbal IQ 22 points and when were biomedical funding objectives going to be funded to explore why some of these interventions worked for her and yet don't work for others.

As her mother I can tell you the list of what we feel made a difference in Rachel's life to the point where she is going to contribute back and impact the system very little is that that list is much longer and that parents desperately need to understand how these biomedical interventions play a part in recovery, for indeed, my daughter is recovering and her biggest recovery year was at age 17.

So the questions that Rachel and my family and may in the community that SafeMinds represents that I've had the privilege to bring the committee would be these, we currently have another new number with regard to autism, it's 1 in 100 and yet that data is close to 10 years old, it represents a cohort in the `90s.

We have a former director, Dr. Julie Gerberdine who says an NVAC study should and could be done and the CDC is very adept at counting, for example 131 cases of measles, we feel that there is not a real barrier to our children being counted, how many are really here that the rise is real.

The reality is, is we have a growing body of data that's environmental that shows that we have an epidemic of a disorder that is environmentally triggered at least for part of this population. We need to understand that.

We have the MBAC report which this

committee waited on after removing two vaccine objectives, which said the very same thing that committee members have brought forward and approved at one point on the strategic plan.

Their recommendations were autism specific at times and we had Dr. Mark Noble come to talk about the optics that Dr. Insel had alluded to that may prevent objectivity on those objectives being conducted. And we have seen no response on the part of how we overcome the optics and conflicts.

We've heard that there's concern about messaging, what message would be sent to explore the vaccine issue. I would ask you to think about what message you're sending by not exploring the vaccine issue.

The vaccine court has awarded 13 awards to families of children with autism from vaccine injury resulting in autism. It's not a question of whether vaccines can cause, it's a question of how many.

This committee is tasked to discover causation. We're not saying that it's totally responsible for all autistic cases, we're saying it needs to be explored and now we have the agreement of another federal advisory panel that there are serious gaps and there are implications for this committee.

I come from Boulder County, one of the most highly unvaccinated counties in the United States. We also are rated as one of the most highly educated. I think if you were to ask parents for permission to gather their records or in fact their records may have already been gathered through their HMOs for vaccine records, that we could build both in perspective studies for the price tag I think Dr. Landis actually mentioned it in panel three, $37 million.

That's about a dozen of our children and what they cost over the lifetime, $3.2 million. That's money that we could

have, it's well spent to investigate this issue from a prospective manner.

From a retrospective manner, NVACs again, gathering those records, it's probably already there. I don't think there are any real impediments to designing the sort of study.

There are also other issues that public members supported last round in strategic planning, greater expansion for biomarkers treatment, environmental factor objectives that were outvoted by federal members. That's a question we have as a community, why was that.

We had all public members raising their hand for this and it was voted down by the number of federal member agencies that we have on this committee.

And lastly, I would say with regard to anecdotal evidence and clinical data, my daughter's not an anecdote, neither are the other children and parents who have

been here. What we've seen in the way of improvement for our children is real.

We're not so desperate as to imagine an improvement that we don't honestly see. We don't miss imagine these co-occurring medical conditions and when they're treated we don't imagine how it mediates autism behaviors.

Had it not been for my daughter's experience outside of behavioral therapies and biomedical treatments, she couldn't even begin to tell you how she felt or what her needs were. And the vast majority of this population isn't able to tell you where they hurt, how they feel or what they need.

I hope that I can bring my daughter back here again and that she can say to you, thank you for looking into it, for overcoming the optics or having a hard look at the numbers and moving forward with greater urgency in discovering all the various facets that make up autism.

And if any of the committee members would like to address any of the questions, certain we would like to hear more about that. Thank you.

Dr. Insel: Thank you. Final public comment is from Ms. Sharrill Hamry.

Ms. Redwood: Dr. Insel, to address Ms. Wrangham's question could we look at the ARRA funding and let the community know what's actually been funded.

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

Ms. Redwood: Wonderful.

Dr. Insel: Yes, you'll get a list of everything that's been funded through ARRA.

Ms. Redwood: Thank you.

Ms. Hamry: Hello. My name is Sharrill Hamry, I am the mother of three children age 12 to 16 all of whom have the blanket diagnosis of autism. I spoke to this group back in March of 2008 and have attended every quarterly meeting since then.

I have watched as you developed your current strategy and have tried to ensure within that strategy that you're attended to both the scientific and individual concerns.

As a result of my observations over the last 19 months, I see that this committee has the potential to make a real difference and so I am here to ensure that you're all aware of new, chronic fatigue syndrome research which I strongly believe will have resonance to addressing treatment in the illness we know as autism.

All three of my children have blood markers indicating that a neuroimmune disease process underlies their illness. The mainstream medical community still does not acknowledge that many of those with autism have a medical illness and thus truly effective treatments such as immune modulators remain a figment.

Like autism, chronic fatigue syndrome has sharply risen in the past two

decades and has been plagued by the mainstream medical community's slow pace of understanding the underlying cause. But new chronic fatigue syndrome research suggests a smoking gun.

On October 9th, Science published a study conducted by research scientists from the Wittemore Peterson Institute, the Cleveland Clinic and several components of the National Cancer Institute, including the laboratory of experimental immunology, the laboratory of cancer prevention and the advanced technology program.

The study, entitled Detection of an Infectious Retrovirus, XMRV, in Blood Cells of Patients with Chronic Fatigue Syndrome identified DNA from a human gamma retrovirus, xenotropic murine leukemia virus-related virus, XMRV in the peripheral blood mononuclear cells of 67 percent of 101 chronic fatigue syndrome patients studied compared to 3.7 percent of the 218 healthy controls.

An October 9th article in the Wall

Street Journal reported 20 of those 101 chronic fatigue syndrome patients whose samples were used in the Science study also had lymphoma, though the link between XMRV and lymphoma has yet to be established.

The Wall Street Journal article also noted that using additional testing, more than 95 percent of the 101 chronic fatigue syndrome samples either contained an active XMRV virus, excuse me, infection or indication of past exposure.

The Whittemore Peterson website augments this information by stating that similar percentages have been found in blood samples for patients with fibromyalgia and atypical multiple sclerosis.

Unpublished information indicates that the blood of an additional 500 chronic fatigue syndrome patients in London is being tested for XMRV and so far the same high percentage is being found in that population.

The Science study question whether

XMRV infection is a causal factor in the pathogenesis of chronic fatigue syndrome or merely a passenger virus in the immunosuppressed chronic fatigue patient population.

The study also postulated whether there is a relationship between XMRV infections status and the presence or absence of other viruses often associated with chronic fatigue syndrome such as herpes viruses and it conceived that these viruses could be cofactors in pathogenesis such as occurs with HIV.

In the study's cell culture experiments, the virus was infectious in both cell associated and free cell transmission while secondary viral infections were established in uninfected primary lymphocytes and indicative cell likes following exposure to either activated peripheral blood mononuclear cells, B cells, T cells or plasma derived from chronic fatigue syndrome

patients.

The study's authors further noted that patients with chronic fatigue syndrome have an elevated incident of cancer, and questioned whether XMRV infection might alter the risk of cancer development in chronic fatigue syndrome patients.

When scientists from Tufts University and the National Institute for Medical Research in London provided written comments on this study, they echoed questions as to whether XMRV alters the risk of cancer development in chronic fatigue syndrome patients.

And they correlated the Science study to another new study, one published in the September proceedings of the National Academy of Sciences in which the University of Utah and Columbia University Medical Center scientists examined prostate cancer biopsies and found XMRV in about one-quarter of the samples with higher grade tumors more likely

to contain the virus.

The October 9th Wall Street Journal article reported that 27 percent of those prostate cancer biopsies in that earlier study contained XMRV as compared to 6 percent of benign samples. And it stated that Robert Silverman, the Cleveland Clinic scientist who is one of the discoverers of XMRV estimates that the virus could have migrated from mice to humans.

The article also noted that after seeing the initial findings from both the prostate cancer and chronic fatigue syndrome studies, the National Cancer Institute convened a closed- door workshop in July to discuss the public health implications of HMRV infection.

To summarize, HMRV is a virus that appears to have migrated from animals to humans, is rarely found in healthy human populations, unlike other viruses associated with chronic fatigue syndrome, has

demonstrated infectious tendencies through blood and other means, is linked to at least one form of cancer and may cause long-term immune deficiency in a sub- population of people.

How does all of this relate to autism? The Wall Street Journal article also reported that the Whittemore Peterson Clinic has isolated the XMRV virus in the blood of patients with autism.

In light of this new information, I strongly recommend that this committee invite representative from the Science study's 13 member six center team to brief at the next quarterly IACC meeting, including at least one representative from the Whittemore Peterson Institute, which has expanded their research to the blood samples of individuals with autism and who would likely have findings to present on that subject.

I also urge Dr. Insel to recommend that the IACC be modified or expanded at some

point in the near future to include a member from the National Institute of Allergy and Infectious Diseases ensuring that the committee is aware of the very latest research in infectious diseases.

Finally, I hope that this exciting new study will act to galvanize both those conducting independent research and those applying for grants to quickly identify medically safe treatment strategies such as putting into trial some of the many unapproved immune modulators that sit dormant on pharmaceutical company shelves. Thank you for your attention.

Dr. Insel: Thank you. Just a point of clarification, I actually don't have the authority to add anybody to this committee, that resides with the Secretary and we're eager to have her make some changes so that we have a broader representation.

Also if I can mention just in passing that within I think 24 hours of the

Science paper being out, the intramural program was on the job looking at XMRV in autism. So this is a really exciting new development and you'll hear about this afternoon because that point of doing an update of the strategic plan is precisely to be able to incorporate science as it evolves.

It's 12:10, I recommend we take a lunch break at this point. We can reconvene at 1:00 and we'll try to get caught up at that point by hearing form the NDAR group, the services subcommittee.

We need to still look at the minutes, so we'll have a chance to review those as well or Della won't let me leave. And then we can get on with the rest of the agenda thereafter. Okay. See you at 1:00. There's a cafeteria upstairs.

(Whereupon, the matter went off the record at 12:09 p.m. and resumed at 1:08 p.m.)

AFTERNOON SESSION

1:08 p.m.

Dr. Insel: -- quick update since July 15th.

Dr. Huerta: All right. Well thanks a lot Tom. And indeed NDAR has been making great progress and a lot of it in the last three months. I list here, I think I list here, maybe I'll try this, there we go.

I list some of the major milestones that we've accomplished since July 15th when I spoke to you last. Rather than go through these, however, in chronological order, one by one, I have decided to select from this list of achievements and talk about them in the context of something that we discussed at the last meeting, which is the data challenge.

We have a great platform, the question came up why aren't there data in there, when will this happen? Well, with databases the medium is not the message. In

our case, the message is a better understanding of ASD through research. And while NDAR's robust medium, the message requires data.

And NDAR, like most databases is not self- populating, we get our data from investigators and data submission is not free, so investigators need incentives to submit their data and incentives in turn depend upon a data sharing regime comprising a strategy, policy and practice.

The original NDAR data sharing regime had been limited to receiving data from the 11 ACEs and intramural ASD research projects. We found this to be insufficient and instead found an urgent need to meet the data challenge by changing this data sharing regime so we can increase the amount of data in NDAR. And I will talk today about our achievements in the last three months in this context.

To address this urgency we've

developed a general strategy and the first part includes, of course, proactively and persistently getting data submitted by the ACEs and intramural ASD research projects.

In addition, however, we are interested and are pursing getting data from projects beyond the ACEs and intramural program. And whenever you're dealing with data submitters it's very important that you provide user-friendly support to all of those. And we have stepped that up, we now have many times a week webinars and other kinds of outreach to folks who will be using NDAR.

The second part of this general strategy that I mentioned actually in July is to link other significant ASD databases with NDAR. And this provides us not only a way to get more access to data, but it also provides the opportunity for us to work across these linked ASD databases in ways that will increase the utility and the quality of the data.

So now let me go through some specific efforts in these regards starting with getting data from the ACEs and intramural ASD projects. We have been aggressively communicating with the PIs of these projects, reminding them of their obligation under the terms and agreement of their awards for them to submit ensure data via NDAR.

We currently have over 2,000 research subjects registered in NDAR from these sources, and I'm not going to go through all the types of data, but I have listed some indicators of the kinds of data that are in there.

The first data that have been submitted to NDAR from these sources will be available for sharing in May, 2010. And I'm pleased to say that in the last three months, compliance with our NDAR data sharing agreements from these sources has been quite good.

Now, we're interested in adding

data from beyond the ACEs and intramural projects. And you heard some of this at the last meeting. I mentioned that we are in the process of migrating data from the STAART and CPEA centers that had been funded years ago.

This represents data from some 9,400 subjects and again, I won't go through all of the data that will be available, but we're in the process now of bringing that directly into NDAR. This data will be available for sharing in May 2010.

The other really significant source of data from beyond the ACEs and the intramural program comes from the ARRA funded grants, and Tom will talk about this in more detail in the next session, but it turns out that 43 of the 60 grants that were awarded using ARRA funds.

These are grants that came in under the RFA looking at heterogeneity of ASD, 43 of those are collecting data that appropriate for NDAR and we see according to

target enrollments certainly more than 12,000 subjects and maybe as many as 27,000 subjects data will be coming in to NDAR from these 43 grants.

In addition to your common assessment measures such as ADOS and so forth, many of these grants add a lot of -- very diverse measures which will increase the number of data elements in NDAR, which is always a good thing, and it will increase the number of data definitions, which will be useful for the entire research community.

The first data sharing from these grants will be made available, the descriptive data, December 2010 and the project specific or experimental data will be available for sharing in February 2013.

The other part of our general strategy is to link ASD databases with NDAR. As I mentioned at the last meeting, NDAR has a capability that allows through this linkage, direct access to the data in the other

databases.

So it's not simply one database talking to another database at this very high level, but it really is allowing the investigators to come into NDAR, do a query, pull data that's in NDAR and pull appropriate data that are in these other linked databases presenting the investigator with data retrieval that is really seamless.

In addition in terms of this, we have been working with the Autism Informatics Consortium to harmonize our efforts. We've been in discussions with the Simons Foundation, Autism Speaks and Prometheus and this will make this linkage more efficient.

We have developed a strategy for linkage that will improve the quality consistency and usability of data across all of these databases. We also see this as helping develop community-based standards and the way we've developed it, it will have a very low cost, but a very high benefit to

investigators.

Finally, the linkage will increase data access to the users of any of these linked databases which means that we are adding value to all of them.

So this is our, the general positive aspects of this strategy and now what I'm going to do is go through the individual currently underway linking activities.

You already know from my talk at the last meeting that we're in the process of federating the NIH Pediatric MRI Data Repository, which has data, longitudinal imaging data from some 600 children. We're doing this with NDAR funds. And we expect this data to be linked to NDAR by March.

We are also, since June, have been working on federating the NIMH Genomics Repository data, which contains data from some 3,000 ASD relevant subjects and we're doing that with NIMH funds. That began in June.

In September, we awarded an ARRA

grant to Autism Speaks and the grant is supporting the Federation of the AGRE database with NDAR. That database contains 5,000 to 6,000 subjects. And again that was started last month.

Also started last month was the confederation of the IAN database which has some 30,000 subjects in it now. We are doing this with NIMH funds, we've done this through a large supplement to a grant to Rebecca Landa at Johns Hopkins and Paul Law is here, and he's the main, key person on the IAN database. Again, that was done last month.

And finally, also using ARRA Funds we at NIMH, awarded a large grant to develop a transcriptome Atlas of Human Development. So this is looking at gene expression over time in the human. There will be 100 some, about 100 subjects that will be looked at here.

This is very unique data set, very powerful data set I think ultimately and this linking activity will go forward as this rolls

out.

This shows our projected estimate as to how many research participants' data will ultimately be in NDAR. You can see it's been broken down into some of these components underneath and you can see that in the next few years we expect to have a large number of research subjects registered and their data will follow thereafter.

So this is all good news. The bottom line here is that NDAR is a robust platform, it's got lots of important capabilities and it is a platform for building community standards and collaboration.

The NDAR team is respected, which allows us to work across the ASD informatics community, which is very important in informatics, to harmonize approaches and so forth.

And I think we now have a data sharing regime in place which we will not leave as is, but we will continue to move

forward and make it more aggressive that allows for direct data submission from a broader ASD research community than we started with and which will allow linking to data in other ASD databases.

The bottom line of this bottom line slide though is important and that is that despite all of this progress and all of this promise, data influx will not be instantaneous. This naturally will have to take several years. So with that, I'm happy to take any questions that you might have.

Dr. Insel: Thank you Mike. Questions or comments from the committee? Cathy?

Dr. Rice: Thank you for the update. I have two questions. One, are there any plans to provide funding opportunity for projects outside of these listed to be able to supplement their projects to have the resources to input to NDAR?

And two, who are the expected

users? Is it only those who input or will this be a restricted use data set or a public use data set?

Dr. Huerta: Yes, so that's a good question. So in terms of the supplements, we actually under the ARRA opportunities offered a large offering of supplements to the community, we had no takers. I think that we are -- I'm uncertain, confident that if supplement requests came in for people to supplement their grant to allow them to submit data, I'm sure we'd be very enthusiastic about that.

In terms of who will be able to use the data in NDAR, that really is open to all qualified researchers. So unlike some other databases in other parts of biomedical research, this really is open to the research public.

Dr. Insel: Cindy?

Dr. Lawler: So this is really nice to see that so much data is now being

deposited, but also to see for the first time that actually release dates that are coming up fairly soon, I guess May 2010 some data will be available publically.

So I wanted to know, do you have some marketing strategies for how to sort of announce what's going to be available so that, you know, the scientific community is, you know, ready to --

Dr. Huerta: Yes.

Dr. Lawler: -- look at it as soon as it becomes available --

Dr. Huerta: Yes, we've been working with the press office at NIMH communications office, I'm not sure what the exact title of the office is to do that working up press releases and figuring out, importantly, the timing of this. We've been trying to get the word out in other ways.

We have hired one FTE through the ARRA funds, Christen Mead, who's in the audience, and her primary role is to get the

word out, more at an investigator level. But I think with these 43 -- for example, we're having -- we're participating in a Mind Institute meeting on Friday, so we're working on many fronts to do just what you're saying, and it's very important.

The other advantage here though is that by linking with AGRE, by linking with IAN and all of these other data resources, you know, that will get those communities involved as well. So, yes, Jim?

Dr. Insel: So can I just follow --

Dr. Huerta: Yes.

Dr. Insel: -- up on that Mike. I mean, this really is meant to be a portal to the world of autism data. So other -- and people on the IACC could help us actually think about how to make sure this is more accessible and whether there are other organizations that need to be involved. This is for everybody to share with. Jim?

Dr. Battey: Yes. I think it's great to have all of that data available. I'm a little worried about the wrong people using some of the information that's in that database to the detriment of the clinical participants. What safeguards are going to be put in place to prevent that from happening from say insurance companies getting access to the data or, you know, somebody who you might not want to have access to the data?

Dr. Huerta: Right. Well so these users will need to be qualified researchers at NIH recognized universities. We use something called the GUID, global unique identifier, I talked about this I think at the last IACC meeting, which the Office of General Counsel at NIH thinks is a pretty safe bet that it's not going to be able to -- people are not going to be able to de-identify subjects.

It's an important question. The other nice thing about the GUID though is it allows data to be accumulated over time from

an individual research subject without knowing who that person is and that has scientific and other positive ramifications.

Getting back to Tom's point about this being a portal, I have limited time here, so I didn't get into all of the things and I really wanted to address this.

