

INTERAGENCY AUTISM COORDINATING  
COMMITTEE

FULL COMMITTEE MEETING

FRIDAY, JANUARY 13, 2017

The full Interagency Autism Coordinating Committee (IACC) convened in Rockville, Maryland, at the National Institute of Mental Health, (NIMH), 6001 Executive Boulevard, NSC, Conference Rooms C and D., at 9:00 a.m., Joshua Gordon, M.D., Ph.D., Chair, presiding.

PARTICIPANTS:

JOSHUA GORDON, M.D., Ph.D., Chair,  
National Institute of Mental Health,  
(NIMH) National Institutes of Health

SUSAN DANIELS, Ph.D., Executive Secretary,  
IACC, Office of Autism Research  
Coordination (OARC), NIMH

DAVID AMARAL, Ph.D., University of  
California, Davis (UC) David MIND  
Institute

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

DIANA BIANCHI, M.D., Director, Eunice Kennedy Shriver National Institute of Child Health and Development (NICHD)

JOSIE BRIGGS, M.D. (For Francis S. Collins, M.D., Ph.D.) Director, National Center for Complementary and Alternative Medicine, National Institutes of Health (NIH)

GERALDINE DAWSON, Ph.D., Duke University (attended by phone)

RUTH ETZEL, M.D., Ph.D., Director, Office of Children's Health Protection, Environmental Protection (EPA)

TIFFANY R. FARCHIONE, M.D., Deputy Director, Division of Psychiatry Products, U.S. Food and Drug Administration (FDA)

AMY GOODMAN, M.A., Self-Advocate, Charles Town, WV

MELISSA L. HARRIS, Acting Deputy Director, Disabled and Elderly Health Programs Group, Center for Medicare and CHIP Services, Centers for Medicare and Medicaid Services (attended by phone)

JENNIFER JOHNSON, Ed.D. (for Commissioner Aaron Bishop M.S.S.W.) Administration for Community Living

LAURA KAVANAGH M.P.P., Deputy Associate Administrator, Maternal and Child Health Bureau, Health Resources and Services Administration (HRSA)

WALTER J. KOROSHETZ, M.D., Director, National Institute of Neurological Disorders and Stroke, National Institutes of Health

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

DAVID MANDELL, Sc.D., University of Pennsylvania

STAN NIU, Ph.D., (for Nicole Williams, Ph.D.), U.S. Department of Defense

KEVIN PELPHREY, Ph.D., George Washington University and Children's National Medical Center

EDLYN PENA, Ph.D., California Lutheran University (attended by phone)

LAURA PINCOCK, PharmD, MPH, Pharmacist Officer, Agency for Healthcare Research and Quality, (AHRQ) (attended by phone)

ROBERT RING, Ph.D., Autism Speaks

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

STUART SHAPIRA, M.D., Ph.D., Centers for  
Disease Control and Prevention (CDC)

JULIE LOUNDS TAYLOR, Ph.D., Vanderbilt  
University

LARRY WEXLER, Ed.D., U.S. Department of  
Education (ED)

NICOLE WILLIAMS, Ph.D., U.S. Department of  
Defense (DoD) (attended by phone)

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## PROCEEDINGS

DR. JOSHUA GORDON: Okay. We are going to get started. Welcome everyone to the Interagency Autism Coordinating Committee meeting. It is a pleasure for me to chair this excellent committee for the second time. I would like to welcome everybody on the committee. Thank you very much for taking the time to come here and work with us on this incredibly important issue. Thanks everyone in the public section for coming and listening in and also for everyone who is listening in through the web.

I would like to take a moment. We are going to do a roll call in a moment. But before we do that, I just wanted to introduce some of the new members and mention some of the outgoing members.

First, I would like to welcome Dr. Diana Bianchi, the new director of the National Institute of Child Health and Development. She will be serving on the committee, replacing Dr. Catherine Spong, who was the acting director. We

are very pleased to have Dr. Bianchi here. She is really a world-renowned expert on child health and development and maternal fetal health. She is going to be a fantastic new director and we are pleased to have her on board. Welcome.

I also want to welcome Dr. Laura Pincock, who will be replacing Dr. Elisabeth Kato as the representative from the Administration for Health Care and Research and Quality. Laura, are you here? Not here yet.

We next have a few announcements of people who are leaving. We are sad to see them go, but we thank them for their service. First is Shannon Haworth is going to be stepping down. Officially she is stepping down from her role as a public member of the IACC because we have the good fortune that she now joined the federal government, working at the Health Resources and Services Administration. I would like to thank Shannon for her service on the committee and wish her good luck in her new position.

I also want to announce that she will be continuing to serve as one of the co-chairs of the Strategic Plan Working Group for Question 5 until the strategic plan is finished. We are very pleased.

I want to announce also that this is the last meeting for Commissioner Aaron Bishop from the Administration for Community Living as he is going to be departing with the change of administration. I would like to thank him for his service on the committee as well.

And then finally this is the likely, although we are still not sure, that this will be the last meeting for Dr. Francis Collins. He has been serving officially on the committee although he has been represented here most of the time by Dr. Josie Briggs, as director of NCCIH. I believe for now anyway Josie will be serving as the representative and the NIH director during the interim period.



Maybe we can get a round of applause for our new members and a thank you for the departing ones. Now, I will turn it over to Susan Daniels, who will be doing the roll call and asking for approval of last meeting's minutes.

DR. SUSAN DANIELS: I would like to do a roll call so that people that are on the phone especially will know who is here. Those who are watching the webcast probably can see us, but we will go through.

So, Joshua Gordon.

DR. GORDON: Here.

DR. DANIELS: Jim Battey.

DR. JIM BATTEY: Here.

DR. DANIELS: Diana Bianchi.

DR. DIANA BIANCHI: Here.

DR. DANIELS: Cindy Lawler.

DR. CINDY LAWLER: Here.

DR. DANIELS: Aaron Bishop. He may be on his way.

MS. JENNIFER JOHNSON: This is Jennifer Johnson. I'm here in place of Aaron Bishop.

DR. DANIELS: Josie Briggs.

DR. JOSIE BRIGGS: Here.

DR. DANIELS: Ruth Etzel.

DR. RUTH ETZEL: Here.

DR. DANIELS: Tiffany Farchione.

DR. TIFFANY FARCHIONE: Here.

DR. DANIELS: Melissa Harris is not going to be attending.

DR. DANIELS: Laura Kavanagh.

MS. LAURA KAVANAGH: Here.

DR. DANIELS: Walter Koroshetz.

DR. WALTER KOROSHETZ: Right in back of you.

DR. DANIELS: I will just interrupt for just a minute. Is there anybody who is on the phone that can hear us who is a member of the committee that wants to speak up for roll call? We have heard that there is a problem with the webcast and people cannot hear. We are working on that and trying to get it fixed.

Laura Pincock is going to be attending by phone. She may be one of the people trying to be heard.

Stuart Shapira.

DR. STUART SHAPIRA: Here.

DR. DANIELS: Larry Wexler.

DR. LARRY WEXLER: Here.

DR. DANIELS: Shantel Meek.

(No response.)

DR. DANIELS: Stan Niu for Nicole Williams.

DR. NIU: Here.

(Connecting with conference center.)

DR. GORDON: Can we get confirmation from any of the folks on the phone? Maybe email your friends you have been emailing to let us know that you can hear us. Actually, are there any members of the committee who can hear me? They can say their names.

DR. NICOLE WILLIAMS: This is Nicole Williams.

DR. GERALDINE DAWSON: Gerry Dawson.

DR. EDLYN PENA: Edlyn Pena.

DR. GORDON: Great. We have got the Susan.

DR. DANIELS: I have not done them yet on the roll call.

DR. GORDON: We apologize for the delay and the start of the audio.

This is Joshua Gordon, director of NIMH and chair of the IACC welcoming everybody. We are doing the roll call so you have not missed really anything yet except some thank yous and some welcomes.

DR. DANIELS: To resume the roll call, we are now going to call out names of public members. David Amaral.

DR. DAVID AMARAL: Here.

DR. DANIELS: Jim Ball is going to be on the phone. Jim, are you there?

(No response.)

DR. DANIELS: Samantha Crane.

(No response.)

DR. DANIELS: Gerry Dawson.

DR. GERRY DAWSON: Here.

DR. DANIELS: Thanks Gerry. Amy Goodman.

MS. AMY GOODMAN: Here.

DR. DANIELS: David Mandell.

DR. DAVID MANDELL: Present.

DR. DANIELS: Brian Parnell is not going to  
be with us today.

Kevin Pelphrey.

DR. KEVIN PELPHREY: Here.

DR. DANIELS: Edlyn Pena.

DR. PENA: Here.

DR. DANIELS: Louis Reichardt is not going to  
be able to join us today.

Rob Ring.

DR. ROB RING: Here.

DR. DANIELS: John Elder Robison is not going  
to be able to join us today. Alison Singer.

DR. ALISON SINGER: Here.

DR. DANIELS: Julie Taylor.

DR. JULIE TAYLOR: Here.

DR. DANIELS: If anyone joins late, just feel free to join in the conversations during the discussions and let us know that you are here. You can also send me an email to let me know that you are here if you were not called.

MS. MELISSA HARRIS: Good morning. It is Melissa Harris from CMS. I am going to be on the phone today.

DR. DANIELS: Great.

DR. LAURA PINCOCK: Good morning. This is Laura Pincock from AHRQ. I am on the phone as well, today.

DR. DANIELS: Welcome Laura. We announced a little bit earlier that you are a new member of the committee.

With that, I would like to turn our attention to the minutes. I sent out draft minutes to the committee from the last meeting. I did not receive anything by email. Does anyone here in the room have any comments on the

minutes? Any corrections that you see that need to be made? If there are none, can someone --

DR. BATTEY: I move to approve the minutes as written.

DR. SINGER: I second.

DR. DANIELS: All in favor?

(Aye)

DR. DANIELS: Any opposed?

(No response)

DR. DANIELS: Any abstaining?

(No response)

DR. DANIELS: The motion carries to accept the minutes as written and we will be posting them to the web shortly so after the meeting. Thank you very much.

DR. GORDON: Thank you, Susan, for the roll call and for the minutes approval. We have a full and dynamic schedule today. We are going to hear this morning briefly from Dr. Thomas Novotny, who is the National Autism Coordinator. After that, we are going to have a couple of talks, one from

Angela Geiger who is the chief executive officer of Autism Speaks to tell us about their new strategic plan and give us an update from their perspective.

And then Sam Odom from the University of North Carolina-Chapel Hill, is going to talk to us about translating science into practice. We are going to hear some developments in the treatment intervention sphere.

Then after that, we will have a slight break and we will get onto committee business, which will include a discussion of the progress on the strategic plan. We have a lot work that has been done by a lot of members of this committee and others on the strategic plan. We will hear about that update. We are hoping to have this finalized by early spring.

There will be, as usual, an oral public comment section and a summary of the written public comments we have received. Then we will also be discussing the summary of advances that



we have to report back to Congress. We have a number of nominations and we will highlight some of those and try to come to a consensus and vote on the ones that we want to put forward as advances to Congress.

Then we are going to hear from the NIMH on the National Data Base for Autism Research. It will be a nice science update. There will be an opportunity of course towards the end of the day for a round robin from committee members.

We have a full schedule. We are going to get right into it. I will ask Dr. Novotny, who is again the National Autism Coordinator and Deputy Assistant Secretary for the Department of Health and Human Services, for some remarks.

DR. NOVOTNY: Thank you, Dr. Gordon. It is nice to see everybody again here at this quarterly meeting. I really enjoy coming to these and staying as long as I can to learn as much as I can. As you know, I was not really a subject matter expert at the beginning of my tenure, but

I am slowly getting some of that expertise on board and I really appreciate all the inputs that I have received along the way from not just from the federal side, but from the stakeholders as well.

I would like to just give you a little bit of a progress report. We are still an unfunded mandate in terms of autism coordination, but I do look forward to further engagement as we go through the transition here. It is something that I think will be a little bit confusing, disruptive, but I think ultimately the work that we are doing is going to be supported and continued.

We have received a lot of great inputs. I think last time I reported that what we had done is to recruit some subject matter expertise to come into my office so that we can produce this report on autism and the transition period. That has happened. We have assembled a working group of members from across the federal

government, not just through HHS, but also the Department of Labor, Department of Transportation, Department of Housing and Urban Development. Even we have sort of participation, but Department of Defense, Department of Justice and ASF, ACL and many of the other HHS agencies that you are familiar with. That has been extremely useful.

The data call that has gone to our members of this working group has produced a lot of input. It is really a sign both that there is a lot going on, but that there needs to be connections and connectivity and coordination to make these things work maximally. Hopefully, that is what our report will be able to point out.

We are in the midst of writing right now. We actually have a substantial amount completed. My objective was trying to get at least a draft done by the end of January. I think we will have a draft that will not be released, but it will at least be something we are going to send around

for a clearance through our agencies and get their blessing on this. That could be delayed given the transition. As you can tell, there is a lot of people leaving and coming. That process will really slow down whatever movement of paper through the system. At least at the functional levels that we enjoy with our working group, I think we will at least get the content right although maybe not the official clearance very quickly. I do not know what to expect on final presentation. But I should be able to give you another good update in the next meeting. I think we will be pretty far along by that time. I want to again extend my appreciation to all the federal agencies that have been providing this input.

One of the things I wanted to really try to emphasize in this report. It is not just the challenges or gaps within the federal system. I do want to really try to emphasize what are the challenges to patients, people with ASD, their

families, and the caregivers that are also part of that whole system. We hope to be able to get some of that input as well.

You might ask where is the stakeholder input. We have to be a little careful of that. This is not a federal advisory committee where there are processes and clearances for members to be participants in this, but we will try to invite input into our product a little later on. We do not have a structure or a plan yet for that. That is something we have to be careful about. It is something we are planning to do on a more formal basis a bit later.

We prepared a fair amount of material for the transition team. I do not know if you know how transitions work. Everybody in the government has been busily preparing documents, briefing books on the key issues that we are all working on and concerned with. That has included of course the work of our working group on autism and the transition period. That has been

transmitted for. We have not yet heard back from anybody on this. As time goes on over the next month or so, I am sure we will have a fair amount of opportunity to discuss and debrief our new partners within HHS especially.

I met with Representative Chris Smith, one of the authors of the Autism CARES Act. That was a very cordial supportive meeting. I hope that he was also positively responsive to our discussion. I really felt that we had a good opportunity to share what we are doing. He did express his disappointment that things have been so slow. We are making progress and I think that is the important thing.

And then I just wanted to emphasize that we have been able to staff up. We have been able to get information. We have been able to begin the report process. Beyond that in terms of further coordination of efforts, we will be including recommendations in the report as to things that might go better with either the coordination or

gaps in terms of needs and services and research as well. Hopefully then that may be a source for further support for the issues that HHS may be responsible for especially.

I do not know if there are any questions, but we have made progress. We have a good group of people working together. I am optimistic that we will be able to get the report to Congress in a timely fashion.

DR. GORDON: We do have a couple of minutes if there are any questions from committee members either here or on the phone. We thank you, Dr. Novotny, for the update and we look forward to being able to review the report and seeing what we can do with that.

Next, it is my great pleasure to introduce Angela Geiger, I am hoping I am pronouncing that right, Angela, from Autism Speaks. She joined the Autism Speaks as president and CEO in February of 2016. She brings to that organization a record of accomplishment of leading efforts to expand and

strengthen family services, field support, development and marketing. Most recently, she was the chief strategy officer for the Alzheimer's Association, of course, a leading organization of global and national and local impact as part of the senior management team there. She worked day to day across all the divisions with chapters to coordinate and execute strategy and to accelerate organizational growth.

She has been overseeing since she came to Autism Speaks. Their update. Their strategic plan. I am looking forward to hearing what she has to tell us today.

DR. GEIGER: Thank you so much for having me here. It is fun - not quite 11 months into my role in this job and it is nice to look out and see familiar faces. It has been a real pleasure for me to take on this role with Autism Speaks and to really have the opportunity to shepherd what the next ten years of Autism Speaks and this community will look like. I think everyone in



this room knows and probably knows much better than I that the amazing things that have happened in the autism community over the last decade, the scientific learnings, the awareness, the availability of more services for people on the spectrum and much of that is due to the leadership of Autism Speaks, but none of it would have been possible without lots of people working on these issues to make the world a little bit more accepting place for people on the spectrum.

One of the reasons the National Board brought me on board was to help them and to help the community craft a vision for what now the next ten years are going to look like. It has been a true pleasure for me over spending most of my time particularly in the beginning months just listening. I have heard so many stories from families and individuals on the spectrum and researchers and service providers and officials and just really learning the ins and outs of what the needs are, what has evolved, what has

changed, what we are still not - we still have issues to tackle and really becoming - I came in too not a subject matter expert in autism in any sense of the word, but have really had the opportunity because of that to listen with really wide open ears and without a particular point of view personally, but just to hear and really reflect back what the needs are.

That is why our vision for the next ten is one that has now been approved by the National Board of Directors. We have a three-year strategic plan that I am going to talk to you a little bit about today. Then I will be happy to answer any questions that I can for you.

Our vision for the next ten is that we on the cusp of a lot of progress. There are amazing things that need to happen. It is our responsibility to make sure that the mechanisms are in place for those things to occur. Whether that is increased federal funding for research. Whether it is us raising more dollars so that we

can push more mission into the field. Whether it is working collaboratively across sectors, across organizations to do things that together not one of us could do on our own. And to really continue the progress about continuing to lower that age of diagnosis to making sure that timely interventions happen more quickly. To make sure that research breakthroughs occur. To advocate and actually provide services that help people navigate this journey in the best possible way they can.

We know at Autism Speaks that this vision for the next ten is bigger than our organization. The only way we are going to be accomplish what needs to be accomplished for the millions of people affected by this here in the United States and around the globe is by working collaboratively with partners so we can get more done together than any of us could be done individually.

As part of our strategic plan, we have five mission objectives, the five ways we are going to work to achieve this ten-year vision. I will back up from that. The other part of this process was actually really looking at Autism Speaks as an organization, how we needed to grow and evolve and change to become truly a sustaining organization for the long term. We know that autism is not going to be something we are going to walk away from at any time soon and that we needed to transform as an organization so that we were going to be here for the long term.

We also look back over the progress that has been made over these last years and the environment has changed and things we have learned have changed. Autism Speaks also organizationally changed our mission statement to really be reflective of what those changes are and what the future we think looks like. You will see that in that mission statement there are some

really important changes I think that reflect back the things that have learned.

I have these really lovely mission cards. I have some if anybody wants one. Our new mission is that Autism Speaks is dedicated to promoting solutions across the spectrum and throughout the lifespan for the needs of individuals with autism and their families. We do this through advocacy and support, increasing understanding and acceptance of autism spectrum disorder and advancing research into the causes and better interventions for autism spectrum disorder and related conditions.

You will see some changes in that language. The first is that I think if anyone thinks about the hallmark achievements of Autism Speaks is about promoting awareness. That is really what has been driving so much of the work, but it is time for us to pivot. Continue to make sure people are aware of the challenges of autism and things that need to be done, but also to pivot to

understanding and acceptance. A true understanding of what it is like to have autism and that means a lot of different things. It is not one thing. It is a lot of different things. That is why you also see this across the spectrum and throughout the lifespan added to this mission statement that we really want to reflect that it is not a single autism. There are lots of ways that people experience that. We want to embrace and showcase all those differences so that people really understand that it is a spectrum.

And then this lifespan issue. In all those conversations this idea of transition into adulthood and what those outcomes look like and the need to do much more there was the majority of the feedback we got. You will see when I talk about our mission objectives that really come out there too.

The other thing is that you also see in addition to all the support pieces for people today, enhancing lives today, you also see that

this dedicated commitment to research stays in there. Research into these causes and better interventions remain a core part of our mission and I know as many of you in the room that is an issue that is near and dear to your heart. That is that change mission statement.

Along with that comes our quick impact statement. One of the things as I was talking to staff and you would ask them what does Autism Speaks do. They are having trouble articulating in just a single sentence. And basically for us that Autism Speaks is enhancing lives today and accelerating a spectrum of solutions for tomorrow. That is what we do.

How do we do that? That is what we do through those five mission objectives I mentioned earlier. Our first mission objective - and you will see that this ties very closely into the mission statement. It is increasing global understanding and acceptance. It is a global public health issue that must be addressed.

Again, you will see that pivot from not just awareness, but understanding and acceptance. You will see that debuted in the language you will see around April in World Autism Month in some of the activities in the things we release there.

The second mission objective is to be a catalyst for life enhancing research breakthroughs with a focus of near-term results. There is a real specific reason for that. I have been in health causes practically my entire career. There is not a one of them that I have worked on as a volunteer, as a staff member, helping with something that has not said we need more federal funding for research. It is a clearing call. But I am going to tell you something that I know to be absolutely true. Not just in autism is there not enough federal funding for research. There is not enough research investment overall in autism. There is not enough philanthropic dollars. There is not



enough corporate dollars and certainly there is not enough federal dollars.

Part of that is I think people misunderstood early on how complicated and complex a research issue this one and certainly that has been learned. I think it is just something that it is still a young issue in the history of disorders and those kinds of things. We think by shining that light on some near term wins will help bring market if you will to the rest of the ecosystem. We are in a place where we can help to do some of that.

The other thing. You hear this life enhancing. It is also about for us a real need to address some of these comorbidity issues, the GI, the seizure, the anxiety. That that can bring real-time, short-term relief to people today. We think that that is an important part of that research agenda as well.

The next two mission objectives go hand in hand. They are broken out primarily because we

want to stress the importance of each. And the third mission objective is one that will be very familiar to everybody because it has been a part of what we have done and all of you have been working on here for so long and that really is decreasing the age of diagnosis and decreasing the time from diagnosis to intervention and making that as quick as possible and as effective as possible. With this one with a special emphasis on lower socioeconomic populations because that is where that disparity is still the greatest. We think we have a special responsibility to really focus there.

The fourth mission objective focuses on the work that we have been doing for a while, but really highlights - this is a new area of importance for our organization and we think from what we have heard from listening to so many stakeholders for the entire community and that really is improving the transition to adulthood and really having successful adulthood outcomes.

We are going to start that work right in schools when kids are 14 and moving forward with really strong transition plans, getting standardized outcomes so that we know what good looks like and then working on issues like employment and housing and community support so that we are really thinking about that whole lifetime of issues moving forward.

And then our fifth mission objective is that while Autism Speaks has helped more than a million families in our first 11 years, it is still not enough. We want to ensure that people on the spectrum themselves and their families, those who care for them have access to reliable information services throughout the lifespan and really just taking all this information that is out there and just making it a little easier to navigate, prospectively offering up solutions.

If someone has called us for 100-day kit, we know how old they were. We know where they are. Maybe we should be proactively giving people a

call at four as they are getting ready to go to kindergarten and say here is some stuff you may have not thought about yet or here is how you can start planning ahead rather than making people raise their hand and stumble back to us and figure out the right way through. Not everyone needs help and assistance and that is perfectly fine. But for anyone who does, we want to make sure that we are there.

In short, we also want to make the experience just a much more embracing one. We are going to open up our arms and make sure that we are really tailoring information to where people are on the spectrum so they do not have to wade through information that is not relevant to them and having people use their voices whenever possible to talk about their experience as opposed to us saying what that looks like. You will see changes with us. The website will be changing over the next pieces. You will see changes in our language.

In essence, we want Autism Speaks to be home. We want it to be the place you can come back to when you need to get a question answered, when you need to tell your story, when you need to have someone be a partner in what is important to you.

We could not be more excited about what is going to happen next. I am personally so excited to work in partnership with as many people as we can to accomplish these goals for the full community. We wear this mantle of responsibility with great weight. The staff and the volunteers and the board know that a lot of opportunity comes with the kind of organization we are. We just want to be the best we can for people on the spectrum and their families and all of those who care for them.

I thank you in advance for what I hope we will do together. Even more than that, I thank those of you in the room who have made everything that has been possible happen over these last

years. You guys have been doing this work, as I said, far longer than I. It is really much appreciated I know by many. I will pause there if there are any questions.

DR. GORDON: Thank you. That is great. Are there questions from the committee members?

DR. SINGER: Thanks so much, Angela. It is great to see you here. I have a couple of questions about the changes with regard to how you will be pursuing research and science. You talked about the fact that you were going to be focusing on near-term wins because that is more likely to bring more money into the community. I agree with that.

I am wondering where you think there are opportunities to pursue wins in the short term and also how focus on the short term will affect Autism Speaks commitment to basic science.

And then secondly, I was hoping you would expand on where you think there are new opportunities for scientific partnerships.

DR. GEIGER: To answer the first question, one of the things as many of you probably know, we are very actively in the search process for our new chief science officer. We have had actually according to our research firm a record breaking number of applicants. The interest in this position was just amazing. We are moving our way through that process and hope to conclude soon. With the new chief science officer, there will be a new medical and scientific advisory committee. It will be a committee of the board be made of experts. Some people on our board like Herb Pardes who has a lot of experience in this, but then also outside experts who are not on the board. It will really be the job of that group to come together and decide how we are going to bring to life that strategic mission objective. I am not a science expert and I am not going to be pretend to be. I really want to have the best minds that are thinking on that exactly what those work streams are going to be.

We will continue some level of basic science investment too, what that ratio is. I do not know to be honest with you right now. But what I do know is we are going to bring together the best of the best and good thinking to make sure that the places that we are uniquely investing can make the biggest difference as quickly as possible.

Partnerships. Once this team is in place, what I would expect that they will do just like I did was start making the rounds and having conversations with people where interests intersect we should be working together. We are going to try really hard not to duplicate anything because it is silly. It is a waste of resources. I think we will just start having those conversations and figuring out the best way to do it.

DR. GORDON: I had a question actually about Objective 3, which was to decrease the age of diagnosis and reduce the time to intervention. I



wonder if you could tell us a little bit more about your organization's thoughts on those two issues. The first one in particular is intriguing to me because of our efforts including efforts that have been presented and discussed in this committee to get screening adopted. It seems to me anyway that one component of decreasing the age of diagnosis will be to institute screening perhaps targeted at socioeconomic classes where their diagnosis age is higher than others. I am wondering if you have had discussions or thoughts about that. And then also on the other side from diagnoses to intervention about how to reduce that time.

DR. GEIGER: On the diagnosis side of it, we think there are two primary levers to pull. One is increasing parent demand and the other is increasing physicians' willingness to make a diagnosis because those are the two biggest barriers. With parents, our thinking around this has been it is really a campaign targeted at

these segmented audiences that you need those reminders because you are not paying attention to this until you are worried. Until you think you are seeing something, you are not as a parent looking for this.

Our idea is to try some more novel approaches and I will give you an example of what we would love to do. In those 12 to 24 months, there are certain things that parents are doing quite frequently. There are products that they are interacting with, diapers, as an example. Imagine we look at and we say these socioeconomic populations, what kind of diapers is the most used brand for that group and then working in partnership with that manufacturer to make sure that those signs, what you should be looking for are printed there so that you are seeing that reminder constantly. You do not have to be watching. It is just that interaction with what your day looks like. It is just a tiny example of that increasing, but going right to the parents

themselves because I think that they know the best at noticing that.

And then on the physician demand, one of the things that we are finding in all these conversations with health care providers is one of the barriers to making that diagnosis, not the only one, but one of them is a lack of knowledge about the resources that are available. The physician does not have to take on this whole burden of care. There are actually people who can do that, but there is a lack of knowledge about that. Educating physicians about - here is how you work in partnership once that happens. We really think that that will help to increase that diagnosis right. Those are just examples of the novel ways we are looking at some of this.

DR. GORDON: Right. What I am hearing from you is you have some ideas about doing some things in the near term on this incredibly important area because we all know that the earlier that we get interventions going in

children, the better the outcomes are going to be.

DR. GEIGER: On the intervention side, I will just give an example. One of the things we are - we have been looking at the global scale - is parent skills training. Maybe there is the opportunity to while you are - certainly, we want to make sure that there are more public services available as well. I am working on whatever that looks like mostly from an advocacy side probably, but also increasing parent self-efficacy so that some of that intervention can be done even as waiting for more publicly-available things.

DR. GORDON: And as hopefully we will talk about when we get into scientific advances, there are some recent studies of evidence-based methods to increase parent engagement in interventions. That is a promising area from the perspective of having interventions that we have good data work that one can then try to implement through the kinds of campaigns that you are talking about.

Other questions from the committee?

Do you have timeline for some of these efforts to get forward? Is this waiting on the new scientific team?

DR. GEIGER: Some of the science stuff will be waiting on the new team, but lots of the other work for the strategic plan is not science based. Our fiscal year starts. Our new year started January 1. We are hard at work in implementing our business plan. If there is anything that I talked about today that was intriguing to you or things you wanted to either learn more about or you have an idea in what we can do, please feel free to reach out to me any time or any of my team. We are excited to work together.

DR. SINGER: What is the time table for getting the chief science officer in place?

DR. GEIGER: I am very hopeful that it is very soon. I think first quarter for sure.

DR. GORDON: Thank you very much. We really appreciate hearing about the wonderful efforts

you have been doing to refocus the organization. It sounds like you have a really promising start. We look forward to working with you to seeing those mission objectives come to fruition.

DR. GEIGER: Thank you all very much. I appreciate it.