But we're adding other functionalities to NDAR that I think the research community will find very useful.

For example, we now have the ability to link data sets that are submitted from a particular project that has been funded with a particular grant to link that to the impact to the publically available impact data and the publications that are linked to that grant as well as an example of the kind of information that it will be available through NDAR.

Dr. Insel: Does that answer your question Jim?

Dr. Battey: Absolutely. It

sounds like you've got very good safeguards in place.

Dr. Insel: Other questions or comments? Lyn?

Ms. Redwood: I think I had asked before about whether or not medical records would be included in this data set and I believe you said they could be. Is there initiative for that to take place or is that something in the future that will happen?

Dr. Huerta: So there are medical record forms, are you talking about just general patient health records like everybody's --

Ms. Redwood: Office visits, illnesses.

Dr. Huerta: Yes. Now at this point, this is a research database and it really -- NDAR itself has collections of the medical history forms that are collected as part of a research project. Now we will be connecting up with other databases such as IAN

and such as, you know, AGRE and data, whatever data are in those large databases would also be available through NDAR.

But this is not meant to be an electronic health records repository.

Ms. Redwood: I was just trying to get to the question if we're looking at whether or not children have infections, things along those lines. Could this database be utilized to try to identify some of the co-occurring conditions associated with autism.

Dr. Huerta: Right. So I think probably the biggest opportunity for something like that might be through NDAR's connection with IAN. So the idea is IAN will be generating GUIDs for participants that are in that database and I think IAN has a lot of that kind of information reported by parents, primarily.

And if those individuals then are also enrolled in studies, and that's

frequently the case because researchers are increasingly interested in using IAN to do recruiting, and that's one of the reasons we see such a good opportunity there, then there will be these individual GUIDs for whom we have this kind of data that you're talking about in IAN.

But if those folks are enrolled in studies and research results are generated and submitted into NDAR, that's the beauty of the system. You'll be able to go in, pull out that individual and bring data from both places. So the answer is, those data will probably not reside in NDAR, but will be accessible through NDAR.

I'm sorry if that's overly complicated, but that's the way it's set up.

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

Dr. Janvier: I was just wondering if the intramural group is going to have a clinical opportunity to take a look at some of

the information there, analyze it?

Dr. Huerta: Oh, yes. Yes.

Dr. Insel: They were -- weren't they the first site for --

Dr. Huerta: I don't -- probably they were the first submitters of data I'm guessing, well they were among the first.

Dr. Insel: Okay. Anything else? Larke?

Dr. Huang: I'm not familiar with these databases or with IAN and AGRE and also is this -- does this include interventions research or services interventions or is it pretty much biomedical databases?

Dr. Huerta: So at this point, it will include those types of research as well, yes. Yes. So right now, the three classes of data that are resident in NDAR are phenotype, and that includes clinical assessment, genotype and imaging data, but those are just the data types.

The types of studies that are

conducted that generate those data include intervention, include the whole range of ASD research.

Dr. Insel: Very good. Thank you Mike. And we're going to move on to hear about an update from the Services Subcommittee and I'll turn this over to -- Lee, are you still with us? No. Ellen.

Ms. Blackwell: Okay. Thank you Tom. It sounds like Lee's on a plan, so I'm going to actually give his presentation today. There were essentially two items that we wanted to talk about.

The first is to remind the committee that we had a Services Subcommittee town hall meeting that some of you participated in in July. It was held at the Autism Society's annual meeting outside Chicago in St. Charles, Illinois. You can click to the next slide.

The idea behind having this town hall meeting was to solicit more input on the

strategic plan, particularly the areas of services and what does the future hold. So we had a great panel, Susan Daniels from OARC came talked a little bit about the committee, the Department of Education was there, Gail, Stephen and Alison, the CDC represented by Melody Stevens and Bonnie Strickland did a great job from HRSA.

So the OARC did a fantastic job, by the way, taking the IACC on the road, which was no small effort. The meeting was broadcast live and it went off very well. Okay, next slide, got to back up a little bit.

I think there were about 200 people in attendance and one of the nice things about this meeting was unlike our meeting today, everyone had an opportunity to interact with the people who were there.

So each agency made a short presentation, talked a little bit about their work in the autism realm and folks came in and, you know, talked with us, not just at us.

So it was really nice. Next slide.

Generally, the responses fell into three categories. There was some feedback in terms of question two, how can I understand what is happening, a lot of feedback on question number four, which treatments and interventions will help.

And I think Tony did a great job today talking about some of the concerns that were raised at the meeting regarding early intervention. Next slide please.

This is kind of a long list and I'll just highlight the ones that came up. Obviously there were a lot of comments about services, specifically they fell into the realm of more training, better infrastructure, improved coordination, better dissemination of what works, encouragement to people who want to participate in autism related careers and also using strength-based approaches.

So to me, those were kind of the highlights and I hope that later today when we

talk a little bit more about our strategic plan, I'm actually pretty pleased that we managed to integrate most of these concepts into the suggested alterations and the plan. Okay, next slide.

Question six, what does the future hold, you can see the ones that the audience raised at the meeting. Generally, these sort of fell into the category, the two categories of what services do adults and transitioning youth need and how can I get them.

So, that's kind of what came out of the meeting. It was really, I think very nice. And again, I can't think OARC enough for the great job that it did supporting us. So that is a brief summary in Lee's absence.

I think he really appreciated having the opportunity in conjunction with the annual meeting. That worked out very well.

So regarding the other thing that I wanted to mention today, we have been continuing to have very nice presentations at

the Services Subcommittee on services and I hope that those of you who are interested can tune in and members of the public can tune in.

We had a great presentation on September 15th, Gail Houle, who is not with us today, talked a lot about Part D of the Individuals with Disabilities Education Act.

You may not be as familiar with part D. Part D is the grants portion that covers personnel development, state improvement, technical assistance, technology improvements, and parent training. And Gail brought with her that day Sam Odom, one of her grantees from the University of North Carolina who gave a fantastic presentation about supporting the use of evidence-base practices in learners with autism spectrum disorder.

Sam talked a little bit about the National Professional Development Center on ASD, which is a multi-university project, University of North Carolina, University of Wisconsin Madison and University of California

Davis Mind Institute.

Most of their efforts are focusing on professional and family training and evidence- based practices. The Department of Education also runs a program that provides technical assistance to 12 states.

So I urge anyone who's interested to send a request to OARC, isn't that correct Susan, that you have Sam's presentation available for those who would like to take a look at it.

So with that, I'll just make one more request. When I attended the recent NASB meeting in California, I had a great discussion with Paul Shattuck from the University of Missouri who next summer should have some very interesting research coming out on the tracks, transitioning youth with autism into adulthood.

So I think it would be wonderful when Paul has that information out to have him present the committees. I wanted to find out

if that was something that you all would be interested in.

Dr. Insel: Thank you Ellen. Great summary. Let's open this up for question or comment. Ellen has posed a question to us, is there interest in hearing about the project? I see a lot of heads nodding, so maybe Susan and Della can follow up.

For those of you who were at the town hall meeting, anything to add or any other comments? Okay.

Ms. Blackwell: I hope that maybe sometime in the future we could consider doing this again, maybe here in the Washington area were we could have participation from other IACC members.

Dr. Insel: Right. So that was actually the only question I was going to ask is based on that experience whether we should try to make this a regular event, perhaps not always at the ASA meeting, but at some other

meetings.

And I haven't asked OARC if they'd like to do that, but if the committee thinks it's a really good idea, I'm sure that they would be happy to oblige. Maybe not happy, but they will oblige. So that's terrific. Thanks so much for your leadership and for Lee's involvement as well. Larke?

Dr. Huang: I'm sorry, I'm always a little delayed on my questions here. Ellen, I have a question on this question two, this need for research on how the use of restraint and seclusion impacts brain and emotional development.

Was there a discussion on that or was that a theme? And I know there are some issues in the Department of Education, and the Secretary has come out with about the use of those practices in schools.

Ms. Blackwell: Yes. In fact the person who made that comment had read the report, Larke, and specifically, you know,

wanted to talk about restraint and seclusion in schools related to children with autism spectrum disorder.

So we had a discussion about that at the meeting. As I said it was interactive, so we talked about it a little bit, but that's pretty much where it went.

Dr. Insel: Okay. Let's move on with the agenda. As I said, we're very far behind -- Lyn?

Ms. Redwood: I was just going to make a comment. If we have another town hall meeting, I think it would be nice to ask all questions and I know it's wonderful to get the services input, but I think it would be important to hear about the other parts of the plan as well.

Dr. Insel: Yes. That's an important clarification. I think this particular town hall meeting was specifically for services, but I wasn't recommending that we only do that. I think if we're going to do

it, we're going to open this up much more broadly. Great point to make.

We have a little bit of business to do, we never actually approved the minutes from the July 15th meeting so if I could just call your attention to those. They're in your folders and I'm hoping you might have even looked at them ahead of time because these have been sent out.

Let me know if there are any revisions, edits, comments, issues. Jim? Let's see if there are any comments first. Lyn?

Ms. Redwood: Spelling error bottom of page 16, last sentence, folinic instead of phthalic acid. That's all.

Dr. Insel: Okay. Somebody got that? Susan, page 16 spelling. Done. Anything else? Jim?

Dr. Battey: Can I then make a motion to approve the minutes with the change that was identified by Lyn?

Dr. Insel: Second?

Ms. Singer: Second.

Dr. Insel: In favor? Anyone?

Dr. Shore: Steven Shore on the phone, in favor.

Dr. Insel: Thank you, Steven. It's good to hear from you. We were afraid we might have lost you at some point.

Dr. Shore: You did for a bit, but I made it back.

Dr. Insel: Okay, welcome back.

Dr. Shore: Thank you.

Dr. Insel: Okay. We are ready to move on to the next item, which is what will take much of the afternoon, which is a discussion of both the ARRA funding that's happened as well as talking about the update on the strategic plan.

These two things are, of course, related because we will be -- we use the ARRA funding to implement the strategic plan, to jump start it, as it says here. And what

we're going to be talking about is first to take a look at what's been done, try to get into the weeds a little bit around that.

You have in your folders a complete list of everything that was funded, it looks like this. There are some, total of some $85 million in grants, this will show the `09 funding, so it will be about half that, because these are mostly two-year awards.

So you have the list of all the grants that were funded, and as you'll see in a moment, this was supposed to be related to the strategic plan because the funds were provided specifically for that question.

Let me take you through this very quickly. You've heard a little bit about this, but it's now time to really review what was done, so you have the details. And all of this, I hope, will inform a discussion about what needs to be done to update the plan.

So ARRA, the American Recovery and Reinvestment Act, it was signed by the

President, I believe in late January. This provided considerable amount of funds, really, for three things. It was essentially to stimulate the economy at that time, it was a jobs bill and it was meant to both create and retain jobs.

And what was wonderful about this part of the ARRA was that, rather than simply doing construction or building roads or looking at what were sort of shovel-ready projects, the President asked for beaker-ready projects that could be used to advance biomedical research or as the White House subsequently said, using recovery for discovery.

The idea was that this was because it was a jobs program and it was meant to stimulate the economy, it was to be done quickly and that meant that the money mostly had to be obligated by the end of the fiscal year 2009, which for us was the end of September 2009.

If -- all of the money has to be obligated by the end of September 2010, the fiscal year we're in now. So for us to make two year awards, and remember NIH usually makes four or five year awards, so a two-year award is a very short time to do research, essentially those funds already have to be out the door, and they are.

So I think 90-some percent of the ARRA money, which in total was over $10 billion to NIH, over 90 percent of that has now been obligated. For what?

Well it's two things, one was to use existing mechanisms for projects that were already underway that could be supplemented or expanded or in some cases projects that had been reviewed, but hadn't been funded because they didn't meet the pay line.

So a lot of the funds were invested in projects that were already underway and that was kind of one big chunk of this. The rest was to use this to do some new

things that we couldn't do with existing funds. And that's actually turned out to be very Interesting.

There were some NIH-wide programs as well as a small number of institute-specific programs. There was only, to my knowledge, one disease- specific program that was developed and that was in fact for autism.

So these are the NIH-wide programs that were developed. One was called the Challenge Grant Effort, which were grants that -- up to $1 million over the two years and there were several that were relevant to autism.

There were hundreds of different topics, so this only provides you examples of some of the things that were out there initially. This was the first thing that was done and one of the Challenge Grant targets was specifically as it says, addressing the IACC challenge, it was addressing the short

term objectives of the autism strategic plan.

And I should clarify that I think part of the reason why there was a big investment in autism was because we had a strategic plan. So we were able to point to that and say, you know what, this was just released in January, here we are in February and March, we know what we need to fund. Having these new funds really will help us to jump start it.

Grant Opportunity Grants were larger. These were over $1 million over the two years and again, there were many different topics that were developed. I only list the three that were created in NIMH because each of those actually has some relevance to autism, but there were many in other institutes that were equally relevant.

And then finally the really most targeted of these efforts was the autism RFA. This was the only disease-specific request for applications and it was focused on the

heterogeneity of ASD with a subtext that it was also meant to implement the short term objectives of the strategic plan.

The five institutes got together, they committed $60 million for this effort, but as you'll see, we actually went a bit beyond that because of the quality of the applications that came in.

This is how it breaks down. If you look at the total funding it's looking now at 2009 funding, the figure's about $45 million. Steven, do you have access to the -- are you able to see this on your laptop?

Dr. Shore: I can, yes, I can see it. It freezes up every two or three minutes so I lose stuff as I reboot, but I can see it. Thanks.

Dr. Insel: Oh, goodness. All right, well I hope you can stay with us here. So the $45 million represents not only the autism RFA, but these other mechanisms like the Challenge Grants and the GO Grants, the

supplements and additional RO1s that were already in the pipeline aren't mentioned here.

We think that, when you put the two year data together for `09 and 2010, the figure will be around $88 million, but it's not yet set in stone because we still have to do some of the coding on this, and that will still happen over the next few weeks.

It's worth remembering that $88 million is in addition to whatever the NIH investment will be in 2009 and 2010. The comparable figure for everything the NIH was spending back in `07 was $93 million, `08 $118 million.

So that's about a 25-percent increase and in `09, the assumption is that figure of $49 million will be on top of about $120-something million. And we'll have the something, again, over the next few weeks, which will take us into the $160 million, $170 range.

So not quite a doubling from `07,

but pushing that and it's getting, you know, some very significant increase from where we were in FY07 based on the coding that's been done here.

This is the breakdown for the six objectives, and we'll go into this in more detail, but it's worth your knowing that, in addition to the strategic plan providing these, I'll call them targets for ARRA investment, it also brought attention to autism as a great area to invest in.

We heard this, the President came at the end of September to thank NIH for the huge effort that was done in implementing ARRA in this FY09 and he talked about three others that he felt were really ripe for huge progress and important for public health.

He talked about cancer, he talked about heart disease, but most of all he talked about autism, which was really impressive to those of us in the audience that this is something he cares deeply about and he talked

about his passion for this area and his excitement about seeing this kind of a new investment, as he said, looking for $1 billion over the course of his administration.

This is really going a long way towards that. He called for a 16 percent increase in autism in his budget relative to a 1.5 percent increase for NIH in general. So it's clearly something he cares about.

And subsequent to that, the Secretary put on her website, I think a very strong message about her investment and her commitment to autism as well.

So the RFA includes a whole range of things. As I mentioned the theme was the heterogeneity and focusing on the short term objectives. We had 590 proposals, so it was a very robust response.

We used a new sort of peer review for this that included an editorial board and then a series of panels. And about 20 percent of the panels and these peer review committees

were members of the public. I don't believe anyone from the IACC, except, Steven, you served on this if I --

Dr. Shore: Yes, I did. Yes.

Dr. Insel: Okay. And you did as well, Chris? Terrific. Anybody else who served on? Okay. It was a large number I think we had a total of 90 reviewers, so 20 percent would be about --

Dr. Shore: Yes, it was huge.

Dr. Insel: Yes, 15, 16 people. It was a very big effort to go through a very large number of grants. It was a massive amount of work, but a great set of discussions. From that, we were -- we got the top cut of grants that ended up getting funded.

As it says here about $35 million in 2009, total amount will be roughly double that because the `09 funding is half of the two years. So you can assume that it's about $68 million from this RFA that will be spent

as it says in the last budget -- in the last bullet.

What do we fund with this? Well, happily, every objective has grants that were funded that will map onto those objectives, mostly in terms of the short term objectives. I'm not going to go through these because you have a list in front of you and you can look as you go through that to see how they map.

But we can take you through different pieces of this in terms of the dollars, so maybe these slides will be interesting to you, we've got these as well.

That objective one has about -- of the 68 about 4 million -- I'm sorry, this is of the FY09 so this would be about of the $35 million about $4 million goes into objective one and it breaks down accordingly.

For objective two it's about another $4 million. Objective three is where of course the most action is. Maybe not so surprising because, if you think about what

can be completed in two years, to do a large scale clinical study of a novel intervention it's just -- it's going to take you two years to even recruit the subjects let alone to be able to complete it.

So it's the kinds of studies that look at genomics, at biomarkers, at mitochondrial measures and inflammatory markers. Those are the kinds of things and many of those fit into objective three, those are the kinds of things that can be done in a short term. So it's not surprising that so much of the money went there.

There are some studies of interventions, some of them are novel interventions and that represents a little more than $9 million of the $35 million, and then -- I'm sorry, $45 million is the total.

Oh, okay. Della corrects me, this is not just the RFA this is also Challenge Grants and GO Grants, so the total is about $45 million not $35 million. That's

why it doesn't add up.

And finally objectives five, which has about $1.5 million, and objective six, $2.2 million, are less than what you're seeing for much more on the biomedical of these disorders.

But all of this is -- so, anyone, you don't have to have our printout you can do this for yourself if you go to the site, the NIH reporter site where you can see everything listed. You have to put in, as a search term, put in autism, which you can see right here and then you can either ask for ARRA projects specifically or you can ask for all projects.

And when you do that, you'll get a print out that looks something like this that will go through every one of the projects by its grant number, its title, tells you where it's from. And you can then click on this and get deeper into the database to get much more information about each project.

In addition to this kind of

reporting, there is a requirement because of the -- for the ARRA projects themselves that every quarter, the principal investigator needs to submit information or their university submit information about how many people were hired, how many jobs retained, what kinds of research has actually been done and what kind of progress is happening.

So this is going to be very much a public effort with lots of oversight. That's a very quick overview. Let me just stop there and many people around the table as well as some on the phone have been involved in this effort and can also reflect back about what it's been like. So I'll stop there. Jim, comments?

Dr. Battey: Just one quick comment for the committee and that's that just in the Challenge Grant category alone, NIH received roughly 20,000 grant applications. So the response to the ARRA initiative globally at NIH was enormous.

Dr. Insel: Any other comments or questions about this? So out of the 590 applications I think it was something like 50 that were actually funded or a little bit more than that. It's less than 10 percent for certain.

We tend to look for a success rate that's closer to 20 percent, we'd like to think that we can support the top 20 percent of proposals that come in in most areas. As Jim said, with 21,000 or 20,000 Challenge Grants we were way below that, I think we were at 3 percent for the Challenge Grants.

For the autism RFA we did much better, but it's still not where we want to be. The good news is that people can come back, people who did not get funded will have an opportunity to apply through the standard mechanisms and we expect to see a lot of these grants coming through our regular peer review system.

Dr. Battey: And in fact they will

have had the benefit of one round of peer review when they come back, which generally, if it's a good idea, makes the priority score the next time around better.