(Applause)

DR. GORDON: Next up, I am going to ask Dr. Larry Wexler from the Department of Education to introduce our next speaker.

DR. WEXLER: Good morning. I wanted to take the opportunity to introduce someone who we have in the Department of Ed have funded over a number of years. My shop handles the discretionary grants program under IDEA. We have a large technical assistance investment across the disability spectrum. We have a saying in our shop that regardless of the state of the research, the school bus pulls up every day. Those children are left off at school. Teachers have to work with them. Early interventionists have to work with

them. We have to do the best we can. We fund a technical assistance center. We never fund it with the idea that we have the answers. That there are a lot of empty heads out there and this new center with well-known professionals and academics are going to fill those empty heads with the right answers.

We have a large knowledge development component of all of our technical assistant centers. What we tend to do is we start with whatever evidence base we have. We begin to work with states and districts. Based on those interactions, the evidence base changes. We change what we are doing. It is an iterative process.

We funded about seven years ago or eight year ago a National Autism Professional Development Center. That went to Frank Porter Graham and Sam Odom was the director of that center. In the knowledge development piece, the first thing they did was a meta-analysis of

interventions that were out there for kids with autism. They did a really nice job. Over the five with an extension of six years, they did some tremendous work in the field. But at the end of their funding cycle, they updated their meta-analysis.

And things over five or six-year period certainly we all understand have changed dramatically. What we were left with in the department was a new analysis, but with no way of really disseminating that analysis in a way that was actually helpful to people who provide services to kids and families.

We legally were able to supplement a grantee about a half a million dollars to have this meta-analysis and modules that had been developed updated. Sam Odom runs this program and has created with his team 27 new completely free downloadable modules that he is going to chat about as well as with some other work. We are really excited about it. You can read his resume.



I do not need to do it. He is very distinguished. They love him in North Carolina although I detest their basketball team quite frankly unless they are playing Duke and then we root for them.

Sam Odom is the director and the co-director is Ann Cox. You have Ann and Sam. They hired a coordinator for the module development and her name is Ann Sam. Truth is stranger than fiction. I will ask Sam to come on up and I will get out of the way.

DR. ODOM: Thanks very much, Larry Wexler, for a great introduction. As we often do - researchers and professionals do at the beginning, I want to disclose that we have funding. We have had funding through Office of Special Education Programs. We have two grants now running RCTs through the Institute of Education Science. I would like to say that I would to disclose that I am getting royalties from a lot of different products, but - I am not unfortunately.

Today I am going to talk about translating science into practice: autism-focused intervention resources and modules. And the first part of the talk is going to be about that translation process so where our work has come from, where it has led to at this point and then where we hope to go in the future.

As many of you know, evidence-based practice at least in our area in education and I think our area flows over to related services to speech pathology, certainly clinical psychology. I think we got our start in the evidence-based medicine movement back in the 1960s with Arnie Cochrane and followed by Sackett's work in Canada around evidence-based medicine. All this spurred on by the fact that health care was not being based on the most current medical evidence that existed.

In the Cochrane reviews and now Campbell collaboration do pull together that evidence about practices and make it available for

practitioners in the field, health care workers, physicians, psychologists, educators.

The clinical psychology field in the 1990s established criteria for empirically supported treatments. And those criteria have been used by other disciplines. We have drawn from it and I will talk a little bit about that.

In education, the No Child Left Behind Act in the early 2000s established scientifically-based instructional practices as the foundation for the kinds of service that needs to be provided in education and in programs for individuals with disabilities including children with autism.

And now Every Student Succeeds Act, ESSA, uses evidence-based practices throughout the act.

That is nice to know that we are basing our work on evidence, but how do we know what that evidence is and where does it come from? That is the devil that is in the details.

For many years, we were in the area of autism interventions. We searched for evidence through books that are titled evidence-based practice, book chapters that have those names. I even have a chapter too about evidence-based practice. And narrative reviews of the literature that examine, pull out in a systematic or less systematic more, more or less systematic way where the evidence is.

When Larry talked about the work that we did with our National Professional Development Center, he mentioned that we had done a meta-analysis and that is not exactly the term that is correct. Meta-analysis is a translation, a re-analysis, secondary analysis often that examines effect sizes. We did a critical review of the literature that did synthesize we feel the literature. I just wanted to be clear about the meta-analysis and systematic critical reviews. There had been systematic critical reviews that appear in the literature.

I want to make a distinction between the two projects that I am going to talk about here and other reviews in the literature such as through the What Works Clearinghouse or the Campbell Collaboration or Cochrane. The What Works Clearinghouse, for example, or the Campbell Collaboration does what I would call deductive takes and a deductive approach meaning that a practice is identified and then one goes out and looks for all of the information, all the science that would underlie that practice and then uses an evaluation approach to bring together that information. It discards studies that are not useful and then makes a statement about a single practice usually.

An inductive approach looks broadly at the literature. In attempts to draw out from that broad literature, the practices that emerge as having evidence.

In the mid-2000s, the first decade of the century, there were two reviews that used that

inductive approach. The National Standards Project that is at the National Autism Center began that approach in the early 2000s. Some of you may have been on those review boards. I was a part of that process early on. Their intent was to examine - to do a broad review of the intervention literature to determine what practices had sufficient amount of evidence using their criteria.

When we applied and received the National Professional Development Center on autism spectrum disorders in 2007, we were going to use the NSP, National Standards Project review. But they were moving very slowly and we had to get things off the ground.

We did a shorter review of the literature from 1997 to 2007 to identify - do the first run on identifying practices that had evidence. By practices, I am talking about focused intervention practices. That is, specific

procedures that result in learning outcomes or skill acquisition for a child.

That is contrasted with comprehensive treatment models that pull together a large set of practices into a package that is conceptually organized or planned. You will see today the practices that we and NSP identified.

In 2007, 2008, and 2009, published in 2010, our investigators did that kind of systematic review where we examined the practices that met specific criteria that we had for evidence. I will talk a little bit more about how we did that in a second review.

As we moved on from the initial review in 2010, the literature continued to keep growing. As you all know, the research on intervention practices moves very quickly. Our review ended in 2007. Around 2010, we had seen quite a lot of studies published.

We launched a second review. We were not completely satisfied with how rigorous we were in

the first reviews. We instituted a process that I think increased the rigor of our examination of literature.

Just to step back just a minute. That review was designed to inform our professional development program. In that program, we worked with 12 states to create a professional development model for teachers of students with autism spectrum disorders. I am not going to talk about that today about how the practices were used, but more focused just on the resources that we generated.

In 2010, 2011, we began working with our School of Information Science at the University of North Carolina to establish a search that generated 29,000 articles. We screened all of those articles and eliminated right off the bat about 25,000 of them and went through that iterative process of then looking at the reviews, screening, looking more closely at the articles' screening to the point that we had about a



thousand articles that had been published. We had expanded our coverage to a 20-year period from 1990 to 2011, 21-year period. There were a thousand articles published in that time that were candidates. We then sent those thousand articles out to a set of reviewers in the field that had to go through training to use our review process and then they determined whether our studies met the criteria that we felt were important.

The studies were single case design studies and group design studies, meaning either randomized clinical trials or quasi-experimental design studies. The reviewers were trained to evaluate whether the studies met the methodological criteria to be included, which resulted in at the end of that process 446 studies.

And then we began looking at the method sections of those studies. What were those interventions doing? What were the descriptions

of the actual interventions and use that information to sort those 446 studies into classifications or categories of practice?

We established a set of categories. We used a criteria for determining whether a specific practice reached the level of evidence we thought was important, which was at least two high quality experimental group designs that are RCTs or high quality quasi-experimental designs or at least five high quality single case designs that were conducted replicated by three different research groups. When you combined those single case designs, they had to have at least 20 participants or a combination of one high quality group design and at least three high quality designs. Those had to be conducted by two different research groups. We are really intent.

When people talk about single case design, they think about a single study that has one person in it. There are hardly any single case designs that are on focused intervention

practices that are like that. If they did, they did not make it in our review. We focused on both the accumulation of evidence and also the replication about across research groups, which we think was an important feature.

We published the report in 2014 and then it was subsequently published in 2015 in the Journal of Autism and Developmental Disorders. We identified 27 practices that we say are evidence based.

The practices largely are applied behavioral analysis practices, as you might expect, but not all are applied behavioral analysis practices. There are the fundamental behavioral techniques, reinforcement prompting, time delay modeling, and task analysis.

There are a group of practices that come together under what we call positive behavior intervention and supports. If you work in schools, PBIS is a term that you are really familiar with. The practices that we found that

fit into that PBIS model are functional assessment and seed interventions extinction, response interruption, differential reinforcement and functional communication training.

There are practices that focus on one of the core features of autism, communication, social communication so social skills training, which might or might not have an applied behavioral analysis basis, pure mediated instruction, social narratives like social stories, structured play groups, PECs, and then another set of what we call broad teaching practices, visual supports, discrete child training, which is a really central feature of many programs, naturalistic interventions, pivotal response training - parent intervention scripting exercise.

And the last couple of categories. One that features cognitive behavior, self-management or cognitive behavior interventions and technology-oriented practices. Some of these were added. When we did the second review, it elaborated the

most current literature and some categories came on line.

We have examined which of the practices produced which kinds of outcomes. We examined the outcomes, social, communication, joint attention and so forth. You can see across that top row.

And then we also determined for which age group there were some studies. Now that does not mean there were five single case design studies in each of those filled in cells that you see. But it did give us some information about what type of outcomes was occurring for which age children.

I apologize for the small print on this slide. My colleagues call these Sam Odom slides because they are really small and tiny. But this was not by design.

We were interested in seeing how we overlapped with the National Standards Project. We examined the 27 practices that we had identified with the practices the National

Standards Project had identified. One of the differences was that they grouped a lot of the behavioral practices under a super ordinate category that was called behavioral intervention, which is okay, but it does not provide the level of detail we needed for working with practitioners. What we found was that for most of the practices there was agreement that they were well supported.

For three of the practices, they reported the practices having emerging evidence. We call them evidence based. That is PACS, functional communication training and technology-assisted interventions. And then for two of the practices we identified, they did not include them in their list, which was functional behavioral assessment and structured play groups. There is a little bit of difference. By and large, our two reviews were generating the same similar sets of information.

Now, the National Standards Project went further than we did in that they have tried to

expand the age up out of the school-age years. I did not mention that our parameters were those school-aged years from birth up to around age 22. That is where we got our evidence-based practices.

The next step in this work is that we are just at the point of watching what we are going to call the National Clearinghouse for Autism Practice Evidence. The event is going to be happening probably next month. It says January. It will be the next iteration of the review that we have done. It will bring in the literature practices from 2011 to 2017.

Our goals if we find funding are to develop a process for continuously updating the literature so we do not have to wait five years to generate that next review. Contingent on funding, we will conduct a review of the psychopharm and behavioral psycho-pharma interventions that are published. We will hopefully move this out into practical

information that people can use. All this is contingent on funding. Right now, we are talking to several foundations about how to continue this support.

We have some information on evidence. It was imperative on us to not stop there, but use that information, translate that information into practical strategies access to practical strategies and tools that teachers, practitioners, speech pathologists, related service providers could use with some supplemental funding.

From the Office of Special Education Programs, we were able to develop the AFIRM website. We had previously worked with the Ohio Center on Autism and Low Incidence Disorders to create an initial set of modules. With the AFIRM website, we have used a more specific instructional design and are incorporating the information on the last reviews.



Modules. There will be 27. The last ones are just now going up. By February, they will be up. In that module design, we followed Kemp's Instructional Design Model. I will not take you through all of those because even though it is morning, I do not want people to nod off.

The target audience for these E-learning modules, the 27 E-learning modules are special educators, early education teachers, related service personnel, early interventionists. This is what the website looks like.

The structure of those individual modules is based on four sections or four lessons. They identify key components of the evidence-based practices and a step-by-step process of applying those practices.

The content is case based. We have case examples that engage the learner in problem solving and in identifying how to apply a practice given a specific context. They are multimedia. We have videos within those that I

will try to pull up in just a second. Interactive assessments and they are free to professionals, which is important.

There is a range of supplemental materials, implementation checklists, step-by-step practice guides, a guide for parents, tips for professionals, data sheets, and a list of the actual studies that document the evidence that exists.

We have a certificate of completion. When individuals access the website, they may decide that they want to go in and pull off the resources. That is how they like to use the website. Also, there is another alternative of actually spending time on each of the steps of the learning modules during a pre-test and a post-test and doing an evaluation for that individual module. If they spend that time on the module and are able to demonstrate some elementary knowledge then we can issue a certificate. It is a certificate of completion.

It just says we have been through it. We know a little bit about how to do this now.

The AFIRM website has those modules. Individuals who use the website do have to register. We only do that in order to keep up with who is using the site. We never send out this information to a mailing list anywhere. We may follow up and ask if they would give us feedback about the site, but that is the only way we get back in touch with individuals.

There are a range of modules that practitioners can access. I am going to go down to the visual support module. They may access any of those. It will ask do you want to get a certificate. If so, go this route. If not, you can just jump right into the module and pull off any of the resources that you want.

It will begin with a case and then there are lessons about the specific elements of the evidence-based practice. I pulled up the visual

support module as an example. It starts off with a case.

(Video shown)

DR. ODOM: That begins the modules. The other sections lead you through the definition of visual supports, different kinds of visual supports and how they might be used in classroom settings or other settings. How to collect data on student's performance given that visual support is a focused intervention that one wants to use with a student along with data sheets that you could use. Very practical information.

The information can be downloaded and is downloaded onto PDFs. Hard copies are almost always useful especially for things like data sheets.

To go back to the website, there are 27 practices. That is a lot of things to remember. We have a process for how to select individual practices. We never expect a person entering this website to know about all 27 practices. We do

think that practitioners can identify observable and measurable goals for students and then track those outcomes to the practices that are most likely to produce learning.

We collected data over the last two years about the use of the website. As expected, we have been adding new modules as we have been going. We right now have 18,000 new users, as you can see. That is a cumulative graph from June 2015 to December 2016.

This is a graph of the sessions viewed every day. As we would expect or hope for, as we have added modules and as information has gotten out about the website, the use has increased across time.

Data down at the bottom I think is useful. There have been 129,000 sessions, a million and a half pages viewed, 138,000 downloads, that is PDFs that have been downloaded to be used, and also which is not on here, 15,000 certificates or

individuals who have gone through the whole process.

Who is using the site? Administrators, early intervention providers. Our target audience was these individuals, special ed teachers, TA providers, paraprofessionals, related service providers. That represents a lot of our users.

But one of the things we had not really thought about, but has happened is that the website is used very much or frequently in professional development programs called pre-service programs for professionals. Teachers, related service providers in training. There have been about 2500 users for that audience, which we are really pleased. I do talk to people frequently about how they are using this website in their professional development program.