Dr. Insel: Steven, do you want to say anything about the review process itself?

Dr. Shore: Yes, I do. Yes. I felt the review process, it was long, and as you mentioned, it was very well organized. And I was also pleased to see that, in addition to myself representing people on the autism spectrum, John Elder Robison was also selected to assist.

I also liked the engagement of people from the community such as Pat Fischer, for example, who clearly is not on the IAAC or any other national boards and she contributed a lot of good information as well. So I felt satisfied with the, very satisfied with the procedure.

Dr. Insel: Susan?

Dr. Shurin: Yes. Just on the --

willing to do some of the work that's supported at Child Health Institute, much of the work that has been supported here is actually going to position us well for future research, because a significant amount of it is developing tools and doing some background work, who's mining those kind of data will really hopefully enable us to move faster.

So I think that a lot of the work that's supported not only is it very, very high quality work, but it's work that it will actually help us to move the next stage of the research agenda along a little more rapidly. We're very excited about that.

Dr. Insel: Yes, I think this is one of the things that's been important to explain is that because it is two-year money, the way that most people used it and particularly the grants that scored the best were the grants that were building infrastructure.

Now how we support all of that in

2011 is another question, but it certainly will give us a lot more opportunities. Was there -- Chris?

Ms. McKee: I just wanted to comment about the process, as well. It was quite grueling. But as you sat around the table with the scientists, there was heavy involvement from the parent community as well as individuals on the spectrum.

And a lot of the research topics were very scientific in nature, but they kept turning back to, before they voted, stakeholder interests, priorities and how we really felt about the science. And I was really impressed that before any voting ever took place that we were back talking to stakeholders and making sure that every single person had a say. So, that was --

Dr. Insel: Other comments or anything else about ARRA? There was also ARRA funding that went to HRSA; is that right, Chris? Anything to say about that?

Dr. DeGraw: Yes. We did get a substantial amount, or at least what we think are substantial amount of funding for HRSA programs under ARRA, but nothing that's directly relevant to, you know, the work of the Committee and autism.

The Agency got about $2.5 billion to spend over the 2009-2010 for programs that coincide with HRSAs mission to improve access to health care for the underserved. $2 billion for expansion of the community health center program, which is the biggest program, $300 million to expand the National Health Service Corps, and since more than half of National Health Service Corps clinicians work in community health centers, that was an additive benefit to expanding vastly of the health centers.

And the third area of funding that we were directed to spend on at HRSA was for health workforce training initiatives, it's like $200 million for that that are expected

to train approximately 8,000 health care professionals with this increment of funding.

This includes $33 million to train more health care professionals from disadvantaged backgrounds, including scholarships for disadvantaged students and increasing nursing workforce diversity. That about sums it up for HRSA.

Dr. Insel: Great. Thanks. Questions for Chris at all? Let me welcome Henry Claypool to your first IACC meeting, we're delighted to have you here. There's been lots of conversations and I know you know many of the people on the committee already, but I guess this is the first meeting you've been able to attend. So thank you for joining us.

Mr. Claypool: Well thank you, it's a pleasure to be here. I think Rosaly has been here, we're really trying to take all of your efforts and better understand where you are today, thanks.

Dr. Insel: Great. Unless there is anything else on the topic of ARRA, I want to move onto the next item on the agenda which is really the work we have for the rest of the day and that has to do with the updating of the strategic plan.

And I think we can -- I don't believe we have slides, oh we do. Where would we be without those slides. So let me just give you a quick kind of overview of what this is about and this is a case in which other people will probably do most of the talking because we have had many people on the committee who have been so involved with this.

So let's just -- the 30,000-foot view is the -- Combating Autism Act requires a strategic plan with budgetary requirements and that that plan be updated every year.

The concept was that the plan should be updated based on, A) new science that comes out and we've already heard about some new science today that might need to be

incorporated as we go forward; B) anything that might be completed that could be sort of taken off of the list of objectives once their completed, which would be nice to know I don't think we're going to hear about many of those; and C) there were some items that we deferred from January and several of the objectives, they were just issues that we felt we didn't have enough information, we didn't have enough time or for one reason or another we said, look, we're going to update this in a few months anyway let's put it off and we'll deal with it then.

So we came back to you and talked a lot about how we should do this update and what you recommended is that we form a subcommittee, which we did with members of this committee and that subcommittee went right to work to develop a process, which you approved now in the spring.

And that process had many steps to it. One of the first things that was done was

the portfolio analysis that was put together and mapped onto the strategic plan objectives. That was a -- by itself when you think about what the IACC has accomplished, that is one thing that we can look to.

It's 19 funders, both public and private who submitted everything that they are supporting in the way of autism research, a total of about $225 million of research.

I don't know of any other disease group where we had that, where we can sit down in one place, look between Autism Speaks or Simons Foundation or CDC or NIH and see what's being invested and for what is it being invested in, who are the PIs and what are the titles of the grants and to really get a sense of how all of this arrayed.

And in addition to that what OARC did then was to take that whole portfolio and then to overlay it on the strategic plan to get an idea of where are the gaps still after all of the funding has been looked at.

In addition, they put out an RFI which got some comments back. You heard also there was a town hall meeting that Ellen's already told you about.

We had the summary of advances, which you approved at our last meeting and that was really integral to this idea of looking at the update because you want to have any new science on the table when you think about what needs to be changed in the plan.

And then of course there were some new initiatives like these ARRA initiatives, which we didn't have funding information about, but which we could at least describe to the Subcommittee.

The Subcommittee with your approval went ahead and did a workshop, they formed a set of panels that -- well they did two things, they formed these interesting panels, one for each of the strategic objectives, except that five and six were combined.

And each panel had, as I'm remembering this, two members of the IACC, two clinicians/providers and two members of the public -- I'm sorry, two researchers. I'm getting -- right, two members of the public. So there were six altogether that would form the panel.

And based on that, there was a workshop that was help on September 30th and October 1st a little bit like the workshop that was done for the original strategic plan, but this one really was to say, let's go through this, what's new, what's changing, what do we need to know about that we haven't heard before.

And then a very interesting conversation over the course of two days on each of these - - for each of the panels going through each of the objectives. So that was fundamentally the process.

Our task now is that each of these panels has sent us what we'll call line edits.

I mean they basically have gone back to the Word documents for this original strategic plan and they've said based on what we're hearing from the scientists, based on what we're hearing from clinicians and providers and based on what we know about from all these other sources, these are the things that we should put in here to tweak the plan, to improve it a little bit.

And there were clearly gaps that weren't in that first version. So if you think about this as strategic plan 1.1 or maybe 2.0, what you have in front of you is their recommendations for line edits.

And what I want to do now is turn this over to the Committee for two things, one is to get some input from those of you who were so involved in this process about what worked, what didn't work and how you, you know, how you saw this as a process, because we're going to have do this again next year.

And the second is, get your best

thoughts about how to handle the task in front of us, because we've got, I mean, I don't think anybody wants to go through this line by line like we did last year, but we do need to actually sit down and go through the text to make sure that it's clear and it's what you want to have in the new document.

Last thing I will say before I open this up is just to remind everybody that I just told you about probably the only big bump we're going to have for doing new funding.

We'll find funds here and there for opportunities that arise, but we put all of this money in implementing the strategic plan 1.0 because we thought that's what the IACC wanted for a strategic plan.

If you just today tell us, oh, forget about that one we want a different plan, all I can tell you is that money has already gone out the door and it's going to take us probably, well two years to spend it

and probably five years to know if it worked.

So before you completely revamp the 1.0 version, let's make sure that any changes we make are changes that we really need to make to improve it and not just because we have yet another idea of something we could put out as a funding opportunity.

So let me turn this over then to the Committee and I'd be interested in your input about the process. First of all, who served on the group? So Yvette, Alison, Ellen, Steven, I think, yes, anybody else here? Cathy, right.

So your thoughts, what do you think? Did it work? Was it a good way to do this? Anything you'd change for next year?

Dr. Johnson: This is Jennifer, just to clarify. I was not a -- an original member of the planning committee so I got involved later on and I think I'm not considered an official member of the planning committee, I just facilitated one of the

panels.

So that though, I think I have feedback on that process and that it was kind of hard to get involved later on and be asked to do the things that I did.

I was happy to do it, but it would have been helpful to be a part of the planning committee from the beginning so that I could have a better sense of the whole process and be a better contributor to that process.

Dr. Insel: I think you just volunteered for next year; you're signed up. And let me tell you this is a lot of work. The people who were involved with this took on much more, I think, than they realized. Yvette?

Dr. Janvier: You know, I was a part of the original workshops and I was able to see some of that continuity, but it was challenging for some of the people that were a part of the group were not, not just Jennifer, but many of the participants.

So that's why I think some of the -- there was a significant shift from our original concept to some of the changes, or there was a little bit of a mismatch with that. But, you know, I think we were able to work that out and we were able to develop a good consensus, I thought, with at least the group that we worked with together.

Ms. Blackwell: Christine's group and my group had a third of the strategic plan, so I need to note that one of our recommendations is the question five and question six be segregated next time and treated separately.

Because as Christine will attest, it was a lot of work for the folks that work with us, I think they did a fantastic job, but we asked -- and we asked a lot of them, they came through, but it was challenging. Do you have anything to add, Christine?

Ms. McKee: Yes, absolutely. I think we could have had two more phone

conferences, we had three. So one more than the other groups, but yes, the issues are distinct and need to be separated.

Dr. Rice: I would add, I think that the mix of the backgrounds was really helpful I think in bringing up a variety of issues in terms of how the panels were divided.

So I would definitely encourage that we keep that, having the researchers, people personally touched, and clinicians. I thought it really brought up a lot of good discussion to get down to the point.

The one thing I would add is an additional step in that I think we had a lot of good information, but then it was a lot of information and me being back up and our panel fell primarily on Alison, so I definitely thank her for all of her leadership.

But having one more step of having the committee themselves do the line edits, and that wasn't as clear whether we should

have done that or not, but it would have helped us know, are we really capturing what they were trying to get at. We had to do a lot of translation there, I think, and hoped that we captured what they wanted

Dr. Insel: But it's not too late if we decide as a group that we want to do that, actually I think in panel four we did something like that. But if other panels didn't, it's still possible that we could share whatever we're working on to make sure it really captures what the panels wanted.

At the end of the day, it's our call so we're responsible for making the edits. But, if you want to make sure that there's fidelity to the recommendations, there's no reason you can't check back. Cindy?

Dr. Lawler: I'll just weigh in. It seemed to me -- I was at the workshop and hear the panel discussion was all ears particularly for panel three because that's

most germane to the institute that I represent.

And reading the line edits, you know, I'm not, you know, certain that they reflect a lot of what I heard, so I wasn't privy to, you know, how those, you know, how the panel consensus was incorporated into these line edits here and that's, you know, I'm not sure how to -- maybe in the future make sure that that, you know, what that process was.

Because as I said, just listening to the panel discussions, it just seems somewhat of a disconnect with the edits that I seen for panel three.

Dr. Insel: Are there other -- Ellen?

Ms. Blackwell: Yes, I would agree with Cindy. In fact, our panel, which had questions five and six, I understood our charge to be that we would, you know, we actually did make line-by-line, word-by-word

changes. So I think our panel was perhaps better poised than some of the other ones.

But when I reviewed this material last night, I also noted that what is in the proposed plan doesn't necessarily reflect what I heard out of panel three in its reporting.

Dr. Insel: So -- Alison?

Ms. Singer: I have to agree with that. I mean having been at all of the panels, I think the other five sections really do reflect the conversations at the panels, but really the material and what was submitted for panel three bears almost no resemblance to what was talked about at panel three.

It's my understanding that before she resigned from the IACC, Dr. Landis prepared her line item changes in conjunction with the OARC. And last night I asked the OARC if we could take a look at that language and decide as a committee whether that was a better reflection of the discussion at panel three. Do you have -- are we able to look at

that material?

Dr. Insel: So apparently we have -- I think we have everything that has been submitted at any stage of the process, so that's possible. I think that I hear the concerns about panel three, the problem for us is that Lee isn't here and that panel was led, the two liaison persons were Story Landis and Lee Grossman and neither of them are here.

So the question is whether, you know, whether we want to just table this until we can get some clarification. I think this is another place, because there's such a concern about the mismatch between what was talked about at the workshop and in the subcommittee meeting versus what you received.

We can go back, you know, Lee isn't here to explain this, so I'm not sure if there's something that happened since the subcommittee meeting last week. But I would recommend that we table this part of it and come back to that when there's a chance to get

some clarification about the two different versions. Other people have feelings about that?

Dr. Shurin: I would agree with that. I think it's the only sort of fair way to go so that everybody here is in the discussion.

Dr. Insel: Okay. Well we can go ahead and take on the other -- there's still plenty to do, believe me, even without that, we'll be lucky to get through much of this this afternoon.

Anything else as we look at items in front of us? Okay. You want to get started and we'll -- I mean there's, unfortunately, no way to do this except to get into the weeds and I realize this can be tedious, but it's actually -- the devil is in the details and these things are really important to get right.

So I can tell you, Steven and I worked on panel four together and it was

really interesting as we started to do that, we realized there were just some things that weren't right in the original version that we were easily able to correct. So I think you'll see that as we go through each of these objectives.

And what we'll do today then is to -- I think we can start with panel one and just walk through the recommendations. Because other than panel three I think we have somebody here for each of these groups who can talk about them. Deb?

Dr. Hirtz: Is it all right to go to a specific comment for --

Dr. Insel: Well, why don't we start with -- who's the liaison person for panel one? So it's Yvette and Jennifer.

Dr. Hann: And I just wanted to add in your packets in addition to the actual line edits you also had the summaries from the workshop panels themselves. Just so you know that you had those materials available to you,

that was all.

Dr. Insel: So take it away. Give us a sense of what you think needs to change here.

Dr. Johnson: Okay. I think, from our panel discussions, both Yvette and I agreed in the end that the panel that we worked with was really recommending refinements to question one and not recommending drastic changes to the plan and that it really captured what we wanted to be looking at in this area and just really bringing out or refining certain aspects of it.

When you look at the question, when should I be concerned, I think the word when is what perhaps our committee really challenged us to think about the idea of when is the when going to happen, I guess, is the best way to put that.

So, I think this question was originally conceptualized as one that was

based on the importance of diagnosing children as early as possible, based on the notion that early intervention leads to better outcomes for children on the spectrum.

And again, our committee really challenges to think about when children are diagnosed and that children are not always diagnosed early on in age and sometimes they're misdiagnosed and some people aren't getting diagnoses until later on in life. So they really encouraged us to think about a lifespan approach in this area.

The other thing is that what came out in our discussions is that diagnosis is not a stagnant thing and it may change over time. We heard about people talking about losing the diagnosis or losing the explicit symptoms of autism spectrum disorder or that conditions may change over time and so we wanted to, I guess, reflect that in the changes to question one.

The other thing that our panel

asked us to look at, or I guess refine, is looking at diverse populations, not only in cultural and linguistically diverse populations, but also lifespan and also in terms of co-occurring conditions and looking -- better understanding co-occurring conditions.

Is there anything that you wanted to add to that, Yvette, before we -- okay, so I think that's sort of a summary of what overall our panel was recommending. And I think those, then, changes were reflected in the edits you see to question one.

And one of the things I wanted to point out in the first paragraph, there's a sentence there highlighted about the current diagnostic criteria and there was discussion at the scientific workshop about changes to that diagnostic criteria.

I'm not an expert in this area so I don't really know what those conversations are entailing, so I just pose that question to

the committee; do we need to revise that sentence based on conversations that are occurring?

Again, most of the edits are just reflecting changes in terms of reflecting the lifespan approach and also again, refining and looking at some of the diversity within the population. I'm just looking through this to see if there's anything else that I want to highlight for you all.

In looking at the -- then looking at the research opportunities --

Dr. Hann: Could you talk a little bit about the aspirational goals?

Dr. Johnson: Yes. The aspirational goal, there was a recommended change to the aspirational goal. That's not reflected in this document only because I, at this point in time, wasn't sure -- no I did delete that original goal and put in the revised aspirational goal.

So again, I think the aspirational

goal was revised to reflect the discussions that came out of panel one. Is there anything else that you wanted me to -- okay.

Dr. Hann: In the prior version -- I mean in the first edition, aspirational goals was something that the committee was involved in and wanted to have the wording done in certain kinds of ways, so I just wanted to highlight that that had been changed.

Dr. Johnson: And I think the original aspirational goal was again, if you look at it, it had in there that children would be identified by 24 months and again, the changes are reflecting the lifespan approach.

And I think that's something for discussion with the IACC to decide if we want to take that lifespan approach under this question or if we still want to be more focused on the notion of the diagnosis early on.

In terms of the changes to the research opportunities, one of the things that was changed, again, was looking at refining the language in there to reflect the diversity that was being recommended and also the issue of the co-occurring conditions. So those are the changes that you're going to see in the research opportunity section.

Do you want me to highlight the specific changes or just kind of do the -- okay. In terms of the short term objectives, you'll see some changes to what is listed there in the short term objectives.

What was done is to categorize them into three broad areas. One being looking at diagnostic tools both in terms of screening and more in-depth diagnosis and then the next being to look at dissemination strategies and what happens with those tools and then the third being at outcomes after the diagnosis, which one could question, does that belong under this question.

But it's here because sometimes children or adults might get a diagnosis, but we don't know what kind of services that it's leading to and if there's a relationship between what's found out in an assessment and then the kind of services that someone might be receiving. So that's why they are there.

There's also some changes to the long term objectives, and again, just refining really what was in there originally. And that I think pretty much covers it. Yvette, is there anything that you wanted to add?

Dr. Janvier: No, I think you pretty much covered it, really. And again, I think a lot of the discussion was really more about incorporating current research and, for example, we said tools.

And I think our concept might have been autism-specific screening tools where there was a discussion about a general developmental screening tools. And the major discussion was really about implementation,

that, you know, we have a lot of things that are out there, but how is that being, you know, carried through in the community, that whole world of implementation research, really, can be very critical in carrying over the certain guidelines that have been published.

Dr. Johnson: The other thing I'll add is that our panel has not reviewed these changes, so we did not do that kind of work with our panel.

Dr. Insel: Do you think that would be -- Jennifer, should we do that or what's the sense?

Dr. Johnson: They did give us very specific recommendations and so those were grouped into broader theme areas. So they might look at it and say that there's a difference between what they recommended and what appears in these edits, but I think it still would be helpful to take it back to them and have them review it to make sure that we

did capture what their recommendations were to the IACC.

Dr. Insel: Okay. Susan?

Dr. Shurin: Listening to you talk tells me why I was confused by some of this, because I think when the question is, when should I be concerned, it sounds like time. And that actually is completely appropriate if you're talking about the early-diagnosis issue.

Once you get into the lifespan issue, which I actually would advocate, I think it's really important here, you actually are sort of asking a different question. And I haven't quite finished rewording it to my own satisfaction, but it sort of would be more focused on benchmarks than time, you know, like what observations should make me concerned about someone or something of that sort.

And as I said, I haven't -- I was trying to figure out why what was here didn't

seem to fit with the question, but listening to you, I understand.

And I just wonder if maybe that would be something to consider is to slightly reword the question if we're going to get into more than early-diagnosis issues and really get into the lifespan issues.

Dr. Janvier: I think the input really was, there are many points when someone could be concerned. I mean our original concept was what Jennifer had said earlier was, you know, our focus initially with the plan was, you want to identify this as early as possible, prenatal, postnatal, biomarkers, biological signatures, et cetera, clinical screening and so on.

But, you know, again with the input from our members, we had a different concept that -- and many of those folks were not part of the original plan so it was really kind of a drift or shift or something.

But I think we all felt that that

was valid including, you know, the recognition of some of these co-occurring conditions that really might not have anything to do with early diagnosis.

Dr. Shurin: And I actually agree with that. I just think that then the question -- because the when question is a time question and that's an early diagnosis question. And as you broaden it, then I think it probably needs to be a little bit reworded. But I agree with it. I think it's actually a really appropriate discussion.

Dr. Insel: Della?

Dr. Hann: So it sounds, just listening to this discussion, I'm wondering if you look at the text, the overarching question is when should I be concerned and that's what you've been discussing. Immediately under that though we have like sub-bullets to try to, like, flesh it out.

And I'm wondering if the first sub-bullet really ought to be sort of reworded

a little bit to become the main bullet based off of your discussion.

So currently, the second bullet or excuse me, the first sub-bullet says what are the early warning signs and what that could be are what are the signs of ASD.

Dr. Johnson: Just to -- I'm glad you brought up the bullets because when I looked at those I decided not to touch those because I felt like we had to make a decision about the lifespan approach. And if we do take the lifespan approach, I think those bullets do need and I agree the question needs to be changed because it is misleading in the way that -- if we take the lifespan approach.

Dr. Janvier: I think that the questions, I thought, you know, that was Joyce's concept, you know, working with children and families and some young adults I thought that was a nice concept though because, you know, we wanted this to be accessible to parents and families so that,

you know, there was something clear and concrete, but, you know, underneath the bullets I think give us enough leeway to cover what we're talking about.

Dr. Insel: Chris?

Ms. McKee: It's very hard to edit by committee. Well, just in reading through this, we ran into this with questions five and six, as well, that as we add language across the lifespan it looks like it's just stuck in there and here it stands out that way as well.

It starts out by talking about a child's primary caregiver, again, by age three and then it talks, oh lifespan, and then the next questions -- the next sentence says some children at risk.

So if we're going to go with across the lifespan, I think that -- I know we don't want broad rewrites, and think we do make it come together and gel really as a cohesive plan instead of as things stuck in at the end of the sentence.

Dr. Shurin: Important to define that because it actually impacts the research agenda.

Dr. Insel: Alison?

Ms. Singer: One thing about this process of looking at question by question by question is that you sort of lose sight of the document as a whole and one thing we talked about in the Subcommittee was, I'm going to jump ahead to question six, altering the title of question six to just focus specifically on adults and what does the future hold for adults with autism spectrum disorder.

And that really feeds back into question one. Last year, in last year's version of the plan, we didn't spend enough -- we didn't have enough emphasis on adults. And I just want to make sure if we're going to add, we're going to make that change to question six, which I think we should make, that we not, in version two, lose sight of children.

So it may make sense if we're going to make that change to question six, to do a little bit more focus in question one on children, making sure that we reference the lifespan, but also making sure that we don't make the same mistake again.

Dr. Insel: This came up in question -- in panel four so I don't want to blur the aims too much here, but it was actually the very first thing we dealt with was the absence, in the original version, of trials in adults and the need to build that in. So you'll see it there as well.

So your recommendation is that we kind of keep this focus, but change the rest of the plan accordingly?

Dr. Janvier: I guess my impression of what does the future hold was much more broad than just for adults, because of where I sit, you know, I am very often the person telling a family their child has autism whether they're 10 months, 18 months, 24

months, 36 months and their first question is always, are they going to get married, are they going to go to school, are they going to have a job.

And, you know, again if I send them back to this plan, I don't think that it meets their needs, so that concerns me just from the work that I do.

Dr. Insel: Let me ask a different sort of question for those of you who are on this panel, what is it -- what is the science that needs to be done in this area to complete the need?

What would you see as the most important research to find out that we got short term, long term objectives and all that, but are we talking about fundamentally better diagnostic and screening instruments, epidemiology? Maybe that will help to guide us with what it is that needs to be in the focus of the text.

Because in a way, the text is

great and it helps to organize it, but what really counts at the end or what, you know, one of the key objective that you want to accomplish and when you'll know you've done it because obviously we don't want to have the same objective 10 years from now. So what is that? Lyn?

Ms. Redwood: I wasn't on this, but I just wanted to comment along those same lines. One of the things I really noticed in looking over this with regard to the aspirational goal is that it's really changed quite a bit because it's reading now, children at risk for ASD will be identified through reliable methods during the preclinical stage, before behavioral characteristics are present.

And last time we had children at risk for ASD will be identified by 24 months and receive appropriate interventions. And I have to say, I really like the fact that we're trying to identify them before it actually happens.

So I think by asking that question, what were we really trying to get at, it seems like that was one of the important things the panel was trying to get at and I really applaud that effort. And I think they did just a wonderful job with these questions, just the throw that in.

Dr. Janvier: Just to comment on a few of the questions. So where are we with the science, I mean, from where I sit, we have some screening tools, are they fabulous, I would say no. Could we develop better tools, I would think we could.

Are other tools that are in existence such as general developmental screening tools, God forbid if they were used, could they pick up some kids with autism, absolutely. But I think a major gap is we have things that are already in existence developed that are not being implemented.

So that was why a lot of our discussion focused on that. You know, we have

a test for autism, we have interviews, we have observational scales, we have all kinds of questionnaires for children, adults, adolescents, you name it, but actually the implementation in the community is really where a major gap is. So that was the scientific issue.

You know what Lyn raised, and again I was the one who was sort of admonished because I put that wording in there about 24 months and, you know, children that were at risk because being a clinician in that world, it's difficult with confidence to say a child has autism. Maybe some of the children we can, but not always.

The idea of preclinical markers is really more the biological signatures of whether it's a genetic screen or it's some other biological specimen that, you know, hopefully our colleagues in that world will develop prior to any change that we've noticed in the child.

So that was really, you know, kind of a different idea. Whereas we started out in the original plan as clinical, we don't have a blood test, a urine test, we don't have a prenatal test, we don't have a, you know, newborn screening test that we'd like to have developed, but that wasn't really our focus, you know, we weren't looking at that specifically, ours was really more of a clinical piece.

Dr. Johnson: I think the only thing I would add to that is the need for tools that would pick up children who are coming from culturally and linguistically diverse populations, that those tools aren't necessarily refined enough to be able to do that and reaching out into those communities and finding those families and those children, I think is another need that was expressed in addition to those that Yvette mentioned.

I think also in the way the aspirational goal was originally written, to

me the way I interpreted that is the goal is that we would reach kids early on so that we wouldn't have to worry about people being diagnosed later on in life, that we would automatically pick those kids up because we have the best tools out there.

So, I think that's where I take the aspirational goal. I understand the recommendation is to change it to be more lifespan because that's where we are right now, but for aspirational then we're really achieving that as our goal.

Dr. Insel: Ellen?

Ms. Blackwell: I wanted to revisit your suggestion for a second about sending the edits back to the panel members. I think that's a great idea, even though panel five did line-by-line, word-by-word changes I think that I would like them to see they contributed to the what do we know, what do we need section. But I would feel more comfortable sending it back to them. So

that's my first comment.

My second comment is I really liked your aspirational, revised aspirational goal. I thought it was great. And then one suggestion on page 6 I believe, where you revised the first long term objective, I would prefer that you used a different word, perhaps issues instead of problems, if you're okay with that Jennifer. Yes.

Ms. Redwood: Could you also explain why the objective was deleted, the one objective. I know there's a reason for it, I just wasn't certain why.

Dr. Johnson: And quite honestly I'm going to try and remember that reason. So I think what happened was the panel had -- was trying to figure out a revision to either add a short term objective or add in a long term objective.

And we decided that it really should go in as a long term objective and it ended up, I think the revisions to the long

term objective one incorporated some of those recommendations where, again, the panel was trying to decide should this be short term or long term and we made it long term.

And because of those changes, it seemed that the objective that was deleted was being addressed by the revisions that were made to the long term objective. And that's how I remember it so, we can certainly talk more about that.

Dr. Insel: Yes, I'm confused by that, but there are a couple of other things that weren't clear to me. I wasn't sure exactly what you meant by preclinical and whether that's going to be clear to everybody else who reads it.

And the second or third question was broadband developmental screening. At first I thought you meant Internet screening; I wasn't sure what that actually refers to.

Dr. Janvier: What that is, is there are general developmental screening

tests so that in theory one of the recommendations in the past has been for pediatricians to screen children's development. So you might look at gross motor, fine motor, speech and language communication skills.

So if you were consistently screening with an interactive test, you could pick up -- you won't miss a five-year-old who's not talking if you're checking if they're talking at 12 months, for example.

And that was from Debbie Fine, her terminology, this broadband developmental screening, I called it a general developmental screening tool, but that was the one thing.

And then preclinical was really, again, my concept of it was kind of like the newborn screening tests that before there are any clinical signs that some type of biological specimen or test could identify a child with autism or identify a potential medical co- existing condition.

Dr. Insel: Deb?

Dr. Hirtz: I'm so sorry I have to go, but before I do I just want to make one quick comment. It's only a one-word change, but I think the meaning is important on the first page on line 18. Rather than talk about cases of autism, I think we should say signs of autism or something like that. I'm not sure cases is actually correct.

Dr. Insel: Are there other comments or recommendations about these edits? Can we go back to Lyn's comment because I'm still confused about -- I mean if the aspirational goal is to identify kids before they have any, let's say, behavioral manifestations, which is I think what preclinical means, then you have to have a pool of biomarkers, right, by definition.

And the only way to do that would be to have something that's non-behavioral that you can detect. But I -- maybe I'm missing it, but I didn't see it in here any

longer. I think it was there and it got pulled out and now we're looking at biomarkers for accompanying immune metabolic gastrointestinal problems or other medical problems.

But are there -- is there a place in here where we're going to actually develop the PKU test to know the diagnostic or biomarker at birth or even prenatally or at six months or something like that or has that -- did we just lose that?

Dr. Janvier: I actually thought that was covered under a different group.

Dr. Insel: Yes, that's what I was afraid of. So we did have this in panel four where it said we can develop biomarkers, but we've changed it now to be specifically for predicting treatment response to identify subgroups. That's why it's really important to have this conversation here.

And the reason we changed it, we said, well panel one's handling the biomarkers

for diagnosis, we don't need to worry about that. So if you've taken it out here and we took it out there, we got a problem.

Dr. Janvier: Again, I always reference back to those four scientific workshops we held initially and the concept of biomarkers were covered in different workshops than these areas, so.

Dr. Johnson: I think to me in the first bullet there, there's the, line 13, a panel of biomarkers, is there, but it's not in the second and third bullets. And that just could have been an oversight in the editing process that that feature of the one that was deleted was not included.

Dr. Insel: So maybe I'm misreading it, but I read that first bullet as being biomarkers for the accompanying problems or medical problems, but not for ASD. Am I misunderstanding it?

Dr. Janvier: I think you're right.

Dr. Insel: So in the original one, the one that Lyn had asked about was actually what I think we had intended originally which was to go after the biomarkers that would allow you to diagnose ASD before there were behavioral manifestations.

Dr. Janvier: Actually, the other Interesting thing is we did not have any scientists from that realm on our subcommittee, we had all the clinical specialists, and not biomarker, genetics, et cetera specialists.

Dr. Shurin: So I actually have a question here because, although I love this as an aspirational goal, I wonder, given that this is something that we're updating on a yearly basis, if maybe the aspirational goal for right now is not that we'll get it before there are any clinical manifestations, but that we get it before there are significant impairments.

Because it's not that you don't get into the biomarker issues, but first of all, I'm not sure that everybody will understand what preclinical means, so I was wondering whether rewording it that, through reliable methods during or before ASD characteristics are present or before they're severe.

Dr. Insel: How about by 24 months? That's where we started.

Dr. Shurin: Yes, except that I think what you really want to do actually is you do want to move it way down before then and I actually think that's an achievable goal and that's actually why I sort of like it.

I mean it's true with many other medical diseases in which you want to do is you want to make the diagnosis not necessarily before there are any clinical manifestations, but before you have significant organ dysfunction so that it doesn't interfere with the quality of life as much and it enables you

to intervene.

Now ideally, ultimately what you'll do is you'll make that diagnosis before there's any evidence of disease, but that may not be something that we're going to be able to do in the immediate future and at least getting to the point where we're making the diagnosis in the overwhelming majority of people before they have really significant impairment would be a massive step up

And then as more and more things like biomarkers and genetic testing or various other kinds of things are available, you know, you can move those into this.

Christine said it was hard to do this editing by committee, and it is, but I think - - I don't think this is a trivial issue because I think what you'd like to -- when you're putting together a strategic plan, first of all you want it to guide what you're doing and it helps to have goals that have some reasonable possibility of being met.

And I think that actually is one that could be. I mean one of the things that it comes back to what Yvette was saying, there are tools available right now. If those were used more broadly, you'd avoid a significant amount -- we'd need more tools and we probably need better tools but there are some available right now.

So you sort of say, what can we do right now that would have a significant impact in the, at least in the short term on a significant number of people.

Dr. Insel: Would you -- would it work to say that children at risk will be identified at the earliest stage of ASD?

Ms. Blackwell: I think that's good.

Dr. Insel: Which is you assume is preclinical but -- I mean, we're -- actually it's a really interesting problem, as you know we deal with this on Type I diabetes now because we're actually trying to redefine what

the earliest stages to make sure before somebody has an abnormal glucose tolerance test.

Ms. Blackwell: It's before you've lost all your beta cells.

Dr. Insel: Right.

Ms. Blackwell: And that's really sort of the issue, and the same thing is true with what we're doing with heart and lung and blood disorders is you don't want to diagnose it after you really got major organ dysfunction, you want to diagnose it when you can intervene to prevent progression of the disorder.

Dr. Insel: So what -- but we're arguing here then is the earliest stage could be before there are any symptoms at all.

Ms. Blackwell: Correct.

Dr. Insel: It would be the stage of risk.

Ms. Blackwell: Or, yes, and they may also be stages at which the symptoms are

exquisitely subtle. Okay, so that -- but either way, but basically things that may not necessarily be outside the range of normal developmental changes, but that are things that make you, you know, make your spider sense tingle or whatever it is.

Dr. Janvier: I just would like to say I was working as part of the group process, but honestly I was not a fan of changing the aspirational goal at all and I think for the next 12 months, under 24 months is realistic as someone mentioned.

You know, in the United States we're still not diagnosing most children before four to five years of age anyway. But there was something else I wanted to say, I'm trying to remember.

Oh that, you know, again you gave us researchers that were working in clinical early identification and these concepts were definitely flavored by that. For example, you know, Geraldine Dawson who has worked on the

first birthday videos, you know, really was pushing the aspirational goal.

But again, I mean in the real world, there are very few children that are being diagnosed at 12 months. I mean it's really not where we are. So, you know, everyone had their own little world and their research and their agendas, but, you know, I really didn't feel we needed to change the goal. We did because we worked as a group on it.

Dr. Insel: Well that's helpful and it's our job to decide what this is going to say. We're looking for their expertise and suggestions, but we need to decide what we want to accept or reject. I'm curious about how other people see the aspirational goal, Alison? Anything else about this? Jennifer?

Dr. Johnson: I was just going to say that I think we need to decide how aspirational we want to the goal to be because the goal was rewritten in a way to reflect

what's going on right now and the fact that the people are missing -- being misdiagnosed or diagnosed too late.

So, again, do we want to be truly aspirational or do we want it to be a goal that we can live with for the next 12 months?

Dr. Insel: Alison, you had a comment?

Ms. Singer: I just was going to suggest that we specifically put in a short term goal for a development for biomarker for diagnosis. I think that was a casualty of the process.

I know in panel two we talked about biomarkers, but we only talked about biomarkers for pathway and mechanism and we said oh well biomarker for diagnosis is going to be panel one. So I just -- I don't want that to get away from us as really a casualty of the section by section by section process.

Dr. Insel: And it was originally, if I'm reading this right, it was a long term

objective, should it be a long term or should it be a short term objective? Is this something to, actually I think it's in the IACC -- I'm sorry the ARRA funding, there are a number of biomarker efforts. So it's being done short term, but is -- was there discussion about that in the panel?

Dr. Johnson: There was discussion about whether that should be short term or long term and I think our panel felt like it should ultimately be a long term goal.

Dr. Shurin: From a biomarker standpoint it's a long term goal because basically the problem with biomarkers is they have to be validated and you usually start by validating it with a clinical outcome. So you're going to start with those later pieces.

To get to the point where it's predictive, is going to take significantly longer and it's going to be a long term goal. I mean if somebody came out next month with a paper that says everybody who has this genetic

marker is going to get autism, I think none of us would believe it.

I mean it doesn't work for cancer genes and it doesn't work for most anything else. It takes a long time to do that, so it's a long term goal.

Dr. Insel: Okay. And that's where it was sitting before, so Alison?

Ms. Singer: Maybe it can be in both. Maybe finding a biomarker could be a short term goal and validating a biomarker could be a long term goal.

Dr. Janvier: We definitely did not have that expertise on our group and I don't recall that discussion coming up even at the two day workshop.

Ms. Singer: I think this just really reiterates the need to when we're talking about biomarkers and biological signatures, I mean we throw those terms around a lot, they were in all of the panels and everyone sort of said other groups were doing

it.

But I think even as we're tracking the funding, we need to be really clear about what our studies that are looking at biomarkers for diagnosis versus biomarkers for pathways versus biomarkers for treatment response and just make sure that we are tracking that properly and calling it out in each section if it needs to be in each section with the adjective.

Dr. Insel: Yes, just so little scientific comment, maybe a reality testing here. We do a lot on biomarkers in the rest of my life and that's what I probably spend most time on. And we even have a public private consortium with a great number of partners on this topic.

One of the things we've talked about is not only as Susan says, how difficult it is to validate them, and FDA is involved in helping with this, but also the sort of unforeseen consequences of this kind of

research.

So you can look at examples in cancer research where the advent of PSA, which was such a spectacular biomarker for so long has generated a huge amount of income, but not necessarily a huge amount of change in morbidity and mortality. In fact, now the question is whether it's created an increase in morbidity, certainly no change in mortality.

There are other examples like that as well, so it sounds great, but we really do need to be thinking about what it is we're inviting here and make sure that it's being done with an eye towards what the ultimate outcomes are going to be because there are, as I say, unintended consequences of these kinds of advances.

Dr. Shurin: It also effects the way you write every one of these sections because it's building the biomarker discovery and validation process into all the rest of it

that we'll end up with having some biomarkers, because if you don't know that it correlates with outcome, it doesn't mean anything and that's really the problem.

Dr. Insel: But it does sound like -- I mean from the conversation and from what I've heard even in the first iteration of this, it sounds like this is fundamental to what people wanted. They wanted a way to move diagnosis earlier and away from strictly being dependent on behavioral disability or behavioral manifestations, right?

I mean that -- so as we look at the and we can -- we're not going to finish this today, I mean what we're trying to get from you are sort of first response to this language. We can begin to morph this to be able to capture that and we do need to go back to the panel and get their input as well.

Let me ask one last thing, actually this will probably be mostly for you Cathy anyway, one of the questions I keep

getting asked by people when I talk about autism and where we're at is the prevalence question.

And I always cite the CDC numbers and now even the HRSA numbers and people always say, yes, yes, but isn't that all about just change in diagnosis or change in ascertainment and all, you know, more awareness.

There's no place in the plan that really addresses the question of incidents or analytical epidemiology to understand whether both whether there are more children who have the disorder and if so, how many more children have the disorder versus just changes in the number of children being diagnosed.