We do not have a way of jumping out of the screen and watching the people who are actually using the practices. We can only depend on their report. In a recent evaluation, we asked how

confident do you feel in implementing evidence-based practices to be reviewed on the module. The respondents reported they were somewhat very confident. We are not naïve about what it takes to actually move intervention into practice in classrooms and therapy settings in clinics, but this is a start. It is a tool to get to that endpoint of training and enhancing evidence-based practice.

In conclusion, AFIRM modules translate research into focused intervention practices and resources that practitioners can use to implement evidence-based practices. It is one tool, but it alone may not be sufficient in some circumstances. Training and support on site is we think important and critical. The modules appear to be important for preservice training. Universities are using them. I mentioned that. Students appear to be using them. As we mentioned, the field does not stand still. Our field of intervention research is constantly

moving and I would say improving. The literature that we are basing this on is now about five years old. Some of the practices that we know would meet our evidence base now have been published. The evidence has been published in the last five years. Moving that forward is a critical part of the work that needs to occur in the future.

I am going to stop here. I am very much open for questions or comments.

(Applause)

DR. GORDON: Thank you, Dr. Odom. That was really fascinating and thorough discussion of a real service that you are bringing to the field and to individuals with autism and parents and educators.

Are there questions from the committee?

DR. RING: Lots of discussion around the emerging growth of parent skills, training, and the value of that. I am just wondering whether or not from the evidence-based approaches you have



used to bring data on that to AFIRM modules.  
Forgive me if you have mentioned this earlier. Is the scope of your work also going to include parent skills?

DR. ODOM: Two things related to that. One is we do have - one of the evidence-based practices was parent implemented interventions. That means ways in which professional can work with parents to implement the intervention in the home.

We do have a small set of parent followers. I think the two areas that we as a project would want to grow is I think, one, making the information more visible to parents and getting their feedback about what kind of information. If this information is useful and if not, how should it be conveyed?

The second group is paraprofessionals. We have had some feedback about how these modules. This information might be adapted for

paraprofessionals. I think family members could give us the same information.

DR. MANDELL: Sam, congratulations. I have some sense of how much work it is to put something like this together. I also know that you are creating this in an increasingly crowded space as a lot of people rush to make online training available to individuals working with people with autism. I think yours has the distinction of being so carefully sourced in the evidence that you provide and in the plethora specific techniques that you propose rather than a branded package in some way.

I wonder how you think about the next steps for something like this. You hinted at the issue that online training. We have a lot of evidence that online training does not change behavior. Ultimately, what we are trying to do is change the practitioner's behavior. How could other organizations like the Department of Education or outside funders continue to support this work in

a way that would increase the probability that you could actually make a change in practice?

DR. ODOM: David, I think I may have mentioned, but I completely agree that the information that we have here is a useful tool and resource, but it will not get us to the point that we want to be. We had an RCT through the Institute of Education Science, actually two that are using a model like this, one of which we work with teachers and provide coaching across a year to determine both teacher's uptake and the ultimate effects of using a - we would call this - in other places, I have called this a technical eclectic model, that is, a model that draws from different theoretical roots so to speak, but is based on science and a process for linking science to goals for students. We are examining that model right now.

I think the next steps - moving the synthesis is really a critical part of what needs

to happen in the future. We are going to search around for a way to do that.

DR. MANDELL: Who knows what will happen with IDEA in the next four years. But one of the great things about the most recent iteration is the requirement for evidence-based practice. I wonder if there are ways beyond reaching out to specific practitioners who might find your website if there are ways to think about this is the evidence base. This is what we know from research to be the evidence base and that there may be ways to leverage policy to incentivize or perhaps even require changes in practice to become more in line with what you proposed and that this offers a piece of how that might happen.

DR. ODOM: I am hoping that can happen. Being a researcher and a professional development person, taking that policy step is not one that we often are skilled at doing. Mostly it is in response.

There have been at least three states that have used these practices. Actually, the Department of Defense uses these practices to establish - policy around insurance legislation. What is it that should be funded? If you are talking about ABA, what does that mean?

DR. GORDON: I am going to interrupt for a moment because I think this is a really important point that this committee is very well poised to discuss. And the reason why I am going to interrupt and I apologize for cutting you off mid sentences, but I think I would like to hear from some other folks on the committee who might be able to say something about how we or what their plans are, Dr. Wexler, for taking this forward and how can we all help.

I think one thing we have learned here at NIMH and working in other issues is that just because we show something works does not mean that people are going to adopt it and we have to

work really hard with other agencies to get adoption and that incentives really help.

Do you have any sense of ways that we can help efforts like this move forward and be adopted by states, by departments of education, by boards of education, et cetera?

DR. WEXLER: I have opinions, but they do not reflect the official position of the United States Department of Education. I will say that first in all seriousness. In my experience, policy by fiat is completely ineffective. I think the perfect example is IDEA has had a requirement for what at the time was called scientifically based and then became evidence-based practices in student's IEPs that that was a requirement. What percent of the IEPs of 6.2 million kids are taking that into consideration? I would shudder to guess.

My experience is that policies driven by demand and demand in our field is driven by parents and advocates. We fund 120 parent

centers. We are constantly saying to organizations, go to them. Build the demand for the practice and then it will happen. If parents go to IEP meetings and say I would like visual prompting to be part of my child's program then it could be integrated into the child's program. But just saying to a state, it would be a good idea for you to have a policy that includes visual prompting and that that is going to translate into practice I think is not really a reasonable expectation.

For instance, with restraint and seclusion, we could not tell states what they had to do. We did not have the authority to do that. I am not talking about OCR's work on them. I am talking about the Department of Ed's work. What we put out were 15 principles. Those 15 principles were incorporated into the law of 33 states and countless local school districts who are examining their practices. That can drive things.

But we cannot simply say do this. We do not have the authority plus it is not effective.

DR. CRANE: I want to back that up. I hate to make analogies between autism and things like medical injuries. But just to give an example, blood transfusions are a great evidence-based practice for auto injuries and physical therapy is also a great evidence-based practice for an auto injury. That does not mean that every single person serving people who have experienced an auto injury should be mandated to give everyone a blood transfusion and physical therapy right there on the spot. It is really not a good idea. Some people are not going to need that. There are people who need both at different times. There are people who are for one reason or another it would actually be harmful. If I were in a minor fender bender and someone just showed up and gave me a blood transfusion, that would be a really bad idea.



I think what really we have to do is give people the tools. I like that this website explains that this is a specific challenge that you might respond to with visual prompts. Visual prompts are not going to do everything. They are not going to answer every problem.

Once people are being held accountable for outcomes and saying you are going to be - whatever you do, it is going to have to - you are going to be held accountable for whether it works or not. Then professionals once they are given these tools can then pick which one they think is going to work.

DR. GORDON: I think that is a great point and it is wonderful that this endeavor - that is one of the best things about this endeavor is it does not have a single point of view or single intervention, but provides guidance regarding interventions that have evidence base. I think that is what the question that, David, that you proposed was how do we make sure that people know

and use resources that are backed by evidence base. It is one thing to say of course to dictate to providers which of the evidence-based practices they should use for which individuals, which of course is something that I think we could all agree might be problematic. But it might be another thing to figure out a way that we can encourage evidence-based practices.

I think, David, you pointed out that this is becoming a crowding sphere and it is not only at least in my understanding - it is not only evidence-based practices that are crowding the universe of online or in-person trainings. I do not want to be presumptuous, but at least from the perspective of NIMH and I think I can say I am speaking on behalf of the organization in this respect that we would really strongly make the statement that if we are going to encourage practices that they should have an evidence base behind them.

DR. WEXLER: First of all, totally agree with that. I will give you an example. I call this dialing for dollars. We have people come and want to meet with us and they have things that they somehow want us to invest in, which of course we cannot just do. Yesterday I met with a vendor actually who vends weighted clothing and weigh lap weights and this. I am not taking a position on it one way or the other although I did ask him. Do you have situations where that eight-pound weighted lap weight becomes 24 pounds in order to hold a kid in one place? They had no knowledge of such practice.

I asked them why eight pounds. Why not five pounds? Why not three pounds? What is your evidence that you have made the right decision for that? He said we just try different ones. They seem to be effective. Why do you know this is effective? We are using this in a particular large school district and we are finding test scores are increasing. I said in the wildest

dreams, establishing a causal relationship with weighted lap things and test scores going up might be a stretch beyond a stretch. That is that side of it.

But the other side and I want to get back to some of Sam's data. I think, yes, demand from parents, advocates is really important, but also building those practices from the get go. I think that the data you had relative to pre-service, the use by students, the use by faculty and having students go through those modules and equipping new teachers, new interventionists with the skill set from the beginning so no one has to demand it is certainly the other side of the coin. The way we encourage that is we make it free and it is easy. Any professor who has to prep for classes if they have the opportunity to have a 40-minute - to have students take a module, some of which in the class, they like that. It is evidence based and it makes sense and it fits into a flip learning model where they do

the modules at home and then they come to the class. That is the kind of thing I think we can encourage. I think it is encouraging that it is in fact being spontaneously used.

DR. GORDON: I want to make sure if there are opportunities for individuals from the committee to ask questions of Dr. Odom in other areas. Perhaps we will come back to this topic of evidence-based practice later if there are questions in other spheres. Otherwise, I am happy to go back. There were a couple of people who wanted to make some comments.

DR. CRANE: I have follow ups on that, but we can put that up until later. Do you have a way for professionals to find - search by problem and find the evidence-based practice that could solve it? Let's say I have a kid who does not use language. What is an evidence base practice for that? Or I have a kid with anxiety. Are there evidence-based practices for anxiety listed on this site, et cetera?

DR. ODOM: We only have it listed by broad categorization of outcomes. Your idea of having identifying maybe the most frequent questions that practitioners might have in looking at what interventions might be most appropriate is a really good one, but we have not taken that step.

DR. MANDELL: I think that would be a wonderful resource for people who do not know what terms to search. They do not know the intervention terms. They just know the challenge they are facing. I also think maybe it was weighted test scores.

I think there are probably nudges and pushes that could be immediately effective for something like this. For example, if one of the recommendations the committee wanted to make is about pre-service training then is there a way to evaluate existing programs and the extent to which their pre-service training provides both training in evidence-based practices and evidence-based training strategies for that? We

know there is a growing number of autism certificate programs. We have no idea the extent to which either programs of special education or autism-specific programs are including these things. That would be an easy thing to do. Hey look. We are not passing judgment. We are just saying here is the evidence base and this program includes it or doesn't.

Another way on the push side. If you look at the class action lawsuits brought within IDEA over the last decades, the overwhelming majority of them are procedurally. Very few. I think only one focuses on student outcomes. A couple focuses on staff training. None focuses on the use of evidence-based practice. I think the challenge is the disconnect between what lawyers think they can sue about and what the real problem is. Not that I am suggesting we give people fodder to sue school districts.

But can we rethink the way we think about using IDEA as a lever focusing more on the

evidence-based practice part and less on the procedural part? I do not know how the US Department of Education thinks about that or how state departments of education think about that. But it would be a great way to shift the conversation in a way that may hasten change in school districts.

DR. GORDON: If there are other questions or other topics, I am happy to entertain, but I have to response otherwise to David's.

One of the things that - as I said before, in other areas of NIMH's domain, we have dealt with this issue over and over again. One of the more recent things that we have done that has been successful was - we had developed a set of evidence-based practices for treatment of first episode psychosis. Getting that adopted was quite challenging. But ended up working was - actually, it started out with advocacy groups who lobbied Congress for funding in that area. Congress then threw the Substance Abuse and Mental Health



Services Administration, gave them money that was specifically used to give block grants to states, which is what SAMHSA does, but with the explicit requirement that evidence-based practice be used for first episode psychosis treatment. Then defined that when the block grants be given out for SAMHSA that they would consult with NIMH for what those evidence-based practices were. In this case, the Department of Education has defined themselves the evidence-based practice. I do not know to what extent we fund these kinds of efforts through block grants or other mechanisms.

Again, it is not requiring anyone to do anything, but it is providing the opportunity for states to ask for help in treatment with - of the federal government - ask for help in treatment for - psychosis. But if we are going to give them the money to do it then they have to say we are going to use an evidence-based practice and those evidence-based practices are defined by a federal

organization that has done the research to define them.

In this case, I could imagine saying to the states we will give you some money. I do not know if this happens, but we will give you some money to treat patients with autism. But if you are going to implement these practices in your schools with our money, you are going to use evidence-based practice. Here is a bunch of evidence-based practices. One of those resources might be this website. That is the kind of way that we have used to move evidence-based practices into implementation when we do not have direct control over treatment providers.

DR. ODOM: Can I make one last concluding comment? It is in response to some of the questions about mandating specific evidence-based practices. One of the early leaders in evidence-based medicine following Cochrane's work states really clearly that the process of evidence-based medicine is built on specific empirical practices

as well as the clinical expertise of the provider. It is a combination of both having the evidence there and looking for the best available evidence combined with professional skill and knowledge. I just wanted to finish up on that. Thanks.

DR. GORDON: It is a great note to finish up on. Thank you very much.

We have time now for a break. We are going to reconvene here at 10 minutes after 11 so a 20-minute break. At that point, we will resume some committee business. Let's start five minutes early and make it 11:05. We will get a 15-minute break. We will see you back here at 11:05. We will make it 11 o'clock back here. I keep shortening your break. Ten minutes.

(Whereupon, the Subcommittee members took a brief break starting at 10:50 a.m. and reconvened at 11:05 a.m.)

DR. GORDON: We had some great presentations this morning. Now we are going to proceed to

committee business. This is a very exciting time for the committee as we are trying to finalize the strategic plan update. Shepherding that along has been Dr. Susan Daniels, the director of the Office of Autism Research Coordination at NIMH and the executive secretary of this committee. I am going to turn it over to Susan. It has been a monumental effort. I want to thank her and her staff as well as everyone on the committee and from the public who has helped in drafting the strategic plan update.

DR. DANIELS: Thank you. We will dive right in because I want to make sure you have as much time as possible to talk about some of this business. I know that we have some new members of the committee so just a quick review. The IACC Strategic Plan is a document that provides a blueprint to guide autism-related efforts across federal agencies as well as private partner organizations.

The first IACC Strategic Plan was launched in 2009 and its focus was research efforts according to the Combating Autism Act. But under the new Autism CARES Act, it requires that the IACC Strategic Plan be expanded to address both research and services to the extent practicable. We have been making effort to do that. We have been doing this through the work of seven working groups around the seven consumer-based questions that provide the structure for the IACC strategic plan.

Over the last several months, we have had these seven working groups meeting to discuss the update to the Strategic Plan. We have had a total of 21 phone calls. Those were all open to the public and information about all of those calls is on our website. Anyone who wants to go back, we have transcripts and summaries of each of those calls. Each of the working groups now has gotten to the point where they have drafted a chapter outline that describes progress in the

field, gaps, needs, barriers, and opportunities, addressing the issues in that chapter. They have proposed revisions to chapter titles and aspiration goals for each of the seven chapters.

They have drafted broad objectives for each question. This was a decision by the committee to now cut down the number of objectives from 78 to hopefully 21. The committee has the opportunity if they want to include examples of responsive research projects, services or policy activities that would be responsive to the objectives in the Strategic Plan. Those have not been fleshed out yet.

Today, we are going to review and discuss the work that has taken place so far and give you an opportunity to provide input into these different strategic plan chapters especially maybe you did not serve on a working group that you would like to comment on. You will have that opportunity.

What I would ask you to do is - I am going to go through four slides per chapter and I would like to go through those four slides first before we start taking comments. If you have pressing needs as you see some of these slides, just jot something down and try to remember your question and we will do them at the end because I want to make sure we do not run out of time.

Just quickly reviewing the structure of the Strategic Plan chapters. It will include a title and aspirational goal, an intro that describes the content of the question area, an overview of progress toward meeting the previous Strategic Plan objectives, which OARC will provide that for each of the chapters based on your discussions. And then the working groups have worked on the overview of progress in the field, gaps, opportunities and objectives.

For Question 1, let's start there. The discussion of the Question 1 working group and you have the roster up on line as well as it was

provided to you in your meeting materials. I do not have it printed for you in the paper packet, but it was in the electronic ones. The working group came up with these several themes that were probably the keys for this question area, which is on diagnosis and screening. They thought that there was a need to improve implementation of diagnostic and screening tools, especially in community settings. To address disparities through improved early access to diagnostic and screening tools and culturally appropriate instruments. To develop a culturally competent workforce through increased workforce training and funding. And to improve collaboration among different sectors of the service system that is involved in screening and diagnosis.

With the question title, the previous one for this chapter was when should I be concerned. And the working group new proposed title is what are the signs of ASD and why is early detection so important.



For the aspirational goal for this chapter, we have a previous aspirational goal, but I will read you the proposed, which is provide the earliest possible diagnosis for children and adults on the autism spectrum, so they can be linked to appropriate interventions, services, and supports in as timely a manner as possible to maximize positive outcomes.

And the objectives for this chapter. Strengthen the evidence base for benefits of early detection of ASD. Reduce disparities in early detection by removing barriers to access and enhance culturally appropriate outreach efforts. And improve or validate existing, or develop new tools, methods, and service delivery models for detecting ASD that will facilitate timely linkage of individuals with ASD to early, targeted interventions and supports, which actually echoes a little bit of what was said in this morning's presentation from Autism Speaks.

These are the objectives. I think that is what I had for Question 1.

I wanted to get your input on Question 1. Is there anything that you think is an important theme or topic that you want to see covered that you do not think they might have discussed. You also have the outlines that are a little more detailed. I did not put those on a slide, but we are open for comments or if you have any comments about some of the proposed new language.

UNKNOWN SPEAKER: Can you put the aspirational goal back up because it is different than what we have on our paper?

DR. DANIELS: The slide should be the most updated. There is a possibility that as we were updating all the documents that it was a little bit - this is the latest version. Does anyone have any comments on it? Do you like the new aspirational goal that has been proposed?

DR. TAYLOR: I like it. I think that we will need to coordinate with Question 6. We have a

little section and we will be thinking about adult diagnosis and some of the benefits and potential drawbacks of that when we get our section. We will just want to have a little bit of crosstalk on that.

DR. DANIELS: That is something I mentioned to the Question 1 chairs as well. There was some discussion in Question 6 although it really was not about the development of research tools. It was more about the services implications and social implications. I think that it is okay for us to maybe focus on the research aspect here and then tie it in with what you are doing in Question 6.

DR. GORDON: I have just a comment on not the aspirational goal, but that first objective. I would say this is a really important objective from the perspective if you recall from the presentation from the prevention taskforce currently screening for ASD. They have decided it does not meet the necessary evidence base to

endorse wide adoption. Although we have some issues with that determination, I think trying to figure out how to establish a better evidence base for screening early detection is something that we are working on hard at NIMH.

DR. DANIELS: And the working group was extremely interested in that question and we have excellent people on the working group who want to write about that and put some information in that we can use.

DR. SHAPIRA: Stuart Shapira from CDC. I am a little bit confused about the title of this where the first part where it says what are the signs of ASD. I do not think that any of the objectives really focus on what are the signs. It is more how does one recognize the signs of ASD because it talks about tools and validation to identify signs of ASD.

DR. DANIELS: That is a consideration. It could be changed to how do we recognize the signs of ASD. There will be some description in the

beginning in the introduction that talks about what those signs are. If you think that that would be more appropriate, that is a possibility. What do others on the committee think?

DR. BRIGGS: I do think that we have somehow lost of when should I be concerned. To me also was how can we have clear quantitative information about specific science and what they mean and to improve our validity of the early detection methods.

In your next slide, improve/validate existing. That is captured there except it almost feels to me improve/validate tools for detecting ASD. Is itself a goal? We are seeing that mixed with facilitating timely linkage. I think one of the reasons that the US Preventive Task Force was hesitant to endorse early screening is some uncertainty about how quantitatively how predictive the early screening methods are. I think more validation of screening methods is

still an important part of building the evidence base here.

DR. DANIELS: What would you be suggesting changing?

DR. BRIGGS: I guess Number 3. I would almost put a period after ASD the first time. Improve/validate existing or develop new tools, methods, and service delivery models for detecting ASD period.

DR. DANIELS: And not have anything about linking individuals to interventions? We are trying to do three objectives. We were trying not to separate into four.

DR. BRIGGS: That is why it has ended up concatenated in a way.

DR. TAYLOR: It almost feels like the second half of that objective is the reason why we need to do that. That was going to sub-text. The reason why we need to do this is to facilitate as opposed to being the objective itself could be one way to get around that.

DR. DANIELS: Do others feel like they would prefer to put the second part about justifying why it is important to do this as something that would be put in the text elsewhere versus having it as a part of the objective?

DR. KOROSHETZ: We kind of did this in Question 2 as well. The thought was that it made the objective more relevant to patients and families. It was clear what the downstream benefits --

DR. DANIELS: I think most of the working groups tried to do that to explain what the purpose was, not just maybe the scientific or services goal in itself, but what possible benefits and outcomes might result if we are able to achieve it. Although obviously you could put a whole paragraph or a whole document together to describe that probably.

DR. BRIGGS: It might be a better phrasing to substitute in order to instead of that will. Then I think that might be clearer.

DR. DANIELS: We can do that. Do others feel that that would help clarify it a little bit? I think that that is very feasible. Anybody else have any comments about Question 1? Any issues that you think were missed? Certainly, the issue of clarifying the benefits of screening was a big issue and then reducing disparities. And early detection was an issue. And validating tools was part of the previous strategic plan, but now with a more obviously stated purpose. Anything else that you would like to comment on before we move on to Question 2?

What will happen after this meeting is any feedback that you all provide will go to the working group. Many of the chairs are here in the room. You are hearing it as well. We will just try to make sure that anything that the committee felt was important gets into the draft. But the working group chairs now have the outlines and are beginning their work with the working groups to come up with a draft.



DR. KOROSHETZ: Maybe I am misreading the emphasis. From reading, it looks like it is all about validating currently available tools where I would think that --

DR. DANIELS: It also says develop new tools. It is either validating existing or developing new ones. If you do not see anything else, I think the working group - I know that chairs are in the room here and are listening to this. They will be working on the chapter draft, which we will discuss later as to the next steps.

Let's move on to Question 2 just to keep us on time. The Question 2 key topics that came up in discussion. Walter is one of the chairs of this group. The points are the need to understand the molecular mechanisms by which genetic mutations or common variants lead to ASD, brain structure and function in individuals with ASD, and brain circuit abnormalities implicated in validated animal models.

Another point was the need to understand the underlying biology of co-occurring conditions as well as phenotypes and subtypes of ASD. The need for more longitudinal data to understand brain development and developmental trajectories. The need to establish standardized data elements and data acquisition parameters and to improve replicability. And to assemble larger research teams, including the participation of individuals on the autism spectrum, and to grow more diverse workforce. These were some of the main topics that were discussed by the working group in their three calls.

With the question title, the original title is how can I understand what is happening. And having listened to all of these calls and have been involved in the discussion, I helped the working group. We did not discuss it on the call, but I discussed it with the chairs to try to put forward a new title just because how can I understand what is happening. You could apply

that to almost topic of any kind. It is not very specific. This was an attempt I put forward to the chairs and they felt like it was okay for something that would be a little more specific.

What is the biology underlying ASD?

DR. BATTEY: I like the change.

DR. DANIELS: The next thing is the aspirational goal. The working group came up with a little bit more detailed aspirational goal. To discover how alterations in brain development and nervous system function lead to ASD in order to enable the development of effective, targeted interventions and societal accommodations that will improve quality of life for people on the autism spectrum.

DR. AMARAL: When I read this again, I thought what gets lost here is an ecumenical perspective on which body systems are affected. I think what happens is the immune system, for example, which is playing more and more of a role

in etiology gets really short shrift here. It is not even mentioned.

DR. DANIELS: Do you have a suggestion?

DR. AMARAL: I think there is probably a lot of work that went into this. My suggestion would be somehow to include back in a stronger link to immune dysregulation early on. I have to think about how to rephrase it, but I am sure Walter and Lewis could come up with something.

DR. DANIELS: Different physiological systems. We could try to work on that. We can certainly just work on it with the working group and come up with something, but just to capture that, but the rest of it you are okay with.

And then on the objectives. The three objectives for this working group are foster research to better understand the genetic and non-genetic components that contribute to the structural and functional basis of ASD. Support research to understand the underlying biology of co-occurring conditions in ASD and to understand

the relationship of these conditions to ASD. And third, to support large scale longitudinal studies that can answer questions about the development of ASD from pregnancy through adulthood and the natural history of ASD across the lifespan.

Any comments on the objectives?

DR. WEXLER: Just a question. The way those are stated, would there be room for the type of study that Alison's group is doing on siblings who are not affected to look at what is the difference? I ask that because my guess is that any grant application under any program that can show they align with this strategic plan would probably - that would make sense to a reviewer certainly. It could even become a requirement under certain circumstances. I am just not sure. It is sort of proving the counterfactual. Is that something that would be allowed under this?

DR. DANIELS: Any comments from the committee on this?

DR. KOROSHETZ: I may not understand exactly the point. Under Number 1, studies of brain structure and function in affected and non-affected siblings would be a very powerful study. Twin studies similarly. That would fall under the structure and function and abnormalities. We have a large section about brain circuitry, brain anatomy that comes under Number 1, studies that go after that. Is that what you are getting at?

DR. WEXLER: Whether it is genetic, whether it is chemical, whether it is environmental, would there be room for studying what does not result in autism? I defer to Alison who knows a lot more about this kind of thing.

DR. DANIELS: Some of that also may be captured more in Question 3 when we talk about genetic risk factors. This is more the basic biology.

DR. LAWLER: I do think there are some shared interest when you look at Objective 1 of Question 2 and some of what we have covered under

Question 3 because one of the themes that arose from our calls is to really go beyond this identification of risk factors to really understand underlying mechanisms particularly related to joint effects of genes and environment. We may need to have some conversations about how to make sure that we - if there are boundaries or if we are fine with there being a flow between two and three. I can see where studies - we could assign them to Objective 1 here and also at the same time to Objective 3. That may be difficult for reporting purposes or something that we need to better understand.

DR. DANIELS: We can look at that when we get to Question 3. Just as a reminder, the strategic plan sets a floor, not a ceiling. Anything that is in these objectives, it does not mean that that is the only work that can go on autism. These are top priority areas that the working groups wanted to identify to help agencies and organizations that are working on

this to say that these are areas of need, areas with gaps. But it does not mean that that is all that there is to do. It does not preclude anyone from doing other things.

DR. BIANCHI: I am glad that Cindy mentioned the word mechanisms because that is what I felt was lacking here as someone who is new and it is hard to be a Monday morning quarterback. Question 2 right now is a little bit of blurring between mechanisms and natural history. I just wonder whether you want to clarify the differences between mechanistic studies and more lifespan type of studies.

DR. KOROSHETZ: Underneath Number 1, we have a whole bunch of different bullets. Going from correlation to causality is one of the major objectives particularly for those where we know there is a genetic cause. The business about there on the other hand there is this question of understanding the biology given the heterogeneity. That is where there is a push to



try to actually look at larger studies over longer periods of time to try to find that. There is actually one bullet, which is all about different phenotypes, different heterogeneity. Because if we are ever going to understand the biology, we suspect that it is going to be different. It is not one autism. There are multiple autisms. To try and nail down the biology in these different phenotypes is going to be important.

Unfortunately, Question 2 - Megan just walked in when she saw this -- she said, this is like a book. Try and understand the whole biology. I think also to say that Question 2 is useless unless it informs Question 1 and Question 3. The biology and the mechanisms get you to therapeutic or a potential circuit abnormality you can diagnose in the fetus would be tremendous in terms of trying to get early diagnosis. Our problem is just the scope is just --

DR. DANIELS: The working groups will all have plenty of opportunity to put any ideas that you cannot fit into the objectives themselves into the text. There is going to be a whole narrative that goes with every chapter.

DR. BATTEY: I think back on the phone calls that we had about this, I think there was a very strong feeling that a long-term longitudinal study would yield an awful lot of very interesting information. I remind everybody about the Framingham Study and how much was learned, how much research was informed, how many public health changes occurred as a consequence to that study.

DR. DANIELS: Great. Other feedback on Question 2?

DR. DAWSON: This is Geri on the phone. I am looking at Objective 3 and I think that was just referred to as well. I do support the idea of a large longitudinal study. But I wonder whether given that it is just three objectives here

whether it would be better to frame this not in terms of the design of the actual study, but rather the intention of what we are trying to understand. For example, if this objective were written as to support studies that can answer questions about the biological development of autism and its - from pregnancy through childhood and the natural history.

The only reason I say that is because there is a lot of different ways of answering that question, one of which is a large longitudinal study. There are also some other - even from a design point of view, there is a way of doing overlapping cohorts that can answer longitudinal questions more quickly without having to follow people for 20 years. I just wonder rather than specifying the design that this question may be looked at in many different ways. There maybe even very interesting animal model studies, for example, that could be relevant here. And also it does not really - in the sentence - just throwing

out the idea of saying and its subtypes with giving a nod to the heterogeneity.

DR. BATTEY: It is true that long-term, longitudinal studies take a long time. Meta-analyses of those studies could yield information in a much earlier point in time.