Did that come up? Was that even part of the panel's discussion? It's not anywhere else in the plan from what I can tell and yet, it's probably the most common, the first question I get asked.

Dr. Rice: Well I wasn't in the

panel discussion, but I know it came up in the workshops as something that really wasn't integrated very well, but was a huge need. And I noticed that I think you guys tried to address it by adding the word prevalence in one of the long term objectives, but I don't know that it -- I think that was an effort, but probably doesn't reflect what we need.

But I think it's somewhat tied to a discussion -- let me go on a slight tangent and hopefully bring it back to this.

This discussion we're having about preclinical versus behavioral markers I think we're missing the interim step about risk. Like we're making the assumption that we understand what at-risk means.

And part of where we are, I think more realistically is not only one, we're still missing very obvious children out there in terms of having the diagnostic tools and not to mention the practical issues of people being able to do the process of diagnosing

them.

But in between, we're building an evidence- base that helps us give an idea that potentially we could head off some, say, you know, clearly we know if you have one child with autism, we need to have heightened awareness in terms of screening future children within that family.

Some of the promising research looking at autoimmune disorders in families or advanced parental age, we're not really putting together a risk profile that helps us improve how we're implementing the screening and the follow up that we have.

And so what I was just trying to go through and think about, you know, rather than thinking preclinical or behavioral, but do we need an objective that helps us put together a risk profile that may be a combination.

Right now I don't think it's realistic of it being based on biomarkers, but

that it is more profile. So that's one thing to say. Maybe let's think about a risk profile issue here, but that relates to prevalence as well.

I think in terms of being able to answer that big question of is the prevalence of autism changing and I'm using the term prevalence versus of incidents very specifically because I think it's almost nearly impossible to do in incidents of autism, but you can do a prevalence study that in some ways approximates incidents.

So what I'm saying here is that we're going to have to be more complex and not just say, you know, getting the numbers is extremely important for us having realistic planning for services, for all the needs that we need to meet.

And we need to be able to go through and subdivide what's happening within that group and say well what is the change and risk happening here, how can we look at -- it

can't happen in isolation as we understand more indicators of risk we can see how they're changing in that population.

So whether this is the place to put that or not and that doesn't necessarily relate to diagnosis as it much does to, well let's have a profile that helps us understand risk, then how can we apply that both clinically for diagnosis and how can we apply it in terms of our research and understanding the population changes over time.

So maybe in some ways putting those together is a way to address both of those issues here.

Dr. Insel: It sounds like another bullet. No, I think you're capturing something that wasn't in the in the first version and didn't make it into this version. We could again, punt until next year, but why? I mean, if we feel like it's missing here, why don't we take this opportunity to fix this. So, Jennifer, go ahead.

Dr. Johnson: Can I just a question, follow up question to that? In looking at the second bullet, maybe I'm being a little too abstract here, but I guess wouldn't we have to get at that to be able to get the information that would be required for the second bullet under the short term objectives?

If we're going to develop or conduct research around both screening and diagnostic tools and looking at population based samples ultimately to in this three population areas, the infants at risk for ASD below the age of 18 months, most particularly in that group I'm thinking that you would have to look at a profile of what those children are presenting with in order to get the instruments, both the screening and diagnostic instruments.

So again, maybe I'm looking at it at too abstract of level and your offering more specificity, but it seems like you would

have to get to what you're talking about to get to that objective.

Dr. Rice: So I'm not sure if I quite understand. But you're saying to get at infants at risk you have to have -- know what risk is. And I think right now, I mean probably a lot of this, us read that as siblings or they have some features that just come to attention for some, you know, particular whatever random reason.

Is it because the parent noticed it or is because of screening? But we don't really have more of a proactive profile besides the siblings to help us understand what the risk is. So, yes, so I don't know I just feel like we're missing a step and that it is an additional bullet of trying to develop that risk profile.

Dr. Insel: So, you know, I think we're never going to be able to edit this totally by committee, you're right and we're not going to finish it here.

But what I wanted to do today is to get out the main ideas, because this is going to require a little bit of reworking and thinking first of all about whether there's anything here that came up that people are very uncomfortable with and I think we've heard a few of those things that we may want to rework and whether there's anything missing.

And Cathy you had said we can't really have incidents, a study of incidents as a goal because it can't be done or what's the reason for that?

Dr. Rice: Well I think incidents typically implies that you have a clear age of onset and that you have a moment of onset. So in cancer, I think it's the case of the diagnosis, people can debate is it when it actually occurred within the cells, but people generally say it's the situation of diagnosis.

So in autism you could say it is the point of diagnosis, but what we find in

our CDC data is there is still a sizable proportion of children who never get that diagnosis, but have the symptom profile.

So would we just exclude them from understanding prevalence of autism if we're looking at incidents based on that measure. That's one example of the challenge and that you have such variability.

Some children being identified very early on versus some much later average between four and five and some never. And so if you're actually trying to look at systematic changes over time, incidents compounds that problem of our diagnostic problems. Does that make sense?

So if you look at an older age and say, okay we're going to look at everybody identified up to that time period, you're at least controlling for some of the variability in terms of diagnosis that plays into the incidents.

Dr. Insel: So how do you get at

the question, are there more kids affected? What's the best way to do that?

Dr. Rice: So I wish I had the exact answer to it, but to give you some thoughts, in terms of, I mean, one is looking at a cohort in a consistent way up to the point where you feel like you're getting peak prevalence, we're capturing the most individuals up to that time period.

So multiple recommendations have been made by other experts as well in that we really -- although we would love to be able to be doing prevalence studies at earlier ages, the problem is we still miss quite a few individuals.

And so really, we're looking at between age 8 and 10 is when we get the most children effected. And so looking at that slice of individuals over time in well defined populations that then we can go back and start to sort out, you know, when we talk about awareness, community awareness, changes in

diagnoses, in addition to changes in risk factors, there's multiple things that you have to control for.

So at least if you're identifying in the same populations and the same standards, you can go back and say, well we know that these demographics switched in that period. We know that we altered our methods in this way in that period.

So it's still an ecologic evaluation, but you can then go back and say if we have multiple areas, we're looking at variations in different exposures, for instance or sociodemographic factors, you can start to piece that together. But it's not a quick process.

Dr. Janvier: Just a comment about the at- risk, and again I think that kind of came from me that at the point of the original plan, you know, the classic tools that we're using to make a diagnosis really were not valid under 24 months even though the CDC

statement we can diagnose kids with autism at 18 months.

And I was kind of shocked by that when there is a test that's not even published yet called the Toddler ADOS that will be able to evaluate children at a 12-month cognitive level. But I can tell you there are 24-month olds that don't have a 12 month cognitive level that have autism.

So, you know, even this, you know, it's not so clear as making a diagnosis at an early age. I think that's why some of this is really very messy. So, you know, I can see a 10-month old, an 18-month old and I might say they're at-risk for autism because I see features, but I'm going to be able to use definitive tools at 24 months and that's really where that 24-month part came from.

And at this stage of the game, it is a clinical diagnosis. We don't have a biomarker, we'd love to.

And again, I'm not even sure we're

going to know what that means because, you know, some of the work on trajectories, how are we going to know if this is the child who's going to be an honors student and go to college or the child who's going to be non-verbal and needs an augmentative communication system that is totally dependent. We're not even close to that.

Dr. Insel: Well the hope, I think the aspiration is that the biomarker will give you that. We know the behavior doesn't and so it's got to be something else. It's 3:00, we've been at this for awhile, so I want to take a break.

Before we do that, let's just see if we can get some agreement about the best process for doing this because we can't do this as a committee obviously, but we do need to get your best input about what the panel members are going to end up looking at and how we can get this done going forward.

We've got to have the revision,

the update by end of January. Now, it doesn't have to be an extensive update, the law requires that we update this every year and I don't think they want us to rewrite it every year, I hope they don't because we certainly won't be able to keep up with that.

But if it is an update, we've got a couple of months to work with. One possibility is that we have this discussion here, make sure that we're all kind of on the same page, we can work with the panel to kind of reshape the language, clarify things, maybe get this closer to what they've heard from this discussion, can go back -- I should say we can work with a liaison members of IACC and then go back to the panel and then come back for an interim meeting where we can actually get something that's closer to a final version.

Is that workable or and I should ask this of Della and Susan who are responsible for making sure we get everything

done on time.

Dr. Hann: I want to just make sure I'm understanding it because sometimes when you say panel I'm not sure if you mean the subcommittee or if you mean the workshop panel.

So, I've heard a couple of things today and one was several of the liaisons nodded their heads sort of affirmatively that they really would like to go back to their workshop panelists to have the workshop panelists take a look at what is written and provide additional feedback about that. That was one option I heard.

Then the other thing that I think I heard you say, and correct me if I'm wrong, is that that information then would come back to the subcommittee.

So the subcommittee, because that's primarily the liaison, we may expand to include Jennifer and Yvette, so there's representation for panel one on that, to then

sort of take a first crack at sort of incorporating all of this and making certain -- bringing up the issue that Alison brought up is there's some sort of continuity across the chapters, et cetera.

So that then, that sort of worked on document comes back to the IACC.

Dr. Insel: So the reason why we're trying to get some of this done today is if there are going to be new objectives, and there are several here, we need to generate budgetary requirements for them and that's going to take awhile.

We don't do that in this committee, but we have program people who help us with that. So, we want to at least get to the point where we know if there are going to be new objectives and if so, what those will look like and then we can come -- but in terms of the text editing and the wording, we can come back to that at a different point.

What's the sense of the group? Do

you want to do that? I'm going to hold you -- we're not going to take a break until I get an answer to this question because we need to know how you want to handle this.

Dr. Janvier: I guess I'm a little confused. When we update the plan, couldn't it just be, you know, a one-page summary, comments, whatever from our workgroups added to the plan instead of rewriting the plan or not?

Dr. Insel: No, I think the way we've interpreted it, although this again it's an IACC decision, we thought that updating meant refining, revising, tweaking so that it's up-to-date with the most recent science.

But if, you know, if the IACC said hey, you know what, we've got this document, it's got a nice cover, we don't want to mess with it and we can just send in two pages that would update, we can discuss that as an option.

I hadn't -- that's a brilliant

option actually, I hadn't thought of it and it would probably save us a lot of effort if you decide to go that way. I think what we heard from the workshop was that there were enough areas that probably did require some rework.

So what's your pleasure as a group? Alison?

Ms. Singer: I'm just not sure what we're doing today and whether it's going to be valuable if we're going through it and then we're going to send it back to the workshop chairs to change and then we're going to go through it again.

Is that -- am I misunderstanding the process? I mean, I agree it would be good to get input from the panel members because we do want the documents to reflect their input since we gathered them together and had a very robust discussion of the plan, but I'm not sure that I get what we're doing today if then it's going to go back to the panelists and be undone and then brought back to us.

Dr. Insel: Well so it's the way I see this is, this is our job. Their our advisors, but we ultimately have to make whatever changes we want. And as you've heard, there may be changes that they recommended that you say, you know what, we're going to stick with the original. That's fine.

So I'm not suggesting that you go back to the panelists to have them tell you what they already told you, but I think there is some value in after having this discussion if we decide that, you know what, we're going to do this, we're going to do that, we're not going to do these three things that they recommended, that we share this with them and make sure we get it right so that next year we don't have to go back over the same conversation.

But that's just the way I'm seeing it. I'm open to however you want to do this. Fundamentally though, bottom line is it's up

to us to decide what's going to be revised. The only other thing is things are moving so quickly that there may be areas where there have been changes in the last month or two that we can also get updated on while we're working on this.

So it is an iterative process and it's incredibly boring, but it's really important to do it in the way that gets us the document that we're all really committed to.

Ms. Redwood: Tom, one of the things is we didn't have this information regarding the ARRA and I'm wondering if that -- if we're going to delay this process, should we also try to incorporate that information in terms of what's been funded into the plans since that seemed to be a critical piece that we've been waiting for.

Dr. Insel: Yes, I agree with that. I think it's a really great idea because it may shift how you, you know, it could sense if you're about to put out an

objective that says, you know, we want to have five such studies and we've just funded seven such studies, I mean it may be that you want to change it accordingly.

So it may be useful to take that additional data into account and that wasn't available at this level of granularity to anybody until very recently. So we certainly didn't have it for the panelists to look at. Larke?

Dr. Huang: I was actually going to make a comment around the ARRA funds and what you just reported on too, but I also had a couple of questions. So in statute we are to revise this, update it every year? So we're going to go through this every year?

Dr. Insel: It's up to the committee how they want to do it every year, but every year it needs to be updated.

Dr. Huang: Okay. And I actually don't think it's boring or tedious, I'm really learning a lot from the discussion, but I'm

also wondering if we might -- given that it's a pretty laborious process, if we might think about doing it differently every other year.

I mean it seems to me in this discussion we've heard about things that might be improving the way we look at more of a lifespan for example, major sort of themes of changes to the current plan, something about the biomarkers being tracked throughout all of the goal areas sort of in a different, with a different focus on the research where the biomarkers were screening versus treatment and predictability.

If there can be a statement or a summary as opposed to changing it every year in detail, but how it's changed with new input and new panel discussions, the current plan and the summary kind of what Yvette was saying and then maybe the next year as things are continued to change we do more a detailed.

Because I'm a little unsure about what we even mean by aspirational goals now.

I thought I knew at the workgroup two weeks ago, but now is it the aspirational goals within the next two years or a long term or short term?

I think all those aspirational goals, the short and long term objectives should be contributing to the aspirational goals. I'm not sure if we have that logical sequence now with the initial questions like when should I be concerned, how is that played out in the sort and long term objectives and how do they feed into the aspirational goals?

I'm feeling we're getting a little bit more of a disconnect than I thought we had earlier. So, and then I guess the other thing that in terms of a process, it might make sense for the co-chairs to meet to see how these are all integrated because they've been done kind of in components rather than us going through every single one, the panels or the co-chairs of the panels might be able to look at how they all fall together.

Dr. Hann: So I'm thinking about this too, I don't have a tea set that will help me to understand the motives behind why Congress decided that we have to update it yearly. But I think in other realms when one launches strategic plans, one often wants to know progress and that is important as part of the plan.

And since now we have a rich portfolio analysis, granted it's based off of the 2008 data and now we have ARRA information, it might be worthwhile to go through, just as we have in the portfolio announcements and indicate in the plan which of these really do have active research this going on and which of them don't because we do know that there are gaps in that regard.

And then we've also heard from the workshops that there are additional items potentially to be added to that. But that may be something worthwhile reflecting in the document.

So then and then the third piece has to do with this introductory sections, which is what do we know, what do we need and are there additional objectives, which are sort of broader kind of issues and that that might be the place to incorporate some of these newer themes or if there's new research that really modifies essentially what we know and so forth like that to include that.

That might be another way to sort of think about this and that way the document really does become something that charts the progress over time as well as then incorporates the new based off of the science and what we're learning essentially as we go through this process.

Dr. Insel: Are we getting closer to having the process here? Cathy?

Dr. Rice: I have a question, just to clarify. I feel the same way as you, Larke, in terms of I've lost site of the aspirational goal and where we're focusing.

So maybe at least we could step back and say when we talk short term and long term what time period are we talking about.

I guess I'm ahead, I had like five years and 10 years, but that -- I have no idea. And then to just say well the aspirational goal is what we would expect to meet by the end of that. Maybe that's a real concrete way, that would at least help me get my head back around where we are.

Dr. Insel: Ten years.

Dr. Janvier: I think originally way back if I can recall the discussions from last year when the aspirational goals were being developed, some of them were more clear than others, but I always sort of walked away thinking about 10 years as sort of like, 10 years from now where would we want to be 10 years from now.

Dr. Insel: Lyn?

Ms. Redwood: We also have a document that we have to turn in which is are

the scientific updates and I'm just wondering if we could somehow combine that process with updating the strategic plan.

So if there's great, wonderful science that's just come out like the new XMRV virus, that that instantly goes over into what was important research for 2009 and then we look at those and utilize those in the process of updating our plan to see if we have objectives that address this new emerging science. And that might make it more streamlined and seem more logical.

Dr. Insel: So I thought we did that this year, is that -- didn't we, you know, but I'm not sure that it was as seamless as it could have been and I'm not sure everybody went through all of the update.

And also the updates are a year old, which is always a problem because the most interesting things, the things you really want to have here are things that are maybe just in press now and aren't even published in

2009 and yet we were stuck with the 2008 reports. Susan?

Dr. Shurin: From the standpoint of the process, if what we're doing in terms of the revisions to the plan aren't going to impact what we're going to be doing in the six months or something like that.

I think that your suggestion of making some minor suggestions and then really putting the time in to doing it right so that among other things, as we do this again in the future we will have defined the mechanism that, you know, that the overall structure is pretty much the same and then you go in and you sort of update and perhaps move things from, you know, one component to another as they move along.

But I'm a little concerned that we're putting a lot of effort right now into something which doesn't have the kind of urgency that would justify the amount of time that it's likely to take and that perhaps

walking it out as a process and investing in it over the next several months would be a more productive way of doing this.

I'm actually hearing an awful lot of consensus from folks around the table. It's very encouraging there's a lot of --

Dr. Insel: Yes, so that's a great comment Susan, I feel the same way. Just to clarify, we weren't expecting that we were going to finish all this, this afternoon and we took on strategic objective one just as a test case. So I knew this was going to take us a long time to get through this.

And that's just fine because we wanted to have -- we wanted to try this out and see what was going to be workable for us in trying to address both the spirit and the letter of the law, which is that we do need to update.

But I think Susan's comment's a really important one. I mean there was real urgency to get this thing done by January 20,

2009, we had to have something, I felt to hand to the Secretary on -- at that point it was his, now it's her first day of work and use that to argue for a major new set of initiatives. And it worked out great because ARRA came right after that.

As far as I know, there's no similar funding opportunity that we're looking at in the next year and it may be actually a bigger funding challenge than anything else over the next year or two.

So I'm not sure that the, you know, generating 20 new objectives right now has the same kind of urgency that we were experiencing in December and January of this past round. So we can think about how, you know, we could back up here, do a series of kind of refinements and tweaks to the document we have and then begin to prepare opportunities for the 2.1 version, something like that.

Also I should tell you that there

are a lot of things going on, very quickly we mentioned XMRV this morning, I don't think that many of the scientists are waiting for this plan to do the very next best experiment, they're running as quickly as they can based on the science that's out there.

So if something isn't in here, it doesn't mean that it will never get done, it simply means that we haven't captured it and we're not documenting it here.

Dr. Shurin: The one area where there may be something that we need to be sure that we're on top of is the area for this as it relates to health care reform.

So we want to be sure that we've enunciated something that we're willing to take to the table and, you know, we already have something, but the question is does that look the way we want it to because I think it's going to be really important that we present something from the, you know, from the standpoint of the services as part of this

discussion.

Because I think this is clearly one of those areas that if you're -- you got to be up there making noise or you're not going to get what you need.

Dr. Insel: So, yes, so we'll come to that and we'll do that after the break. So let's - - I'm not sure we've resolved the question, I promised that I'd hold you here until we did, but let me put this on the table and see if you can live with this.

We're going to walk through everything but panel three fairly quickly in the rest of the afternoon to give you a sense of what came out from the workgroup effort and from the panels that looked at each of these.

We're not going to do line by line edits, but we want you to see some of the themes, and you'll hear they're actually very similar, each of these objectives, it's the same themes that come up over and over again that we're trying to work into the language.