UNKNOWN SPEAKER: I would not preclude a longitudinal study and maybe that is the intention and I concede to the work group on that. If you are really trying to understand mechanisms of development from pregnancy throughout lifespan, there is a lot of different ways of answering that question. I do not know whether it is more that we want to answer the question and there are a lot of different ways or if we want to specify let's invest in a large longitudinal study. That is just different strategies I guess I would say.

DR. KOROSHETZ: I would just say that - there are two things. Maybe we should decide what we are going to do here. All those that you

mentioned, Geri, could all be done under 2 and 3. Objective 3 is taking a shot over the bow. There was among the group a consensus that the many small studies that has been done in the past that their time is over. If we are going to make a big impact, we have to somehow develop standards. It could be overlapping cohort study. That would be fine. But that the time has come for the community to come together and develop standardized methods of collecting data over long periods of time, comparable data so that we can see the spectrum across the lifespan.

DR. BATTEY: Most of those studies, the smaller studies are way under powered to draw any kind of firm conclusions. If you want to change things, you have to do a powerful study that is widely accepted and not questioned by people who do not want to see things change.

UNKNOWN SPEAKER: Fair enough. That is fine. I think I made my point. I concede to the perspective that you are offering.

DR. DANIELS: Just to mention that I think the Question 3 group also discussed the issue of longitudinal studies. As I was working with Question 2's group, they felt that this might help Question 3 along as well. David, go ahead if you have a comment.

DR. AMARAL: I just wanted to actually say that, Susan, I think you preempted in a sense. What we found in Question 3 is there is a disconnect between genetic approaches and environmental approaches and what a large scale longitudinal study allows is to bring it all together. Geri, I take your point. But I think endorsing a large longitudinal study is really something that is important at this state.

DR. DANIELS: Excellent. Anything more before we move on to Question 3?

The Question 3 key topics that were discussed. This is on risk factors. I guess at the top of the slide we did not put titles. This is the chapter that is going to be on risk

factors. We talked about the need to identify genetic risk factors in the context of diverse populations and sex differences. To understand how multiple risk factors combine to result in a phenotype. To understand the effects of environmental exposures during early development in diverse populations. To understand interactions between genes and environment and the biological mechanisms underlying risk factors. To improve data access and data sharing. To foster a multidisciplinary workforce.

The title that was proposed for this chapter, the new title by the working group, is what causes ASD and can disabling aspects of ASD be prevented or preempted.

The Question 3 aspirational goal that was proposed is causes of ASD will be discovered that inform diagnosis, prognosis and intervention and lead to prevention or preemption of the challenges and disabilities of ASD. There was just a small change.

And the Question 3 objectives are strengthen understanding of genetic risk factors for ASD across a large population representing the full diversity and heterogeneity of those with ASD, enabling development of strategies for reducing disability and comorbidities in ASD.

Number 2. Understand the effects of ASD risk on individual and multiple exposures in early development, enabling development of strategies for reducing disability and comorbidities in ASD.

Third, expand knowledge about how multiple environmental and genetic risk factors interact through specific biological mechanisms to manifest in ASD phenotypes.

With this, do you have any comments and feedback for the working group?

MS. SINGER: One thing that I think the scientific community has been focusing on across the board, not just on autism, is looking not only at factors that confer risk, but factors that confer resilience. I do not really see



anything in the objectives that speaks directly to resilience. I think it could be added either to Objective Number 2 or Objective Number 3. I think the word resilience should appear somewhere.

DR. DANIELS: That was discussed. We did not put it into the bullets on that first page, but that was something that was discussed by the working group. Where do you see an opportunity to add that in?

DR. GORDON: You could almost put it in everywhere it says risk. Just put risk and resilience.

DR. DANIELS: How do you feel about that?

MS. SINGER: I would support that.

DR. GORDON: I have a general comment about these objectives and that is that they are incredibly ambitious and incredibly difficult. It does not mean we should not be making them. From a scientific perspective, these particularly integrating multiple risk factors and trying to

understand the combined effects. These are problems for which we do not currently have solutions. It may be that those solutions are beyond us because of the numbers involved although I doubt that. But there are certain people who would advocate that we cannot even if we had every patient with autism in the world and every person in control have enough statistical power to truly understand how multiple environmental risk factors interact. I do not subscribe to that point of view. I am not advocating that point of view. I am not advocating changing the language at all.

But I think somewhere in this chapter it has to be acknowledged that these objectives in particular are very ambitious and potentially very long term.

DR. AMARAL: Josh, I think the working group would completely agree with you. But I think this acknowledges the fact that you see papers on one risk factor and isolation, another risk factor

and isolation. Maybe it is difficult or impossible at this time to try and integrate them, but at least then we should be addressing that and saying even though we think it is not wise to think one factor at a time, at this point, we do not have enough information in order to bring it all together. Very good point. I think we need to address it in some way.

DR. BATTEY: Josh, you may very well be right. But if we do not look, we will not know. You have to do the study and you have to let a lot of people analyze the data to try to pull things out. If it is too many risk factors in the environment and too many allelic variants of too many genes then the study would have to be infinitely large to ferret that out, but it may not be. There may be some things that come up very quickly that pop up. I think in the genetic world that is not likely. Those are going to be very hard to tease out because we have already got a lot of data there. In the environmental

world, not so much. Cindy, correct me if I am wrong.

DR. LAWLER: There was quite a bit of discussion among the group assembled just in the exposure domain, really focusing on emerging exposomic technologies so that we are not just targeting known neurodevelopmental toxicants, the bad actors that are well established that we are doing or we are taking advantage of technologies that allow us to look more agnostically and also more cumulatively. Are we there yet? No, but we have a number of programs that are trying to look at and pull out exposomic signatures using metabolomics primarily.

DR. BATTEY: But you could imagine questions like do you live in or near a big city. There are certain environmental exposures that are associated with that. Do you live in an environment that is noisy, for example? Those sorts of questions can be asked. It does not cost a lot of money to answer those questions. That

may help you focus in on where to look. In my view, anything whose biological incidents are progressing as rapidly as autism is cannot possibly be all about genes. There has to be something in the environment because genes simply do not change that fast. Generation times are 20 years. It is in the environment. I am quite convinced that that is the case.

DR. GORDON: And these last three comments I think underscore what I hopefully made across in the beginning, which is that I think these are really important objectives, but it should be reflected how challenging they are. Maybe that is all the more important that we throw things at it, everything that we have it at it.

I just want to say your use of the word exposomics. The reason why I do not subscribe to the point of view that these are impossible problems is that we have experienced in these areas tremendous growth of technologies and

mathematical approaches and theoretical approaches that I think will help us a lot.

DR. AMARAL: One final comment on that. I think the committee thought that there were some potential missed opportunities where we are actually doing big genetic studies, for example, and yet we are not asking about exposures. I think bringing this to the forefront may put the seed of change in how those studies are designed.

DR. CRANE: I just wanted to bring up because as Jim raised the issue, there is a presupposition when we say this disability is growing way faster than the human genome can change. That presupposition is that there actually are more kids being diagnosed with autism than we would expect given the adult population. One reason that we are not seeing as high a number in the adult population is because the diagnostic criteria have changed dramatically over the course of several decades. We still do not have a comprehensive review of autism in the

adult population like we have from the CDC for eight year olds. It really worries me that we would be dramatically expanding all of these investigations into different factors that might be causing autism if we are not also really prioritizing an adult survey, which we still do not have.

DR. DANIELS: You can wait until we get to Question 7.

DR. CRANE: I do not think that this can possibly be limited to Question 7 since it is coming up now in Question 3.

DR. DANIELS: There is an objective in Question 7 that addresses what you are talking about because it is on surveillance. That is one of the topics in Question 7.

DR. CRANE: I understand that, but if we are talking about it now - if we are basing Question 3 objectives on the assumption that there is a growing incidence of autism then I wanted to bring that up while we are talking about --

DR. GORDON: That is a great point. It is clear to me though and hopefully to you as well that that is not the only basis for the search for environmental risk factors although it is a compelling argument if indeed the incidence is increasing.

DR. DANIELS: Any other comments on Question 3? Issues that you think that might not have been covered? Thanks for bringing up the resilience factors. We will make sure that that is highlighted. We have all the comments there.

Let's go to Question 4. The key topics that - Question 4 working group. By the way, I did not acknowledge Cindy and David who were the co-chairs of Question 3. Question 4. Kevin Pelphrey is the chair. Their discussion included the need to develop a range of different intervention types including technology-based and parent- and caregiver-mediated interventions, among others. To improve evidence-based approaches, community-based approaches, and treatments for co-occurring



conditions, minimally verbal individuals, and different age groups. To improve outcome measures and metrics for measuring treatment response, including in the context of sex differences, subgroups, and personalized medicine. To recommend strategies for accelerating research translation, providing incentives for industry involvement, and increasing access to treatments and interventions in the community. And then lastly, to prepare a workforce skilled in implementation and dissemination of evidence-based practices. In a nutshell, those were some of the big themes that came across in the working group discussions.

They looked at the title and decided to keep the title, which is which treatments and interventions will help.

For the aspirational goal, they have proposed develop a range of interventions that optimize function and abilities across the lifespan to achieve meaningful outcomes and

maximize quality of life for people on the autism spectrum.

And for the objectives, first, to develop and improve pharmacological and medical interventions to address both core symptoms and comorbidities in ASD. Number two, to develop and improve cognitive, behavioral, social, developmental, and naturalistic interventions for ASD. And three, to maximize the potential for technologies and development of technology-based interventions to improve the lives of people on the autism spectrum.

They had four crosscutting themes that they felt needed to be highlighted with respect to those objectives, which are enhance understanding of the brain basis and mechanisms underlying these therapeutic approaches. Maximize effectiveness for individuals by taking advantage of combination therapies. To develop more robust standardized outcome measures, including adaptive measures, predictive measures, measures that

address heterogeneity, and measures of practical outcomes that will help better target therapies to individual needs. Fourth, to ensure support for the entire intervention research and development pipeline. And fifth, to support translation of research to community-based practice and use of effective dissemination strategies to maximize uptake of evidence-based practice.

This is what the Question 4 working group has come up with. Do we have any comments from the working group or anything that the chair would like to add?

DR. GORDON: I almost had the same comment to the objective as I had the last time particularly around number one because I do not know that we have good targets yet. It is incredibly important that we make that as a challenge. But at this point, it is maybe acceptance in specific areas quite aspirational.

But I love the crosscutting ones because they are things that focus down the objectives onto achievable next steps in each of those areas.

DR. DANIELS: And in coming up with these objectives in comparison to the previous strategic plan, that was - in that strategic plan, the objectives were more project based. They were things that we thought were realistic projects we could achieve in five years. As we worked on this in the last year in the committee, I think the committee agreed that we wanted to be broader and more ambitious because you will not achieve what you are not trying to do.

DR. MANDELL: I was really heartened by those objectives. That is very exciting development and transition within the realm of treatment. The focus on translation and to community settings. Very much fits with Question 5 as well. I was wondering what the thought was

about how we should work together on these kinds of areas that are on the blurry line between --

DR. DANIELS: We discussed those synergies between the Question 5 working group and this group and your name came up of course several times. I told them that this working group can put some text in there that addresses it, but we will want to make sure that it follows into Question 5 because I know that is a major theme that you are going to carry through in Question 5. They were very interested in this as well, which I knew that you would be happy with and I think the working group would be happy with as well.

Other comments?

DR. PELPHREY: Echoing David's comment about working group 5 and 4, linking together - three is mechanisms. I am on 3 and 4. It is really two entirely different mindsets when we are on the phone on the calls. To some degree, we are trying to keep it that way because we are trying to

stake out chapters to write. It occurs to me that - and what we intended for most of the objectives and the crosscutting themes were to make the experiments that we are doing in the context of clinical trials aimed at generating mechanistic insight into the neural circuits and their development over time. I think that that is something we want to very much make clear. Even at the level of community intervention, we want to try to understand how that translates back to changes in brain function and structure that represent our best effort at getting mechanism in humans.

DR. DANIELS: The working group also talked about ensuring that during the research process that they were thinking about community settings, keeping that in mind as they are working in experimental settings so that it is not a huge step to translate.

DR. TAYLOR: I think for both Questions 4 and 5, we will want to have some conversations

about how that relates to Question 6 too. One thing that came up a lot in Question 6 was thinking about interventions and treatments for adults and services for adults. As a developmental psychologist, I very much like that 4 and 5 take a lifespan approach. I think that they should. I would not want to see them limited to children and to not address the older half of the lifespan. But at the same time, I think we will just have to have some conversations to make sure that each of the questions are addressing different aspects of this. When we get to Question 6, we talked a lot about these same issues, but in relation to adults.

DR. DANIELS: I think some differences in Question 4 in this particular version of the strategic plan will be addressing a wider range of age groups and a wider range of types of interventions. I think the first strategic plan really focused on medical interventions and behavioral interventions, but we wanted to be

broader. There was a lot of discussion also technology-based interventions. There is a lot going on in that area. We have a wider scope here. We have good experts on this working group to help flesh that out.

Geri, I know that you were not on most of the calls because of scheduling issues. Is there any comment that you had on this chapter? I know that you had mentioned you were interested in providing input.

DR. DAWSON: Thanks very much. In fact, I just sent both you and Kevin an email because I now have had a chance to look over everything. I think it is extremely well done and I feel very comfortable with it. Thank you, Kevin, and the rest of the group. For some reason, the calls were scheduled exactly when I was traveling. I had very little input on this part, but I have reviewed it and I think it looks very strong. I would be happy to work on the writing part of it.



DR. DANIELS: Wonderful. We had a lot of different experts helping us throughout this whole process. We did our best with scheduling, but it was difficult.

DR. DAWSON: It is hard to accommodate when you have that many people. It looks really good.

DR. DANIELS: Excellent. Samantha.

DR. CRANE: I also really liked that this is including a lifespan approach. I have one suggestion for Objective 1, which is to add mental health. There are a lot of psychiatric comorbidities with ASD that are not core symptoms and would not necessarily work under cognitive, behavioral, and developmental. I am thinking of things like anxiety interventions, sleep issues, eating issues, that type of thing.

DR. DANIELS: Under Number 1, it says comorbidities. That covers all of that.

DR. CRANE: It says medical, pharmacological, et cetera.

DR. DANIELS: Those are the interventions.

DR. CRANE: You would not necessarily have a medical or pharmacological intervention for anxiety. You have other interventions as well.

DR. DANIELS: You mean like drug interventions for anxiety and things like that.

DR. CRANE: No, not necessarily. You could have - there are lots of non-pharmacological mental health interventions.

DR. MANDELL: I think one easy way to address that would just be - you have core symptoms and comorbidities for Number 1, but you do not have it for Number 2.

DR. CRANE: That could work too. It does not include things like counseling or core psychological services that you would normally see for a mental health intervention.

DR. MANDELL: I would argue that most of the evidence-based places where we would start to develop or test those interventions would fall under cognitive or behavioral or social. For

instance, if you think about the best tested treatments for anxiety are CBT.

DR. CRANE: There is also emerging evidence in mindfulness, dialectical behavioral therapy for certain kinds of mental health.

DR. GORDON: I would say those would all fall under cognitive, behavioral, social treatments. You could if you wanted to make sure to be a little more inclusive to cut those out and replace them with psychosocial instead of cognitive, behavioral, and social. Psychosocial might be perceived as slightly more inclusive unless there are reasons why the group explicitly put in those words. I do not want to --

DR. DANIELS: No, not really. I think that that actually would work well. Different people on the working group were just throwing out different terms. We just threw them all into the bucket.

DR. GORDON: Psychosocialists - often what we use when we are trying to be as inclusive as

possible regarding potential - I hate to say non-biological because psychosocial all work through biology, but non-pharmacological --

DR. CRANE: That sounds good to me. I like psychosocial.

DR. DANIELS: I think we can do that. We can change it to psychosocial and then be more explicit about both core symptoms and comorbidities and then I think we will get everything covered. Great points. Thank you.

Other comments?

Then we will move on to Question 5. I see that we are close to 12 o'clock. Can I just get a read on where we are with lunch? We will just continue on then until the lunch arrives. As far as I am concerned and if the chair is okay with this too, if we need to, we could continue eating as we go into the next session so we keep everything on time.

With the Question 5 working group, we have Julie Taylor here who is one of the co-chairs and

Brian Parnell, who is not here, as the other co-chair of this working group. I am skipping ahead. Sorry. David Mandell. This is Question 5. I got distracted by the lunch discussion here. We are on Question 5. We have David Mandell. Shannon Haworth is also in the room who was a co-chair of this. I am sorry. I did not acknowledge the Question 1 co-chairs who were Ann Wagner and Alice Kau, both from NIH who are in the audience as well.

For Question 5, David is at the table. Shannon is in the audience, chairs of Question 5. The key topics that were discussed were improving the quality of the education and health care systems through increased portability, better access, and valid outcome measures. To ensure lifelong supports, including services for co-occurring conditions, person-centered planning and choice, and housing and communication supports. To foster a larger, appropriately trained, diverse workforce, including providers

and practitioners who can meet service needs across a variety of community contexts. And addressing existing policy barriers to coordination of services, providers, and personalized services. These were some of the main points. Anything that you think that we have missed there, co-chairs, that were major points?

In terms of the title, the working group had a suggested new title, which is what kinds of services and supports are needed to maximize quality of life for people on the autism spectrum.

For the aspirational goal, community - and this just has a couple of changes. Communities will develop, access, and implement high-quality, evidence-based services and supports that maximize quality of life and health across the lifespan for all people with ASD and their families.

The objectives are fully and successfully scale up evidence-based interventions in

community settings. Reduce disparities in access and in outcomes for underserved populations. And improve service models to ensure consistency of care across many domains with the goal of maximizing outcomes and improving the value that individuals get from services.

Just as a reminder, the strategic plan now is not just about research, but it is also covering some other service and policy implications. When we talk about ambitious, we may be getting more ambitious as we go through the plan.

Any comments here or feedback for the working group?

DR. GORDON: I will stick in a comment. I think the last crosscutting thing in section 4 although of course it deals with these issues. It is really good to have it in section 4 because it is nice to think about implementation when you are developing treatments. You try to develop a treatment that you are never going to implement

because it is impractical. I do not think it is too overlapping to think about it in Question 4 even though Question 5 is really about that.

DR. SINGER: I will just add that we have now heard in Questions 1, 3, 4, and 5 so far about the need for a highly trained skilled workforce, which we also cover in Chapter 7. We may be able to take some work away from the other chapters by keeping it in Chapter 7.

DR. DANIELS: When we were talking about it I think in a previous IACC meeting, we were talking about having the different working groups that are working on particular issues to try to flesh out issues that might be specific to their area whether it is the education workforce or the research workforce. They might have different issues. I think there is room for Question 7 to talk about overarching issues and for these individual chapters to flesh out specific issues for different types of workforce needs. We



certainly will want to coordinate it and not duplicate.

Anything else from members of the committee on this one? Did you feel good about the work that was presented here?

Let's work on Question 6. Julie Taylor and Brian Parnell are the co-chairs of this working group. The key topics that were discussed were supporting individuals with ASD as they transition to adulthood, including aspects of health, employment, education, and social and community participation. Improving the full range of health and health care for adults on autism spectrum, including preventative care, mental health, physical health, co-occurring conditions, and aging. Addressing issues of safety, including wandering, self-harm, criminal justice issues, and victimization. Providing adults with employment and financial planning supports, social and recreational opportunities, housing,

and long-term supports. Increasing research on effective caregiver supports across the lifespan.

For the title, the new proposed title is how can we meet the needs of people with ASD and a couple of alternatives, either as they progress into and through adulthood or across the lifespan.

Let's go to aspirational goal. The new aspirational goal just has a couple of word changes. All people with ASD will have the opportunity to lead self-determined lives in the community of their choice through school, work, community participation, satisfying relationships, and meaningful access to services and supports.

And the Question 6 objectives. Support development and coordination of integrated services to help youth make a successful transition to adulthood and continue to provide additional supports through the lifespan. Improve health, safety, and well-being of individuals on

the autism spectrum across the lifespan. And increase acceptance, accommodation, inclusion, independence, and integration of people on the autism spectrum.

Any comments on all of this?

DR. GORDON: Can you go back to the title?

I think we do need some resolution. The way I see the differences - across the lifespan is yes, more inclusive, but Question 6 was really specifically about adults. I am gathering that is why the committee had a hard time deciding between those two options. Anyone who was not on the working group want to weigh in on this issue?

DR. DANIELS: Is there a preference among the people here on the committee.

DR. BIANCHI: I would just say that as they progress into and through adulthood is clearer if the focus is adults. I would favor that one.

DR. FARCHIONE: The previous title said particularly for adults, which makes me think that it should be more adults, but still

inclusive of the lifespan. Is it really supposed to be focused specifically on adults?

DR. DANIELS: For example, transition is here. We have transition in youth and they are not adults yet. We did not say adults only and then have transition get lost. For example, when we start classifying studies, some of them are across the entire lifespan and they might even include kids, but it is a lifespan focus. We did not want to say adults only and then have a lot of things excluded.

DR. FARCHIONE: But even if you go with as they progress into then the focus is really only starting at the transition age and excluding --

DR. DANIELS: That is why it was a little bit difficult. But lifespan is now also becoming more and more integrated across the entire plan as we have seen throughout this as well. I think it could go either way.

DR. MANDELL: The reason we have this chapter is because of the absolute paucity of

services and research on adults. I think we do not want to lose that focus. When we are doing as good a job with adults as we are doing with preschool kids then maybe we could think about changing the title. I think we really want to keep the focus. I agree that it should include transition to adulthood because if you do not do that then you are too late. But it is about what the experience is going to be like in adulthood.

DR. TAYLOR: When we were thinking about titles in the group, I think what we were trying to avoid was this idea of adult research and adult studies are separate from everything else, but because the other sections are all incorporating a bit more of a lifespan perspective I think for this section keeping the focus and having the wordier, but clearer title is - I agree. I think that is probably the way to go. I feel much better about that with the other chapters taking more of a lifespan perspective as well.

DR. GORDON: I think the work group has the feedback that they need now.

DR. DANIELS: It is the committee's decision ultimately. If the committee sounds like they are happy with that, we can just set the title as they progress into and through adulthood.

DR. GORDON: David wanted to say something. He is the only thing between us and lunch.

DR. AMARAL: Go to the objectives please. My comment, which will be short, is about number two that says improve health, safety, and well-being of individuals. It is very vague. I think there is actually a real crisis in our ability to understand the health challenges to adults with autism. I would like to see maybe the committee to think about putting some oomph into that objective or editing it so that - actually, John Robeson, who sends his regards to everybody, was at our place yesterday and said that his major concern now was worrying about the fact that people do not understand why adults with autism

die 16 years earlier than general population. I really do think it is a crisis. And just to say to improve the health would be more like understanding the health challenges. Was that short enough?

DR. GORDON: That is great. I think we heard last time about some of the research that has exposed basically the increased mortality. Maybe your group could include that.

DR. TAYLOR: As I was read these over the second time even before you spoke, I was thinking about - we can talk about specific language, but I was even thinking about better understanding and implementing methods too. I think we all want to make sure that understanding what is going on in addition to thinking about how to better treat is something that we want to make sure gets reflected.

DR. GORDON: I think in their acknowledgement in that objective acknowledging

the fact that health outcomes and mortality are worse for individuals with autism.

We are going to take a break for lunch. Don't worry. We are going to get to Question 7 after lunch. We will convene at 1 o'clock.

DR. DANIELS: We need to go to public comment at that time.

DR. GORDON: Let's come back at ten to one. You can still be eating if you need to, but we will do Question 7 before 1 o'clock.

DR. DANIELS: And then the duplication of effort, which is not hopefully going to take too long because we have a full statement already drafted.

(Whereupon, the Subcommittee recessed for lunch at 12:05 p.m. and reconvened at 1:50 p.m.)

DR. GORDON: We do want to try to get through Question 7 and through the response to the duplication of effort statement before we go onto the public comments at 1 o'clock.



DR. DANIELS: Question 7. The key topics that were discussed were supporting brain banking, tissue collection, and efforts to encourage donation and participation in research. Continuing ongoing surveillance efforts, and considering methods for understanding prevalence in adults. Providing resources to support and expand data networks for the purpose of improved data sharing and data accessibility. To build virtual cohorts and use technology and surveys to collect data. Supporting workforce training that fosters skills in collaboration, dissemination of science, and communication with the public. Engaging in global efforts, sharing strategies and best practices to support people on the autism spectrum and their families.

For the title, there is a new proposed title. How do we continue to build, expand, and enhance the infrastructure system to meet the needs of the ASD community?

The aspirational goal had a couple of changes. It now reads develop, enhance, and support infrastructure and surveillance systems that advance the speed, efficacy, and dissemination of ASD research and services.

For the objectives, we have promoted growth and integration of the biorepository infrastructure. Develop, enhance, and link the data infrastructure. And develop the human infrastructure to disseminate research, support community-based service delivery, and communicate science. Those are the objectives.

Any comments on the work that has gone into Question 7?

DR. MANDELL: As with a lot of the questions, a really expanded view of the original intent of the question, which again I applaud. I think it is great that we are thinking about these kinds of things more broadly.

As I mentioned to you, Susan, it starts to get me excited about what could be and also

worried about how potential the appearance of the duplication may be perceived. I wonder if there is a way to - do we need to rethink some other aspects of the structure of the report for how we present findings from chapters to make it clear that these questions that overlap are really partnerships between or among groups? That is a really big question, but I will leave it there.

DR. DANIELS: Partnerships among -

DR. MANDELL: The different chapter - the work groups that are -

DR. DANIELS: As I discussed outside of the session with a couple of chairs, we have the possibility that once we have drafts together, the chairs exchange drafts and start to try to help streamline and coordinate as well and if you need to draw a few boundaries so that you are not repeating information, et cetera. It is not the same as the duplication of effort in terms of spending money. We do not want the plan to have two different places where it completely talks

about the same thing. There may be two places where we have different aspects of a problem for good reasons. If you all are able to look over each other's chapters where you think you might have intersections, I think that would help.

Other comments?

We are going to move on to the statement on duplication. Just as a reminder, the Autism CARES Act requires the IACC in its Strategic Plan now to provide recommendations to ensure that autism spectrum disorder research and services and support activities to the extent practicable, of the Department of Health and Human Services and of other federal departments and agencies are not unnecessarily duplicative. They are meaning that programs should not be duplicative or grant funding and other things that are administered by federal agencies.

This requirement was based on a 2013 report by the Government Accountability Office that

stated concerns about potential for duplication specifically in the research portfolio.

At the October 2016 meeting, the committee shared input on this topic. Alison Singer volunteered to draft a statement to meet the Autism CARES Act requirement. And then I also worked with Alison on helping flesh this out. You have a draft of that statement that was circulated to you. I think it is in our packets as well.

Does anyone have any comments on the statement, anything else that you feel is missing? We did try to incorporate what you said that you wanted to see in October and what was provided by the working groups.

DR. BATTEY: The only thing I would say is I think whenever we get questions like this from folks who are not scientists, we have to remind them that on reproducibility is really the hallmark of good research. We have noticed that at NIH that there are problems with

reproducibility, big problems with reproducibility. I thought the statement was very good. I think it is really important to - we do not want to come out and say we have a big problem with reproducibility, but I think pointing out that when a study has been done and then independently reproduced, its scientific value is significantly enhanced.

DR. DANIELS: Did you feel that point came across strongly enough in the statement?

DR. BATTEY: I actually thought it was very well written.

DR. DANIELS: Anything else from anyone here on the committee about the duplication statement? Hearing none, then we are going to accept the statement as the statement that will go in the strategic plan on behalf of the committee.

DR. GORDON: Do we have some more business on the strategic plan? Anything that will fit into four minutes before public comment?

DR. DANIELS: If our public commenter or our oral commenter is here, I would rather we move into public comment if that is acceptable for folks. Is our commenter here?

DR. GORDON: I probably do not think we should start until 1 o'clock on that because I think there were more public members who were planning on coming back at one for that even if Ms. Swanson is here. Are you here? Is Ms. Swanson present?

DR. DANIELS: She might be coming back at one.

DR. PELPHREY: Something that occurred to me in between the discussion of the duplication of effort and the surveillance task force and then thinking forward to talking about NDAR. I give credit, although I will probably slaughter the idea, but the credit for the idea is Fred Sheck. Whatever comes out of my mouth that is good is Fred's doing, and everything else is my fault.

He has argued strongly for a system of the kind that you would see in more FDA monitored research where you can tag studies, similar ideas in the realm of neuroimaging have come out of Russ Poldrack's work and other people, related to data integrity and rigor and reproducibility. But thinking about the usefulness of NDAR, we could increase its usefulness and increase our assurance that we are not duplicating things by requiring or encouraging or registration of studies so that they kind of get a GUID and have some hypotheses put forward ahead of time and then as data is collected has a unique signature.

So some sort of method for actually following a study from its logical beginning to end, so that you have a sense of how the data were utilized, analyzed, what analyses were run. Did individuals run 10,000 analyses and report that which was significant? Just something to be able to track that.



I think a lot of investigators would like it in this day and age. Being trained back when you could lab notebooks and keep up with everything to now running an institute with 20 different people doing 20 different studies. It keeps me up at night thinking could I ever detect if somebody did something amiss.