We'd like to take this time to get input from the whole IACC about anything that we're missing or anything that you've seen that's come forward that you think is really awful so that we know whether to change it or not.

The end of the day, we'll try to get through everything but panel three and then we'll take this back to the liaison people, the two people from the committee who are going with OARC and come up with integrating your comments, just the way they did integrating the comments from the panelists.

We can take another round with the panelists, if everybody feels that's a good idea, and then we'll bring this back in some other form. But what I'm hearing now is that it sounds -- if I'm hearing this right, it sounds like the committee may want us to do less, not more in terms of the changes, but making sure that we integrate some of these

themes especially around lifespan kind of approach.

Is that acceptable? I know you don't want to finish this today, because we couldn't even if we stayed here all night. But if we could use the rest of today to at least get your -- the big picture from you and then we'll end up doing another round of this, very much like what we did for the strategic plan originally, that was an iterative process as well to get to the things we really needed to.

Remember that one of the things driving this was that we had deferred some items and those were items that we need to come back to as well. Okay? If you don't say yes, you're not going to get a break.

Ms. Singer: It make me very uncomfortable to hear us talking about doing less not more. I think we should be doing more not less. I think we've done a lot to update this strategic plan. I think we have

held workshops and the liaisons have done the line by line edits as we were asked to do.

To now go back and take all of that work that was done and transfer it into a two page update I think is heartbreaking and --

Dr. Insel: I'm -- okay.

Ms. Singer: -- a waste of a lot of effort.

Dr. Insel: Oh I didn't think anybody was suggesting that, I'm sorry. Let me be really clear about this. I wasn't suggesting that we throw out everything that's been done. What I am suggesting is that as an IACC, there are a lot of things that I feel still are not here and I would like to bring them up. I think we should all hear about them.

But maybe we don't need to do everything this year. I'm still not happy with the plan we've got. I think it's great in some respects, but there are things missing

and I, you know, what I'm suggesting is we work with what we've got, but we not -- I don't want to extend this whole process to many other iterations, right.

So, what I'm really looking for is that we use today's meeting for the big stuff. Remember when Dr. Zerhouni first came and he said, you've got the boulders and the rocks and the sand? We're kind of in the sand right now when we do line edits.

I want to use today to do the boulders and the rocks, especially if they're rocks or boulders that are missing or rocks or boulders that have been added that people don't want so that each of you who is responsible for this document as the liaison members know what needs to be tweaked.

And then we'll bring it back once we've got this input for something that's more final. That's all I'm suggesting. But, is that okay. I just don't know how much further we'll be able to get today by doing line by

line.

Dr. Hann: So let me just see if I can clarify, because I can still tell people are like, "what". So, what I'm hearing is that we will go through, we'll take a break, we'll come back.

We will have a general discussion about the other chapters, except for three because Lee's not here, that the liaisons being part of the general discussion will think about if there are additional areas that they think the wording could be modified in some manner. Is that what I'm hearing? And then that would come back?

Dr. Insel: Right. That this is a general discussion for big topics. I can tell you for panel four, Steven and I cam summarize this in five minutes. I mean there were a few ideas based on new research, there is not a profound reorganization or change in what was originally there.

But there were some mistakes in

what was there originally, we want to make sure we get those fixed. And that's it. That won't take us a long time.

But we'd like to know, since ultimately it's this committee that's going to decide what to do, we'd like to know if there's something that you feel is missing that you'd want us to integrate.

Ms. Singer: I mean, I think there's going to be a point where we're going to have to go through the plan. I thought we were going to do that today, it sounds like we're just going to take another step. But I would bring us back to the overarching theme that we try to think about which is the urgency of autism as a health care crisis.

And frankly the idea that we're not going to discuss section three because one person is unable to attend this meeting is ludicrous to me, but if that's the decision, you know, eventually we're going to have to talk about it if not today then another day.

But, we've had great input on what needs to be changed in this plan, we've always talked about the plan as a living document that at some point has to be cut off, we have to stop discussion, print the document, but then continue to talk about what needs to be updated.

And I think that's the reason that the law requires us to update the strategic plan annually because we have to think about that document not as it's done but that it's always evolving.

So some of this conversation makes me very uncomfortable, the idea that we're going to do less not more is -- we should not be saying that at this table. We should always be doing more, not less.

Dr. Insel: So Alison, how would you like to proceed this afternoon? How do you want to go through this?

Ms. Singer: Well I understand the procedure that you're proposing, which is

basically to add an additional step, which I think is a good one to take the material back to the panelists and get their input.

I think it's unfortunate that we didn't think to do that prior to this meeting or that the time frame was so compressed that we weren't able to do that. I think that would have been the ideal situation which was to run the line by line item changes that we did so painstakingly back through the panelists for their input and then bring that to the table.

I think it does make sense to get their input, so I'm agreeing that we should take another meeting, but I don't -- I can't imagine that the output of this process is just sort of a prose-based update rather than a line by line change of the document.

I think we really have to have a goal of having a line by line update of this document every year.

Dr. Insel: What I think we're

struggling with, at least this is what I hear looking around the room is how to do that, because it's so difficult to go line by line with a full committee through a document of this length, when at the same time we're trying to bring in some new concepts.

And you've already heard that just with this first objective. It will take us, I think it will take us the rest of the afternoon to do the first objective because we haven't, you know, we've left a lot of questions in the air here, a lot of things that are still not resolved on that and we have five more to do.

So, what's the best sense of the way to get this done?

Ms. Redwood: Tom, I agree with Alison.

Ms. Singer: I'm happy to sit here until it's done. I mean, I don't mean to interrupt.

Ms. Redwood: No. And Alison I

feel the same way. I think this is the most important thing for me as a panel member that we do and I think that we need to dedicate a significant amount of time and resources to doing it.

And I think when we schedule it for maybe two hours at the end of the day, then it always puts us in this position where it's not quite complete, we have to schedule another meeting. And so I would like to see us dedicate the amount of time that we need and I think I heard Larke say the same thing.

And as a committee, if we want to decide that we want to do that and, you know, we'll all need to vote on that, but I'm willing to come back for eight hours and work all day long and go through this line by line until we get it right.

Dr. Insel: Well, I'm so glad to hear you say that because we already have a date picked out and we, as I said to you, we were not intending to get this finished today,

what we were intending to do was to develop a way forward and we wanted to make sure there was a really good conversation about what parts of this you want to do and how far do you want to go with it.

If you really want to embark on this, which is fantastic, November 10th we can take the day and we can really start, at that point, you know, if we don't get it done then we can spend more time after that.

But we could begin to find ways to go through this in a way that really does grab the most exciting opportunities and identifies the best science. And line by line will take us time to get the language right.

And we can help you from our side by providing early edits so that you can look at them electronically. But, they do have it, but you only got it in the last couple of days and so it takes more time often than that to really -- if you want to do some of the revisions and make suggestions.

If that's the way the committee wants to process, let me -- I mean we hear that from two people, I want to know that the rest of the committee is willing and able to do this. I see Chris nodding her head, Ellen?

Ms. Blackwell: Well I have a comment about the last two chapters. I think that they were perhaps well developed than some of the other chapters and they come at the end, and yet they are usually the first thing we hear about from our public commenters, services and adults.

So we did, as Alison mentioned, spent a lot of time making a really concerted effort to update those chapters and I think it is important that we consider them and get them in.

Dr. Insel: Were you suggesting that we move their position?

Ms. Blackwell: No, just simply that I do believe we should take the time to look at them and consider them. Not

necessarily today by the way.

Dr. Insel: For those of you who weren't at the workgroup, that -- they're probably the most extensive changes in those chapters, so that will take real time. And they're not simply semantic changes, these are changes of real substance. So we do really need to spend time on that.

Ms. Singer: I think there's also going to be a suggestion made to add a chapter seven to focus on infrastructure needs. A lot of the items in that section were tabled last year and we need to consider those as well and that's going to take some time.

Dr. Insel: Yes, we will come back to that because there are some uber questions like that that need to be looked at. Cathy?

Dr. Rice: I would just agree that I think it's really important to go through the line by line because I think that the document that has been created, although it's a living document, has really done a great

deal for the research community in terms of autism.

I know I frequently refer to it and I frequently encourage people to look at it for establishing ideas and gives us a common way to talk.

And the more we can refer to this specific document and keep the momentum I think that has been established by the ARRA funds and the use of the plan, the more we could keep on that track of saying this is a specific yet living document and this is the best we've got right now I think is really helpful.

So I definitely would just second, third or whatever the effort is needed to go through it specifically.

Dr. Insel: All right. So the proposal on the table, I promised you a break, we'll actually ultimately do it, but the proposal would be then we'll come back and we'll go through the rest of this at a fairly

high level knowing that we're going to come back at another time and do a much more granular review.

And what we really need, I mean I just, you know, full disclosure, parts of chapters five and six are going to take a substantial amount of time, we're not going to get very far with that today, but I think you need to hear from Ellen the sort of overview of what that conversation was about and what the major issues were and why the group felt that we needed to do really a transformation of this.

So I want to make sure we have time for you to hear that. Anything else before we take a break? Okay. We'll see you in 10 minutes.

(Whereupon, the foregoing matter went off the record at 3:33 p.m. and resumed at 3:50 p.m.)

Dr. Insel: Okay. We need to get restarted. If you'll take your seats.

Dr. Hann: Also for our members who are flying out this evening, we are preparing cabs. We have three members right now who are willing to share a cab because they are all going to National, a fourth. Is there anyone else who wants on the cab bandwagon here? Thanks.

Dr. Insel: Okay. Panel two, let's go through this and give us a sense of what came out of the workshop panel discussions and items that the committee needs to hear about. Who were the liaisons for panel two?

Ms. Singer: The liaisons are Cathy Rice, Ed Trevathan and myself.

Dr. Insel: Okay.

Ms. Singer: Panel two was really focused on the underlying etiology, biology and pathways in autism. I say in general the panel has felt that the content of section two of the current plan was still correct and there was nothing that needed to be removed.

The panelists did have some concern that of the six objectives in the current plan, there were two that had received no funding, although I saw on the ARRA slide that one of them now does have some funding, specifically the one that targeted research specifically focused on females.

We had four specific areas that we wanted to add to the plan. The first focused on a developing a -- really focused on the technology behind skin fibroblasts and the new ability to create pluripotent stem cells.

We talked about the need to develop standards and protocols for this and we also talked about the need to develop a repository for depositing the skin fibroblast so that they could be converted to the pluripotent stem cells.

Secondly, we focused on the need to really look at individuals who were non-verbal and who had cognitive disability.

Third, we talked about the need

for studies that associated specific genotypes with functional and structural phenotypes including behavioral phenotypes and medical phenotypes and we talked about the need to better understand the association between behavior and symptoms. The idea being there that different subtypes might have different underlying biological etiology.

And our fourth area was really the idea of targeting the underlying biologies by examining pathway similarities and pathway differences in co-occurring syndromes like Fragile X or tuberous sclerosis and also in co-occurring conditions like familial autoimmune disorders.

But in general I would add that we really didn't see that we needed to take out or amend any of the existing areas. We made a few tweaks, but in general there was a good sense that section two was on the right target.

So we made some line edits that I

can walk through, or I guess maybe at this point we should open it -- I should say if Cathy wants to add anything and talk first about the four overarching themes.

Dr. Rice: No, thank you. You captured everything that I had.

Ms. Singer: Okay. So did anyone have specific questions on those four themes before I go through the section two? Okay.

We made a slight change in the first bullet, we changed are there subgroups of people with ASD that have been identified to people with ASD which relate to etiology to make it more focused on the concept of biology.

We added into what should we know, information that we gleaned from the list of scientific advances that the IACC prepared so we did discuss that on our panel.

We did really look not only at where were their gaps in the plan, but what had changed over the course of the year that

warranted adding information to the strategic plan or changing the goals in light of new studies that had come out.

So we added some of that material into the what do we know and we added three lines into the what do we know.

In terms of the what do we need, again we focused on the issue of phenotypes having different etiologies and the issue of combining genotyping and functional analysis.

We also in the what do we need, we talked about the other three areas that I identified specifically looking at individuals who are non-verbal and have cognitive impairment and then we talked specifically about the need to create standards and protocol for collecting and scoring skin fibroblasts.

We also talked about an issue that came up on our panel which was placing a priority on the translation of research into clinical practice so that whatever findings

are uncovered can be immediately used to improve people's lives.

We didn't change our aspirational goal. We did elevate skin fibroblasts within the plan. Last year we had talked about skin fibroblast sort of as an example, this year we specifically called out the technology for skin fibroblast because there's been so much movement in the development of that technology and the panel felt that that was really right for additional studies, so we elevated that.

In the research objectives, basically we outlined the four areas that I discussed. We added them into the short term goals. I mean, I don't want to read line by line, but this is where we added the -- we translated them into specific studies.

And then we added one additional long term goal, which was to evaluate the applicability of ASD phenotype in biological signature findings for diagnosis, risk assessment and clinical use.

Before we go on, I just want to thank the panel members on panel three -- everyone on panel two. We worked really hard, it was a lot of intensive work and a lot of great discussion, very respectful discussion and a lot of great ideas.

Our panel members were Pauline Filipek, Sara Spence, David Amaral, Emanuel DiCicco-Bloom, Ashara Buckley, Denise Resnick and as I said the co-liaisons were Ed Trevathan and Cathy Rice.

Dr. Insel: Cathy, anything to add? Okay, this is open for recommendations or suggestions from the committee. Lyn?

Ms. Redwood: Yes, I'm wondering about the new initiative that's under long term, launch three studies that target the underlying biological pathways and conditions related to autism, Fragile X, Rett syndrome and tuberous sclerosis.

And it just seems like we already have a lot of research into those areas, I'm

just was wanting to hear from the committee whether or not they see that as a new long term goal. It's bullet number -- page 7.

Ms. Singer: I think the idea there was not to specifically do research just focused on those disorders, but to really try to understand what they had in common and what they lacked in common in terms of pathways with autism spectrum disorder.

So it was really using the fact that there were similarities in clinical presentation to really get at the underlying biology and that there might be information that we could glean from the fact that the clinical presentation was similar, but that they were a lot that we could learn from both.

The differences in pathways and the similarities in pathways, but Cathy might be able to --

Dr. Rice: Yes, I mean that's exactly it. It wasn't just let's keep establishing that there is a co-occurrence,

let's go beyond that and say well what's different about those children that get autism and Fragile X from those that get just autism or Fragile X.

Dr. Insel: A study was done, there was a paper I think it was in *Neuron* two years ago, Dan Guessman, Steve Warren and crew it's very large looking at kids with Fragile X with or without autism and doing RNA profiling, lymphoblastic.

It was interesting. I mean it was definitely some striking and consistent differences, but I don't think there's been any follow up on that.

I don't think that's been done for TS, which is really important because we're now in both in clinical trials in TS so that would be a really great place to find out whether the rapamycin, which is being used for tuberous sclerosis will also reduce the symptoms of autism in those children. We don't know that yet.

Other comments or other suggestions for the group?

Dr. Johnson: I just have a question. I'm still interested in how these different questions relate to each other. And I think your question relates in many ways to the question that we had, in question one, when to be concerned.

Because in order to know when to be concerned and how to screen it and diagnose autism spectrum disorder, you have to know what's going on underneath. You have to understand what's happening.

So did your panel talk at all about the relationship between assessment tools and the research that needs to be done to understand what is happening?

Ms. Singer: I think all of the panels face this, which was because of the way the process was set up, each panel looked in isolation when really at the two day workshops everyone was saying, oh this is really more

for panel four, this is really more for panel one.

So yes, a lot of the issues about when should I be concerned came up with our panel, but we really tried to say well panel one is going to handle that. That's why I was so concerned before that it not get lost in the process, the idea of the biomarkers for diagnosis.

But we really tried to look at the question, how can I understand what is happening, we defined it in terms of biology, what is the etiology or the etiologies and biologies of autism.

Dr. Insel: Alison, can you clarify this same bullet I think that Lyn had asked about. I don't quite understand the language. It says launch three studies to target the underlying biological pathways related to autism to understand how they were similar and/or different.

And then there's another section

it says, three studies that target the underlying biological pathways of familial autoimmune disorders co-occurring with autism, diabetes, celiac disease, rheumatoid arthritis. So there are lots of questions I have about that including whether diabetes mellitus is always an autoimmune disorder.

But beyond that, is the panel recommending that we fund studies of those disorders that instead of doing studies of autism per se? Is that?

Ms. Singer: No. Again, and this, I think this is the same issue that Lyn raised, we are only -- we were suggesting those as examples because of similar clinical presentation and specifically with the autoimmune disorders, that was generated out of the list of scientific advances from 2008.

There was one paper in there that really talked about familial autoimmune disorders, particularly I think they were maternal autoimmune disorders.

We're not saying that we should be doing studies specific on celiac disease or arthritis, what we're saying is that there is information that we can learn by looking at the pathways that cause those similar or related disorders or conditions and that there might be information for us -- there might be a way for us to learn about the etiology of autism by understanding how autism is the same -- the pathway for autism is the same or different than the pathways in some of these co-occurring conditions or syndromes.

And I think the panel really focused a lot on understanding how the pathways might be different, even though a lot of the clinical presentation might have been similar. Again, I'm going to defer to Cathy to add anything else.

Dr. Rice: Yes, again, I think you summarized where it was. But that's certainly, when we go back to the panel can clarify, you know, was -- did it capture the

intent or not and that it's not very clear in terms of maybe the wording is -- it was coming up in the issue of the overlap, again and I think it was very similar in terms of, you know, is this an indicator of a common connection here between autism and these conditions or not.

Dr. Insel: I guess it's just not clear to me. I wouldn't want to see autism funding going into studying diabetes or Crohn's disease or celiac disease or arthritis. Maybe that's not the intent. Okay.

Ms. Singer: Let me word it a different way. I'm trying to find the --

Dr. Insel: Microphone.

Ms. Singer: Let me see if I can find something on the slides from panel two where we fleshed that out a little bit more.

Dr. Rice: Just saying, one, first recommending research on co-occurring syndromes versus co-occurring medical

conditions. So again it's the co-occurring that's the key.

Ms. Singer: And I think this is where we'll benefit from taking this back to our panelists and helping them flesh out exactly what the discussion was there.

Dr. Insel: Okay. That would help. Other comments? Cindy.

Dr. Lawler: I wonder if there was any discussion in this panel on the use of cellular and animal models. We think about what was incorporated in the -- I think question four last year, there was a specific objective related to developing and validating sort of models, but animal and cellular models, but that was focused on really identifying new targets for treatment.

And when I think about mechanisms and what's happening, I, you know, tend to think of those kinds of studies would be very useful for answering, you know, questions under number two.

And I don't think any of the objectives as they've written would necessarily exclude animal or cellular studies.

But I wonder if there might be value in sort of explicitly acknowledging the value of those kinds of studies and that when you're talking about pathway analysis it's not just you're doing, you know, transcriptnomics with individuals that are affected with the disorder, but you could do, you know, some elegant studies in cells and animals and whether that was something that had been discussed or maybe you could bring back to the panel for their consideration.

Ms. Singer: We didn't discuss it, but I think it would be great to bring that back to the panelists.

Dr. Insel: I think where the field is going, and this is reflected in this write up, which I thought was terrific, was that IPS cells will get you much further

because you can use the actual cells of people with the disorder rather than having to guess whether this monkey or this mouse has autism.

So there's a lot of excitement about that and already we've seen in ALS and in SMA it seems like it is really paying off. So, it hasn't yet been done, well it has been done, but it hasn't been completed in autism, but we have several groups running down that path.

And you can see in the ARRA funding that's probably one of the most popular areas to apply for.

Dr. Lawler: I think that's a good point, but certainly for environmental risk factors, I mean that's, you know, our bread and butter is really being able to do kinds of experiments in intact organisms and certainly those are not, you know, experiments or even, you know, can define exposed populations that will allow you to really rigorously test your hypothesis.

So I don't know whether just sort of cellular models with this fibroblast would really provide us with the information that we need if we really have a clue from an environmental risk factor in a human population, really want to understand what the -- you know, the pathways are and the susceptibility is, you really need an intact organism to do that.

Dr. Insel: Yes, I just add one last thing and we'll move on. But there are a couple of ARRA projects which are actually doing both. So they're taking cells, putting them into the mouse embryo, creating some, well it looked like human neurons in mice and then they're able to actually get whole organism studies where you've got the genetics you want.

So, it's a new day and there's a lot of really interesting stuff here. By the way, none of that was available when we did the strategic plan 18 months ago. So that's

why we're doing the update, there's a lot of really exciting science in this area and I would think that a year from now it will even be better.

Anything else for Cathy and Alison? So we're going to jump over panel three and then panel four, Steven are you with us? You may still be on mute. Steven?

Dr. Shore: I'm still here.

Dr. Insel: Well don't go away, you and I are on for panel four and as we talked about, I will just quickly --

Dr. Shore: Yes, I'm here can you hear me?

Dr. Insel: We can hear you, can you hear us?

Dr. Shore: I can hear you, you're kind of soft and think there's about a second delay between what I hear, and you talk and then when I finally get to hear it.

Dr. Insel: Okay. Well why don't I go through this and I'll turn it over to you

for additional comments if that's okay.

Dr. Shore: Yes, that sounds like a good way to go.

Dr. Insel: We had a really terrific group of people looking at this -- which treatments and interventions will help question. The clinical experts were Bob Hendren and Eric Samstad, the research experts Ed Cooke and Brian King, family and person experts Joyce Chung and Sharisa Kochmeister and then Steven and I did the sort of liaison coordinating function of this group.

They were generally positive about the plan. They thought that the objectives and the what do we know, what do we need were pretty good, but they right away recognized what they called gaps.

They were surprised that we didn't focus at all on the opportunity to use new technologies, the sort of borrowing from robotics and creating interventions that were specifically targeted at communication, at

improving function.

They were also, and you heard a little bit about this from Susan before, we heard that this -- we're in this era of comparative effectiveness research and this might really be an opportunity to direct more attention to autism treatments by creating some large efforts that would compare currently accepted or currently widely used interventions.

And they, of course that wasn't on the table a year ago, but it's very much on the table now. And in fact in the Recovery Act, there was $1.1 billion that were dedicated to comparative effectiveness research.

They also -- we heard a lot, especially from the clinicians about the inability to know how to sequence interventions, what do you do first, what do you do second, if neither of those work, what's the right third choice. So they asked

for a kind of treatment algorithm.

And then I think just like every other panel, I mean one of the things that came up right away was, we don't have enough work here on adults on the spectrum and that the original plan was almost conspicuously ignoring anything beyond adolescence and they were concerned about that.

Also concerned about the lack of focus on non-verbal populations. And they were very clear with us that the word is not low functioning, but non-verbal. They wanted to make sure we understood that distinction and that we specifically needed interventions for non-verbal people.

And then two last things that they asked for from us was the need to look at how to get from panel two and maybe panel three to panel four.

They were concerned, and they talked a lot about it as kind of attention between putting, you know, spending a lot of

our resources on interventions that we now have and we can find out, you know, how to optimize them versus developing cures or developing novel interventions based on a mechanistic understanding of the disease that would really be profoundly more effective.

And they understood that that was high risk and it was long term and it would be difficult to do, but they felt that we needed to do both. And they were really concerned that we not simply focus on comparative effectiveness, you know, kind of optimizing current treatments but that we think about what was coming through the pipeline for the earlier panels and really move those into novel therapies.

Last thing that they pointed out was that we didn't have anything really in that original plan that spoke about functional outcomes and they wanted to make sure that we were looking at -- that our intervention trials went beyond the typical clinical

outcomes to look at employment, quality of life, a whole series of issues around function.

So, they did provide a few ideas for what do we know and what do we need and I'll tell you what those are.

But I think the major things that they recommended were kind of tweaking the short term objectives in a way that would bring in the adults, would bring in non-verbal and would also make sure that the biomarkers, which originally were just kind of set aside as a separate entity were integrated into all of the clinical interventions, all of the RCTs that we make sure that we have predictors of response.

That's one other thing that doesn't show up so much in the workgroup materials, but it was clearly something in the conversation and you heard about it this morning from the talk that Tony Charman gave, try to figure out what treatment for whom.

And they are very concerned that our interventions portfolio not simply come up with mean data that says, this intervention is effective relative to placebo. They wanted to know who should get which intervention. So, personalizing the interventions as opposed to just providing kind of population or group data.

So with that as a quick introduction, Steven anything else to add before we go through the line by line?

Dr. Shore: I think you pretty much covered it. I just want to reiterate that there also a lot of discussion on looking at approaches that seem to work that have some scientific basis, research behind them, but we may not want to wait until we reach the gold standard, you might say, of evidence-base practice.

So it's a real tug-of-war between how long do we wait for the research or should I say formal research to come out and what

about all the other interventions that such as the Miller Method or floor time and so on that don't have this hard core, you might say, evidence-base research.

Because research into the social aspects of autism and other aspects as well is inherently it's messy.

Dr. Insel: Okay. So let me quickly go through the line by line changes. There are not that many of them here. Again as I said the panel was pretty happy with most of the language.

They didn't, but Steven and I added a reference to the what do we know because of the recent SSRI paper that suggested that medications may not be as good as we had hoped so we put in a sort of equivocal statement saying that there are mixed results of SSRIs.

Under what do we need we've added in this sentence that says going forward, research needs to be balanced between two

poles. One the one hand we need novel targeted interventions based on an understanding of the molecular mechanisms.

These interventions analogous to ongoing efforts in cancer and cardiovascular research require a successful commitment to earlier elements of this strategic plan. So we shifted the wording around a little bit there.

And then we added in a paragraph under what do we need about comparative effectiveness, head to head comparisons of interventions or policies. One of the things that comparative effectiveness research can do is also look at, for instance, state policies on reimbursement between two states to find out which ones, or other kinds of coverage, which ones are more effective. So we've added that in.

And then we go right -- we didn't change the aspirational goal, we added in under research opportunities this comment

about emerging technologies such as assisted communication, provide opportunities for people with ASD to become more engaged in the community.

And then short term objectives, we did something, it's maybe a little hard to follow, this is actually the main change.

We drop this thing that was there before, launch at least four research projects that seek to identify biological signatures that measure significant changes in ASD core symptoms across the lifespan, because we didn't think that had anything to do with interventions.

And that was the one we were hoping would shift to other elements in the plan, so that's part of what we wanted to get out on the table today. And then we took from that the biological signatures or biomarkers ought to be integrated into every one of the RCTs.

And so there's a new bullet that

says launch randomized control trials of interventions including biological signatures and other measures to predict response in monitoring quality of life and function -- should be functional outcomes in each of the following groups.

And before we already had infants and toddlers and children and now we've added in adults, because that was clearly missing in the original version.

And the last thing we did is under the bullet that we had before about why we used interventions, the last bullet, I'm sorry the penultimate bullet under short term, we've added in assisted technologies Sensory Integration as examples of why the used interventions that need to be rigorously studied.

And that's pretty much it from what we got from the panel and what Steven and I decided to incorporate for you. Comments about things we're missing or things you would

not want to see changed?

Dr. Lawler: I just have two brief comments. One, I think I heard a lot at the workshop about dissemination science and we need to do a better job of communicating results in this, you know, under this question it would be communicating results in clinical trials which can be confusing to not just practitioners but to affected families.

And it might be nice to think about including that as an objective. The other question I had, I didn't see it in this plan, but I thought we had at one time talked about this idea of sort of creating an infrastructure that would provide a test bed for, you know, testing really innovative mechanism-based, you know, treatments in small numbers of individuals so that you'd have something that could help translate from a mechanism, you know, at the stage before you launch a full scale, very expensive and lengthy trial.

Am I misremembering or did we have some discussions earlier because I don't --

Dr. Insel: No, I think we talked about, and I think it's still in here, let's see if I can --

Dr. Lawler: I couldn't find it. I thought it was in here.

Dr. Insel: You know Cindy, I remember that as well and I don't know where it is. I thought it was actually in the original plan, but I don't see it now. I remember because we talked about these N of 1 trials, we had that whole discussion about this.

Dr. Lawler: That might be in infrastructure if we're going to add another chapter.

Dr. Insel: Okay. That was -- we did talk about, and this came up, there were -- people on the were concerned that we had -- we were doing RCTs for some things and not for others and they wanted to know why.

And we kind of left it the way it was originally, which was to say that yes, we're going to do RCTs, but then we'll just test the safety and efficacy of these five widely used interventions without necessarily requiring those to be RCTs.

And I think part of the sense there was that it would be more feasible to get that done quickly because people really need information about safety as well as efficacy.

But the other point you make was one that wasn't apparently didn't make it into the final 1.0 version of the plan. Although I got to tell you, I seem to remember it being there, but it's not there. Lyn?

Ms. Redwood: Along those same lines, we had talked about multiple baselines and N of 1 studies and that was something during the presentation this morning on discrete trial training that might be useful to determine in these N of 1 where we do

multiple interventions.

And right now that is so hard to capture and research because parents, as you heard, are throwing things at their children. They're not going to wait to try something new. And we really don't have good metrics for measuring response when you're doing multiple interventions at once.

So if there would be a way to develop some type of tool for evaluating multiple interventions, whether they're N of 1 studies with multiple baselines I think that would be real helpful.

I know a lot of the clinicians who follow sort of a biomedical protocol for treating autism may be treating three or four different things at once and that's so hard to actually research. And as you're saying they're all individualized because not one thing is going to be the end all be all type treatment for every single child.

So I think that is sort of an

infrastructure need to determine how we would actually measure response to treatment in those types of situations where there's multiple interventions, whether it's behavioral therapy or addressing co-occurring medical conditions as to what, you know, really gives you the most bang for the buck.

Dr. Insel: Alison?

Ms. Singer: I thought one interesting idea that came out of the public comment period during panel four was this idea that we really don't yet have consensus on what the core symptoms are that we want to target treatment, to target for treatment and that it might make sense to convene a workshop or a meeting to create some consensus.

I mean the treatment trials right now are really all over the map. It would be, I think, might more sense if we were proceeding a bit more logically with some agreement as to what the high priority symptoms were.

Dr. Shurin: Can I comment? I think that's really, really important and that's actually implied in your comment, Tom, about the focus on non-verbal as opposed to low functioning because it gives you some idea of what it is that you need to be targeting.

But it also comes back to Lyn's comment, people are throwing different things at people, but they are usually throwing different things at different aspects of what the manifestations are.

And first of all, just capturing that kind of data, you know, getting it together, I'm not even sure you necessarily want a consensus as much as you might want some kind of survey of, you know, what are the major manifestations and be able to pull that together so that it has at least some evidence-base.

And if it has an evidence-base then you're going to be in much better shape in terms of saying what the outcomes and the

benchmarks that you're looking for, you know, how are you going to measure these.

But I think that's going to be really crucial because it's going to -- it ought to - - it will help you determine what are the things that are -- that need to be targeted to modify.

You may not be able to modify globally, but you may be able to modify specific manifestation that are particularly troublesome and having a sense both of, you know, sort of how those things are manifested overall and what interfere the most with function would be really helpful.

I mean I think everybody here can come up with a list that those things are clearly going to be on it, but really having some basis for that would be, I think would be incredibly helpful.

Dr. Insel: Other comments or suggestions before we go back? Yes.

Ms. Correa-De-Araujo: I just

would like to suggest that we make it here that there is a need to look at outcomes data by gender and whenever possible across race and ethnicity.

Because sometimes those studies are conducted and we have a population, sometimes it's not possible to speak because of issues with the number of individuals involved. But there is a need to be looking into these consistencies to assess how people differs or how people respond differently to treatment.

Dr. Insel: Cathy?

Dr. Rice: Cindy may have touched on this, but I think one thing that came up during the workshop was the need for dissemination and having a specific goal. So I mean, one thing I would suggest is maybe there is a need for a specific goal that has a structure for translating these intervention findings into community dissemination in some way.

And maybe that again goes into question seven about infrastructure development of how do we get the findings of science out there.

But one thing we heard from the panel of, you know, family and affected individuals this morning is, you know, the need to have a source of information that everyone knows about and they can go to and say well what's the latest research on interventions that are going to help affect me.

So whether it's here or in the infrastructure goal of knowing here's the latest source on what works and what doesn't.

Dr. Insel: So, you know, I think they're two different things. I mean what you're talking about would be a resource, which might actually end up more in a later section.

By Cindy's comment about the need for actual dissemination science, that is

figuring out what is the most effective way to scale up or to implement an intervention that you know works is a little bit like what we heard this morning where, you know, it's great to have these research studies showing that ABA works, but if nobody in the community can actually do what it is is being done in an academic center, you're not getting to where you want to be.

So that's dissemination science, it's figuring out how to make that translation. And we were -- I actually had somebody review our portfolio and that was the first comment he made is that, unlike many other areas of medicine, that has not come to the autism field yet and he was really struck by the absence of it.

And I think it's a great point that we can now put this into -- we can make it a bullet. And it didn't come up actually in the panel discussion, but it came up at the workshop as you said. It's one of the places

where the public comment was very helpful.

I should also mention that we also got this interesting public comment from someone from a pharmaceutical company who said that for the first time the companies, I think it was Pfizer were developing a drug development program for autism, which had never been done before in any of the companies.

So it was clear that we had another effort there that's new and potentially very exciting if it actually happens. Anything else? Okay. Ellen?

Ms. Blackwell: I just have a quick technical correction on page four that would make the wording consistent with the rest of the plan. In the text for what do we need it says, individual patient and I think it would be an improvement to say each person.

Dr. Insel: Can you give me a line number?

Ms. Blackwell: Yes. It's line 6

on page 4. Thank you.

Dr. Insel: Terrific. Steven, anything? Any last comments? Steven are you there?

Dr. Shore: I don't know if you can hear me because I can't hear you through the phone.

Dr. Insel: Oh, okay we can hear you fine. I was just asking you if you had any final comments.

Dr. Shore: The only comment I have is that I don't know -- it's hard to know if you can hear me.

Dr. Insel: We can hear you fine.

Dr. Shore: Oh, okay. All right, well we're dealing with a delay between what's coming over the computer and what's coming over the phone.

Dr. Insel: Just wanting to see if you have any final comments before we move on.

Dr. Shore: All right then what I'll do is I'll just make some comments

regardless of the delay and hopefully it will work out.

Dr. Insel: Steven, we're going to move on to doing objectives five and six, but you and I can work on this offline.

Dr. Shore: All right. I think that sounds like a good idea. We'll work on it offline.

Dr. Insel: Okay. Great. I think that will be easier. Ellen, it's up to you. It's Ellen and who did you work with? Christine, great.

Ms. Blackwell: Okay. Well as I mentioned earlier today panel five was actually panel five and panel six because we had two of the six chapters of the plan, perhaps the least well developed chapters.

And I wanted to acknowledge also the people that served on this group who really did a great job, Tec Chapman; the Deputy Director of Developmental of Disabilities for the State of Missouri. Tec

also was a Kennedy Fellow he worked for Mike Enzi on the Combating Autism Act. So Tec brought a unique perspective to this panel.

Kathy Pratt from the University of Indiana, many years of experience providing services to people of all ages with autism. Peter Gerhardt, certainly acknowledged as one of the country's leading experts in adult services for people with autism.

Our colleague David Mendel, who many of you know from the work that he's done on Medicaid data and also for NIMH on interventions. Ann Gibbons, Autism Speaks our astute observer, wouldn't you agree Christine. And Marjorie Solomon from the University of California Davis Mind Institute who works a lot with people with -- youth and adults with Asperger's syndrome.

So we had a really good group, not necessarily all clinical research and family experts, but a group that I think was really uniquely poised to address these two chapters.

And we had a big job, not only did we have two questions, but we also had a lot more public input than some of the other groups.

We had the RFI that some of you may recall from the services subcommittee that was issued last October where we had 137 commenters, about 500 comments. We had the input that came from the town hall meeting you heard about this morning and then we also had the same input that the other groups had from the RFI on the strategic plan.

So, we asked a lot of this group and I think that they really came through. We really didn't want to them to blow up chapters five and six, but we did want them to clarify the present objectives. We knew that some of those would be funded with Recovery Act money and then also clarify and identify new opportunities and short and long term objectives.

So what did we do? We took chapter five first and as Christine said we

met three times. We met for almost seven hours and we identified some really important themes. The first being the lag between the development of efficacious interventions, services and supports from research to community settings.

And I think this also relates to what Tom was talking about in terms of dissemination. A lot of our discussion focused on there are great things happening in communities in terms of services and how do we get those translated from one community to the other.

We also wanted to increase the emphasis on quality of life and we wanted to focus on the fact that we were looking at everyone across the spectrum of ASD. We wanted to address access to services and supports and we also wanted to talk about services and supports as they apply across the lifespan.

We had a lot of discussion about

issues surrounding systems collaboration and we also talked about new models for service coordination and case management, particularly important in terms of the layers that people have to go through in terms of trying to access services.

And we also talked about underserved groups and we discussed a lot principles of self direction and self determination and how they might impact this population in particular.

We did not assign numbers of studies or many to any of these new items. We felt that that was better left to the committee. So there are some extensive revisions here and I know we're getting to the end of the day, but we had a lot of help in terms of -- I had a lot of help in terms of rewriting the sections here on what do we know and what do we need, a big boost from David Mendel who really attacked this with a lot of vivaciousness.

So I tried to integrated David's suggestions into this introductory piece. And, you know, Steven you talked early about getting things out there and I think that we did get that into this what do we need section.

So although you see some revisions, I think that they are pretty good and that they reflect our discussion. We did alter the aspirational goal. We suggested that it read as communities will access and implement necessary high quality evidence-base services and supports that maximize quality of life and health across the lifespan for all people with ASD.

So we just felt like that was a better and more thorough approach to this chapter. We certainly didn't change the first research opportunity. In fact we have this project underway now at CMS thanks to our partners at the National Institutes of Mental Health.

And I don't know if you want me to go through each one of these Tom or just sort of sum up. What do you feel is the best approach?

Dr. Insel: Well, I think you should go through them if you can quickly because this is worth really looking at the details.

Ms. Blackwell: Okay. Well as I said, the first one is already underway so we skipped over that. We wanted to make sure that in the second research opportunity again, that we focused on across the spectrum and across the lifespan.

We wanted to emphasize in the third research opportunity that what we really wanted are comparative effectiveness studies regarding services and supports. We did the same in the next research opportunity. We thought the next one was fine and then we added some new research opportunities here.

The first was really aimed at

looking again at what's out there in communities and trying to get that into other communities. The second is trying to straighten out what could be considered a rather fragmented services system so we, you know, again these are just summaries of what you'll see in the short and long term objectives.

We wanted to look at case management as a specific issue, we wanted to look at self direction as a specific issue and we wanted to talk a little bit about how researchers and consumers can work together to make progress.

So how does this play out in the short term objectives? In the first one, which is the second bullet on page 6, when we talked about underserved populations we were looking at both, you know, rural populations and minority populations we chose to use the word underserved to represent everyone. Do you have anything to add to that Christine?

Okay.

The third bullet was really our way of trying to attack how to find those things that are happening in communities and getting them out to other communities and we suggested a number of what we think of as promising practices brief and CMS actually did issue three of these on autism to support the IACC a couple of years ago.

We thought this might be the mechanism to try to spread the word. We talked about a demonstration project, one of our members Tec Chapman as I said, who was in the developmental disabilities services field in the state of Missouri wanted us to look at simplifying the case management system.

So Tec suggested that we look at a single case management across delivery systems. Again, we wanted to really look at how self direction impacts people with autism specifically. We know a lot about self direction, but we don't know a lot about self

direction and children, youth and adults with autism.

We wanted to look at how to integrate all the different service systems that people with autism and their families access to improve their quality of life.

And the group felt really strongly about the needs of transitioning youth who are, you know, being served by mostly the education system as youth and then being transferred to a different system, whether it's vocational rehab system or the developmental disabilities system, but they felt like that group was particularly vulnerable.

In terms of the long term objectives, we just modified the first one to make it a little bit clearer that it would be addressed to everyone across the spectrum.

And this was something that you all saw come up repeatedly in the comments on the first iteration of the strategic plan that

we needed to be including everyone. So our group really tried to get that into this.

And then we really wanted to make sure that what we were looking at was not only out in the community, but that it was sustainable. So again, we clarified the second bullet.

We added a third bullet because although we know that there are tremendous challenges in the service providers field, we're not sure that there weren't special issues surrounding serving people with autism.

So that was one issue that was again, very important to this group. And then as I said before, the single model of case management or how to try to collapse case management to make this system easier to navigate for people with autism and their families.

So that is kind of where we went with chapter five. It was not really a well developed chapter before, but I think it's in

better shape now. Christine, do you have anything to add to the work of panel five?

Ms. McKee: I think you did a wonderful job summarizing it. One of the main themes that we talked about was how research done in university settings, particularly with interventions shows some real positive outcomes and it's not translating into the communities.

And we heard the PECS example this morning that they couldn't find a program that didn't utilize PECS, but once you get in and you look at it you see that it's not PECS. The same thing with ABA.

The other thing that they highlighted was the highly selective samples of the exclusionary and inclusion criteria in the studies. And when you use a highly selected sample, then it doesn't translate into the community because you can't get the same results when you take away the exclusion criteria.

Dr. Insel: Susan?

Dr. Shurin: Taking up on -- as I was listening to you, I had the same response I think that Christine did to the quality issue and just see it under the research opportunities. I wonder under the second one, it says development and effective dissemination of evidence-base, I think some indicator of quality in here really needs to come through.

And it's partly the issue of, you know, sort of defining what the quality is is hugely important if it's linked also to funding it tends to increase the quality that people aren't going to get reimbursed if they don't meet certain criteria it tends to be helpful.

But the other is that particularly since most of these interventions are very heavily dependent upon the quality and the characteristics of the person who is doing them. Not just -- some of it's just dependent

on their personal characteristics, a lot of it is certainly dependent on their level of training and expertise.

And it seems to me that defining that as a research question because I think the better that can be defined, the better it can be implemented as you're trying to move things out into the community where there are going to be less control.

It's not just that the patients are less control and interveners are less control. And Tony mentioned that this morning. He was talking about the, you know, they had specially trained post docs, you know, doing the interventions. Well that's a lot different.

But I was wondering whether just sort of emphasizing some of those issues, what does it really mean to be implementing some of these interventions because I'm not sure that's well enough -- I think it still belongs in the research agenda because I'm not sure

it's well enough known.

Dr. Insel: You know, we could be a lot more ambitious on this if we wanted to. I can just tell you in PTSD, you know, the VA said we have 3,000 therapists treating PTSD and we want to make sure by next, at the end of next year 1,000 are trained up on this particular method with supervision and they know what they're doing and that we'll get to 3,000 within three year or something like that.

I mean they, you know, it's very concrete and maybe we ought to think about whether, because this is such an important issue, this dissemination part, I'm worried about just leaving it to kind of vague language about a demonstration project and whether we need to just go a little further and try to provide something that is a concrete goal that we want to do by 2011, 2012, whether it's training the trainers or having X number of people able to do Y, Z and

some other intervention.

I'm not sure what that would be yet, but if you're going to go back and think about this further anyway, I just hope we can get a little more grain size to think of it in a way that we'll know whether we've done it or not.

The other comment I had was that some of the things that are, and this is just wordsmithing, but the research opportunities are really written more like objectives and it would probably be good to clarify what the actual opportunity is that you want to go after.

And there was one other thing, oh, this again, I'm not sure how you want to deal with this. I have to say I was a little disappointed that under short term objectives that transitioning youth issue, which we keep hearing is one of the most urgent problems ends ups as the last of many new objectives.

So I'm just wondering as you shape

this if is there a way, I know these aren't prioritized in order, but I wouldn't want that to kind of get -- be left as an afterthought. I think somehow we need to figure out how to give that more attention.

Ms. McKee: Well I can tell you that I was going to take this up in terms of chapter six, but the group wanted to make sure that if indeed we do change the title of chapter six to adults, that that would be the place to also address, you might recall from the discussion, Tom. So chapter six is supposed to be aimed at transitioning youth and adults.

Dr. Insel: So then it's kind of a handoff, so that makes sense. Okay. Alison?

Ms. Singer: On page 6 at the top you still have initiate a state of a states assessment, I actually think we've already done that and the 2009 deadline will be out of date in a 2010 plan so I think we can take

that out.

Ms. Blackwell: Thank you.

Ms. Singer: And then I had a question about the third bullet point on page six, which was support promising practices briefs. What are promising practices briefs?

Ms. Blackwell: I mentioned that, you might recall, Alison, that CMS provided to the committee promising practices briefs, one on early intervention in the state of California, one you might remember Cathy Reddington from the state of Connecticut who talked about her program back in November.

So there are these promising practices briefs on the CMS website if you --

Ms. Singer: But I guess my question then, that is what I thought they were, but I'm not sure how supporting those briefs is research.

Ms. Blackwell: Well, I don't know how to answer your question. I mean support is not the word, maybe it's issue.

Dr. Insel: It's the same problem though, it's important to do but I'm not sure that it should be in the research plan.

Ms. McKee: I think the group's objective was to try to figure out a way to get the promising practices from one community to the other, how to get the word out. So this is what we came up with.

Dr. Shurin: What that is often -- the way that's often framed in many other settings is as developing a knowledge network so that you have means of disseminating information so that would be one of the pieces of the knowledge network, but it's a place that people can tap into to get information so that no matter what their needs are.

Dr. Insel: I wonder if that should be, because that's going to be important for so many parts of the plan, I wonder if that should migrate to that earliest section, which is before any of the objectives around an infrastructure need.

I know we're going to talk about this later, but it does sound like it's a more fundamental question. Anything else for this? Cathy?

Dr. Rice: I was just going to add that, you know, it could be for research in terms of evaluating the effectiveness of the practice briefs if that's what you, you know, are they actually reaching the people that they need to reach.

Dr. Shurin: And does it have an impact on the outcome.

Dr. Insel: Anything else for Christine or Ellen?

Mr. Claypool: Tom, just one thought, perhaps if you're trying to formulate a research topic, is there anything unique about these networks that exist and are the current dissemination strategies that are used in other areas effective, you know, just trying to get to what Ellen was driving at with her point.

I'm not sure if that's helpful, but there may be unique in these networks that have emerged around supporting people on the spectrum.

Dr. Insel: Good. Okay, well we've got only about 10 minutes left, Ellen can you take us or both of you, through chapter six.

Ms. Blackwell: Okay. I'll zip us right through chapter six. You know, the first change, actually the very first thing the group approached was the title of chapter six which they found confusing because chapter six, at least in its present form, is mostly focused on the needs of adults and they were also very concerned that much of the public comment focused on the needs of adults and transitioning youths.

So when they looked at this chapter and we talked a little bit today about perhaps designing some other piece or chapter in the plan that would address infrastructure,

what we found was that there were some infrastructure goals in the chapter that appeared to be about adults, so we didn't quite know how to deal with that.

And, you know, that's one of our recommendations or that's one of that we'd like to make today that perhaps we have this other chapter. So that was the first thing we discovered in chapter six and we decided to recommend that chapter six, based on the numerous public comments and other input that we'd gotten from stakeholders, be changed to fully address the spectrum of adults with ASD. So that's where we start.

The second thing is that again, we wanted to talk about emphasizing principles of self direction and self determination. We wanted to talk about transitioning youth and make sure that they were included in this chapter.

We wanted to talk about training of service providers, especially for the adult

and youth population. We wanted to talk about community integration and not just how are people with autism integrated into the community, but how does the community integrate people with autism. So we had a lot of discussion about that.

There was significant public comment on the use of medications in the adult population in particular. So that came up and translated into a goal. Access, again, becomes an issue specific to the adult population. And we wanted to focus on principles of individualized quality care.

So that's what we really tried to pull into and out of this chapter. So, you know, really those are the highlights and I think that they play out in these rather minor revisions.

The last or the middle paragraph on page 10 kind of sums up in the terms of what do we need or what do we know that there were a number of areas that did not get

mentioned in the first part of this strategic plan.

The first being that we know there are numerous adults with autism involved in the criminal justice system, a topic that does not come up very often but needs to be addressed.

That there may be adults with ASD who are not diagnosed or misdiagnosed that as I said in the services chapter, there are issues that are well articulated surrounding the long term workforce, but we don't know if they differ in terms of adults with autism and that the service system for adults, it may not meet everyone's needs.

And then this last issue about the safety of psychopharmaceutical medications and how they're used in the adult population.

So we did change the aspirational goal to make it what we felt was a lot more aspirational. All adults on the autism spectrum will have the opportunity to lead

self determined lives in the community of their choice, through work, community participation, satisfying relationships and access to necessary and individualized services and supports.

In fact, we spent a long time hammering that out. So, you know, you start to see that play out in terms, I think, of the research opportunities and, you know, again this promising practices idea maybe something that we want to talk about in dissemination moving to a proposed new chapter on infrastructure.

I'm not actually sure if it's a chapter or if it's a section, but if it is a chapter we might want to call it what other infrastructure needs must be met. So that's something that I think the group will probably want to talk about.

Another one of the things that we added was that, well there was a lot about data collection in this chapter that wasn't --

it didn't necessarily pertain to adults, so we, again we weren't quite sure what to do with it. So those would be objectives that could be shifted to this new infrastructure chapter or piece.

The group talked a lot, not a lot, but we did talk about housing because it keeps coming up as an issue with stakeholders. It's certainly an issue in the larger disability community. And what they wanted to know was, were the housing issues that surround adults with autism different from the housing issues that surround adults with other disabilities.

So that's why you see it on here in chapter 12 -- I'm sorry page 12, thank you Susan. I know we don't have a chapter 12 yet, okay. Sorry, oops, Freudian slip.

So again, you know, we got to -- we tried to get to identifications specifically in terms of adults. We wanted to emphasize in the short term objectives quality of life and cite some particular measures that

come up often times in terms of measuring quality of life for people with disabilities.

We wanted to make sure that comparative effectiveness was mentioned. We wanted to get to that diagnosis issue in the adult population, we wanted to try to get to the training issue in terms of the workforce. We wanted to look at how all these service systems are coming together for transitioning youth and adults.

We, again, tried to clarify in the long term portion -- there weren't very -- there was one objective, so we tried to get it to look at individualized interventions that improve quality of life and health outcomes, language, by the way, that I think could be used in earlier sections of the plan.

We wanted to conduct a study and try to clarify, you know, what this was. If you take a look at what we had before, we practically rewrote the whole objective to make it more clear.

And basically this was to get at what Tony talked about earlier, the fact that we don't really know what sort of early interventions, what their impact is later in life. So that ended up in this adult chapter.

The third bullet on page 13 deals with what I mentioned earlier which is this give and take between communities and people.

The fourth bullet we heard a lot about psychopharmaceutical medications and how they're being used and what we don't know about how they're being used in the adult population, specifically to address behavioral issues in adults. So the group wanted to make sure that there was an objective in this chapter that addressed that.

And then the last bullet is actually reflective of one of the short term objectives which is to test the effective services and supports that resulted from the comparative effectiveness research that included a cost effectiveness component.

So lots of work on chapter six and a potential chapter seven.

Dr. Insel: Chris?

Ms. Blackwell: Christine my co-chair do you have anything else to add?

Ms. McKee: Ellen is the expert on adults now. I think you did a wonderful job.

Ms. Blackwell: Not me. We did have some really good experts on adults working with us.

Dr. Insel: And you deleted a bunch of objectives, was that because you -- the group just didn't think these were worth doing?

Ms. Blackwell: I think some of these are the infrastructure objectives Tom that we talked about moving to chapter seven, the prevalence estimates in adults.

So we collapsed one, I actually have to go back and look at my slides because I -- if there -- let me look at my slides. There were three long term objectives, the

first is develop, and these are the ones that we -- actually we had three that we took out and we collapsed them into this one.

Develop and have available to the research community the means by which to merge or link administrative databases that allow for tracking adults with ASD involved in various services systems and then we actually cited some examples.

But there were three data objectives that we didn't quite understand how they got into this chapter.

Dr. Insel: Alison?

Ms. Singer: I think this is a big improvement, Ellen, and I think you guys have done a great job. Reading it though, it feels to me very much focused on the needs of adults who are very high functioning and who's outcome potential is very high.

So for example, the way you phrase the aspirational goal of all adults on the autism spectrum will have the opportunity to

lead self determined lives. I just don't know that that's attainable. You might want to restate it as maximized opportunities for all adults on the spectrum to lead self determined lives.

I also think that's what's missing is some sort of research opportunity that looks at studies that support care giving and that look at best practice for care givers who are continuing to work with their adults who are not able to meet the goal or achieve the goal of independence and self determination.

Dr. Insel: Lyn?

Ms. Redwood: I think this is wonderful Ellen, but I just have concerns that in making this transition to focus totally on adults that we're not really answering a lot of the questions that family have, like the young mother this morning who has a four-year-old diagnosed, she's probably going to want to know about kindergarten and we hard concerns from the young man who said

transitions from elementary school to middle school were really rough.

And when I look at what came in in the RFIs, one of the very first ones was conduct longitudinal studies of outcomes for people with ASD that includes developmental trajectories, aid related illnesses, mortality, et cetera.

And I think that's real important for us to continue to do. And maybe it's reflected somewhere else in the plan to look at these trajectories of outcomes over time. I know I hear kids who are doing wonderful and then for some reason in middle school they have regressive episodes.

So I think that if we just focus this whole chapter on adults then we've got to make sure that children are addressed too because we're not meeting the needs for parents to know some of these other questions that occur that aren't related to just transitioning into adulthood that have to do

with. Just my two cents.

Dr. Insel: Yes, thinking back I think that was the conversation originally when this was drawn up. I'm trying to remember the whole thing, but I think a lot of it was what do you tell parents with a young child about what they can expect.

So it's morphed and I guess for the committee the question is, is this what you want or do we want to send a message back that this ought to find a different focus. Cathy and then Alison.

Dr. Rice: I agree with having a heavy emphasis on adults in terms of the ultimate outcome in that you want to keep the eye on where you're going.

But I definitely agree that we're missing the whole trajectory and I don't think we want to throw out, you know, there are research opportunities talking about longitudinal studies, but it's hard to not think of that as happening early on in life

with the, you know, various outcomes throughout.

So I would say heavy emphasis on adults, but let's not throw out the children.

Dr. Insel: Okay. We're going to have to finish. Alison, go ahead.

Ms. Singer: I was just going to suggest that we might look at adding back some additional opportunities specifically focused on children into section one where we're looking at when should I be concerned, the when doesn't necessarily only have to be at the time of diagnosis, it could be at the time of transition, it could be -- you might also be concerned when your child's going to middle school, you might also be concerned.

So I think there's a way -- but I agree that we don't want to repeat the mistake. In the first plan I think we under emphasized adults and I don't want us, in the second version, to under emphasize children. So I do think we have to figure out how handle

this.

Dr. Insel: Is this helpful Ellen?

Ms. Blackwell: Well I'm trying to think, I mean I know that we had a similar conversation when we closed the scientific workshops and I guess the group was sort of led, if you go back and look at the original plan, the fact that most of the objectives do look at adults.

So they weren't quite sure what to do. So I guess we would be -- I mean when I go back to them or when Christine and I go back to them what direction do you want us to give them?

That the chapters should be, you know, it should be squarely directed at adults or that we should, you know, try to aim at all transitions throughout various age groups? I mean what's the general sense here?

Dr. Insel: I think what the committee's telling you is they're looking for a different balance. They don't want to lose

the original sense of this, at the same time they think that we were missing the adult piece just as Alison said. So see if there's a way to find some middle ground where you can have both in there.

Ms. Blackwell: I'm sure they will be willing to attack that.

Dr. Insel: Well it's your job actually. They'll have to -- I mean you're really looking to them mostly for anything that's missing. But at the end of the day it's up to the liaison folks to come back with what you think is best and then the committee can get to the final wording.

We're after 5:00 so we do have to, by FACA rules, we need to wind this up. This is fun, we were actually making real progress and I think this is a very rich discussion.

I want to thank everybody for staying engaged through the day. This is a lot to do and we have a lot more to do. We didn't -- we ducked the panel three issue

because Lee wasn't here.

Is there -- I heard four or five people saying that they think this panel three needs to look closer -- look more like what we heard from the workshop. Is that something we should send back to Lee right away?

I see all the heads shaking, everybody's -- okay. So we'll give him the message that whatever we got doesn't look like what we expected. And final comment from Della?

Dr. Hann: So speaking of messages, so my understanding is that liaisons now, based off of today's discussions will look back over the documents they already have, they can reach back to their panels if they so choose, okay, and try to incorporate as best they can any rewrites to this information.

We will have to set a due date for that so that we can then get it back out to the committee before the 10th. So we will

follow up, OARC will follow up with sort of some instructions and a timeline by which to do all of these different pieces, okay, so you'll be hearing from us shortly with regard to that. Alison?

Ms. Singer: The subcommittee also had talked about creating a chapter seven that looked at what other infrastructure needs must be met. Do you want us to take a crack at drafting that section?

Dr. Hann: I think what I had prepared a few slides, but we didn't get to it today in terms of what that might look like because it still wasn't clear to me.

But if you all have a clear decision that you definitely want a chapter seven of if you want to figure out how to build some of those other -- some of those themes into the existing chapters. And that part's not clear to me.

Dr. Insel: The other option is rather than doing it as a chapter whether you

want to go back into the introductory parts of the plan, we haven't even talked about that. But if there's a piece there that you think needs to be reworked or rebuilt as a cross-cutting theme we can do that.

Ms. Singer: I know we're over time. The concern that the subcommittee raised with regard to putting it into the beginning is that it wasn't tracked.

That the way we were doing measurement and metrics of our success was only on the short and long term objectives so that some of these things didn't become short and long term objectives we would not have a clear way to measure our progress.

Dr. Insel: Great argument. So let's put that on the table for when we meet next time. I think -- and if somebody wants to -- like anybody wants to draft some ideas, you know, give us something to work with, it would be much better to have something to start with than to just begin the discussion

from a blank slate.

Thank you everyone for your work on this and I think we're making progress. We'll see you soon.

(Whereupon, the above-entitled matter went off the record at 5:09 p.m.)