DR. GORDON: One thing with the new clinical trials rules at NIH is you have to do that. You actually have to register in advance the strategies using the outcome variables you are going to use, the numbers of people you are recruiting and any changes that have to be noted as well in the register before. For the clinical research, I think that is going to be - for grants from now on out actually, that is going to be a requirement, but it is a really good point.

There is talk about doing something similar in the pre-clinical realm although I would say those thoughts are in their infancy.

DR. DANIELS: It is unusual for us to have a couple of minutes where we are not racing to finish anything. Any other comments?

DR. PELPHREY: Just one more follow up to that. A lot of us in the autism world feel like NDAR has been an important. It is sort of an unfunded mandate and actually doing it right requires so much. In thinking about moving forward with strategies to increase rigor and reproducibility, either developing through infrastructure or helping the individual investigators to not have to go out and reinvent the system by which they track things would be very valuable. Just thinking about IUs of particular companies. It is incredibly expensive investing in developing things so that they could be free and open source and what not would be --

DR. GORDON: I am nodding for those people who cannot see me. I think it is 1 o' clock now so we are going to go ahead and proceed with the public comment period. Is Ms. Swanson in the

audience? We can wait for her. There is a written. Maybe we should start with the written summary and then we will go with the oral after that. Susan, why don't you just remind us about the protocol for public comments and then we will have the summary.

DR. DANIELS: We have adopted having a summary of the written comments given verbally so that you can all just hear some of the main points that were shared in written comments. We have Dr. Karen Mowrer from my office, who will be giving the summary of the written comments. Karen, you can go ahead.

DR. MOWRER: Since the October meeting, the IACC received written public comments from 11 commenters. For the purposes of this presentation, we have organized these under five broad topics. The committee has been provided all of the comments in full, but they will be summarized briefly here.

The first topic we had was the role of the IACC. We had six commenters under this topic. They included Toby Rogers, Susan Reilly, Dwight Zahringer, Dr. Eileen Nicole Simon, Lisa Wiederlight, and John Best. Their comments made the following points. Two commenters expressed concern over the IACC's revised policies for accommodating oral public commenters. They would like for a single designated individual from an organization to be allowed to participate in multiple oral comment sessions per calendar year rather than be limited to one opportunity for any given individual to provide oral comment per year and to be asked to submit written comments for the other meetings.

One commenter also felt the IACC should schedule more time for public comments to be discussed during the meeting.

One commenter recommended that the IACC facilitate a survey of parents of ASD children in

the United States and the high prevalence of autism in the US should receive more attention.

One commenter felt that the IACC should be required to focus on preventing all causes of brain injury that lead to autism rather than focusing on the role of genetics.

SafeMinds requested an update on the status of four working groups. It has asked the IACC to convene. These include working groups on autism and wandering and elopement, environmental factors contributing to the rise in autism prevalence, co-occurring conditions, and caregiver support. By way of an update on that, last year the IACC agreed to form three working groups on somewhat different topics and these were on housing, safety, and improving health outcomes, which includes co-occurring conditions. These working groups will be convened after the IACC has completed its work on the strategic plan.

And then finally under that topic, one commenter expressed general frustration about a lack of progress on addressing autism since the formation of the IACC.

The second topic was vaccines and autism. We had four commenters and they included Dr. Kerry Scott Lane, Pam Rockwell, Dwight Zahringer, and Dr. Christian Bogner. Their comments made the following points. One commenter asked the IACC be made aware of the US patent on methods for treatment of autism. The FDA should disseminate information about the potentially harmful effects of Tylenol during the peri-vaccination period.

One commenter expressed concern that influence of vaccine use during pregnancy could cause autism through the mechanism of maternal autoantibodies. The IACC should assemble scientific experts to present data on this topic.

Two commenters said the IACC should recommend that researchers examine how Glyphosate

in vaccines may be affecting children with and without ASD.

Two commenters asked the IACC to request that Congress investigate the CDC whistle blower issue and provide a full debrief of the study on autism and the MMR vaccine.

The third topic was autism research priorities. There were three commenters. These include Marilyn Kissinger, Dr. Eileen Nicole Simon, and Dr. Christian Bogner. Their comments made the following points. One commenter urged the IACC to recommend research examining whether common household pesticides could be causing neurodevelopmental disorders in children.

One commenter asked the IACC to request that research be done on the beneficial effects of phytocannabinoids.

One commenter asked the IACC to consider research on complications resulting in brain injury such as umbilical cord clamping, asphyxia

at birth, and developmental disruptions as they investigate causes of autism.

The fourth topic is treatment and health services' needs. We had one commenter and that was Mark Harrison. He made the following point, which is that he wanted to voice concern about health insurance providers refusing to cover ABA therapy for autistic individuals and citing exclusion of educational services as the justification. Federal policy is needed to rectify these types of coverage issues.

And the fifth and final topic was adult service needs, employment, and quality of life. We had one commenter under this topic, Dr. Eileen Nicole Simon. She made the following comments. Job training and computer skills should be included in adult care programs. And wandering and safety issues affect adults with autism and are of great concern to caregivers and the community.



That concludes the summary. Thank you again to everyone who submitted written comments. Thanks.

DR. GORDON: Thank you, Karen for that comprehensive summary. We do have, as I mentioned earlier, one oral commenter. Come on up to the mike. This is Patricia Swanson who has requested the opportunity to talk with us today.

MS. SWANSON: Anyone who knows me, my husband and I are in constant argument. He likes to slip in at the last minute. I am always on time. I apologize today for being the late Pat Swanson, but here I am.

I am here to talk about my twins, my identical twins genetically who are very different in who they are and how their lives are going to play out. I just want to share with you before I get started that our daughter got married, our daughter is a special education teacher, just this past weekend. She and Andrew have always been extremely close. She went into

special education because of her brother. When Andrew saw his sister in her wedding gown, he started to sob. He said everything is going to change. This is just Andrew's way of saying I cannot move on. Everybody else is moving on and I cannot. I am here today to talk to you about my passion. I really thank you for allowing me to talk about my passion about what is going to happen to my son.

As we have established, my name is Pat Swanson. I thank you. I consider it a privilege to be here and for you allowing me to testify before you today. I am a proud parent of 26 soon to be 27-year-old identical twin boys. Andrew is an adult with autism. His brother Benjamin is neurotypical. In fact, Benjamin has an interview with the state department on February 9.

When Andrew was diagnosed at age 2, we embarked on a pathway of extensive therapies to help him meet the same developmental milestones as his brother. Moving through life, we started

to accept that Andrew's life would have limitations and at age 12 right here in Montgomery County Maryland, we had to make the decision to remove him from an academic track into a functional life skills program. I cannot tell you how difficult that decision was. It was I think one of the most painful decisions of our life because we felt like we had given up on Andrew.

Despite our feelings, we knew - we are intuitive people - we knew somehow that this was the best for him. In this environment, Andrew not only flourished, but he met children, other kids who were like him. He finally had a peer group. He became very content and very happy. It was clear to my husband and me that in making this choice, we had made Andrew's choice. For us to continue to assist him in making correct choices, we had to accept the realities of his disability.

I have parented identical twin boys. Now that they are grown, the least restrictive and

most appropriate environment, which we hear constantly when we discuss this population for these two young men, is literally worlds apart. Ben lives - is married and works in China and has mastered the language. I would give all that I own to have Andrew capable of this life. But I have had to accept his limitations and this reality. He will need help to live day to day for the rest of his life. I will never give up on my son. I never have and I never will.

But I have to accept that there are things he will never do. I must accept that despite what I want for him, I can no more change his intellectual capacities than a parent of a paralyzed child can ask that child to get out of their wheelchair and walk. This is not the way I think out of fear for ease of my own life. I am his mother. This is what I know.

There are those with autism who are not as disabled as my son. They can and should speak for themselves. In developing policies for the future

of all individuals with autism, I really implore you to hear all voices even if they do not come from that individual. I am Andrew's voice.

Andrew still lives at home with us and has expressed in his own way his desire to be on his own. Katherine's marriage was one of those expressions. I can be seduced by the ideal of total inclusion for Andrew. I would love that. But I learned the reality of what was best for him years ago, when we made the decision for school. Obtaining this dream for him is dependent upon the proper supports.

Another little aside. He currently has a job at our local hospital. He works in the community every day. He needs a support person beside him to accomplish this goal in his life.

As an almost 60-year-old parent and yes, I am willing to admit that, my obvious questions are will Andrew be able to find his place before I die. And when I am gone, who will know him well

enough to truly speak for him the way I am speaking to you today?

I would urge this group to consider the wide range of abilities and interests of this population. It is a spectrum. I see through that many policies and attitudes limit the options for our family members with autism. Sometimes broad strokes may be needed and be what is necessary for policy to make it more inclusive. However, broad strokes can also have the opposite effect and by not taking into consideration of the complexity of autism. Those policies in housing, funding, and research can harm our loved ones and become impediments to a successful life. I will give you an example.

To put Andrew in an apartment would isolate him because everything he would need to do he would need help with. If he were to go into an intentional community that would have natural supports, he could move about freely and feel

more independent. I can tell you I know this is what my son wants.

Please be thoughtful and recognize the vast needs of adults and target efforts of this committee to opening and not closing off solutions that form meaningful lives.

This is a time of great change for the disabilities community. I should be and want to be excited about the future for those with autism. We are in a time of great change that holds unlimited potential for positive movement forward. But I am extremely concerned about the future of many individuals with autism and their families.

The goal of full inclusion for all may ultimately isolate and exclude many. The disability world mirrors the mainstream in requiring a range of needs and wants and the right to have a full menu of choices to meet these. People should not be cut out just because they cannot express themselves like my son. One

voice in this community cannot speak for everyone. Since I am Andrew's voice and I know my son, I can say with great confidence that he thanks you for listening to me today. Thank you very much.

One last thing. I am in research. Related to Question 6 and on research, I have identical twin boys. It would be wonderful and they have been in some studies. I am telling you. I am amazed. I worked at the NIH for a while. I kept contacting people to see if there were studies for twins. If you want to look at medically how the neurotypical community versus the autistic community ages, what better population of an automatic control genetically identical. Thank you very much for hearing me.

(Applause)

DR. GORDON: Thank you, Ms. Swanson, for your eloquent comments and for bringing the plight of adults to our attention and also - your twins underscore what we were discussing earlier



about the importance of environmental and other non-genetic factors in the origins of autism.

We now have some time to discuss the public comments. I welcome any questions or discussion from the committee on either the written or oral comments that you just heard.

DR. PELPHREY: Related to the last of the written comments regarding insurance coverage for behavioral interventions, I just wanted to make people aware especially the Virginia residents in the room that a bill was just put forward to cover or require insurance companies to cover behavioral interventions at any age. We had won previously the push to cover 2 to 5 years of age and then move it from 5 to 10 and now it is in committee to cover any age. We are very excited about that. It is a first policy win. This is moving forward nicely. It is an important thing as highlighted by that last public comment as well as the last written one.

DR. CRANE: To follow up on what Kevin said, I wanted to say that we monitor a lot of these bills as well. One thing that we consistently see coming up is that they tend to be focused exclusively on behavioral interventions or they claim to lump in all of other evidence-based interventions for people on the autism spectrum as behavioral interventions. They will say PECS is a behavioral intervention too or family training is a behavioral intervention. A lot of the time it is not.

We have been cautioning people to remember that when we talk about insurance coverage, we are talking about insurance coverage for the full 27 as we saw evidence-based interventions that are out there right now.

DR. GORDON: Thank you. That is an excellent point. I wanted to emphasize the several commenters who were asking about environmental risk factors. My comments about the difficulty of the Dutch work notwithstanding, there are a

number of efforts funded by the NIH in general and NIMH and NICHD and the National Institute of Environmental Health Sciences to try to look at these environmental risk factors and neurodevelopmental disorders including autism. I think there is some hope especially as Cindy mentioned as the technology advances that we can answer some of these questions that the commenters were asking about at least in specific individual risk factors.

DR. MANDELL: To follow up on the questions about availability of services and state mandates that are being passed, I was wondering if there are any recommendations to be made at the federal level about enforcement of these mandates. One of the things we know both from looking at private insurance data bases and also anecdotally what a difficult time parents have and actually taking advantage of the services that are supposedly available to them. Even though these are state

mandates, is there any federal role in looking at enforcement of the mandate?

DR. GORDON: Unfortunately, Dr. Novotny is not here to talk about the perspective from the HHS, which I think would be most informative and perhaps we should follow up with him about that. Maybe Susan we can do that and get an answer back to committee members.

I know that with regard to the enforcement of federal insurance mandates such as mental health parity that there has been a lot of discussion about bringing a little bit more teeth into that. I do not know right now what the status of those efforts will be. But I think it is something for us to certainly look into is to try and figure out what role we might have. I should say we now, not NIH, but the federal government, and what this panel could do to recommend measures or discuss measures that we might do to help.

It goes along with our earlier discussion about what can we do to make sure that evidence-based treatments that are developed by research that this committee is encouraging actually get picked up. I think those two things go hand in hand.

DR. CRANE: We actually have a toolkit out on insurance coverage both under Medicaid and for private plans. We have our individual and family toolkit that we put out as part of the Autistic Self Advocacy Network. We are going to be putting out a toolkit for private plan administrators soon. But one of the things that we talk about is not only these state mandates, but we do talk about mental health parity. There are a lot of ways that you can use mental health parity to gain access to autism related services and supports. One thing that we do not see discussed as much at all is the essential health benefits coverage that the Affordable Care Act included.

We do not know if that is going to stick around.  
Come back to me in June.

Assuming that the essential health benefits requirements continue to exist, they require that insurers cover habilitative services and habilitative services are services to help people gain skills that they did have before as opposed to rehabilitative services, which are designed to help people regain skills that they did have before.

Sometimes you will see services for people with traumatic brain injury that are very similar to services that you might be providing to a child on the autism spectrum except for the fact that with a traumatic brain injury, you are regaining motor skills. You are regaining communication skills that you did have before and lost. For a child on the autism spectrum, you are trying to help a child develop those skills in the first place, things like motor training, speech language pathology, occupational therapy,

language interventions and alternative and assistive communication devices. Insurance companies usually before the ACA did not cover habilitation. They usually only covered habilitation or sometimes neither. But now that states are trying to regulate on an individual state basis and that is the divide that the Affordable Care Act allows. States are trying to flesh out and define what is a habilitative service and what do we consider essential for all of the plans in our state. That is a place where I really think that people should be paying a lot of attention to as those regulations are fleshed out.

DR. GORDON: Thanks for bringing that to the attention of the committee and to the public listening. That is really important information. I should add it is really tremendous service you do to the community to provide help and guidance regarding working to make sure that individuals can get the care coverage that they are entitled

to. I know that is challenging. I can speak from personal experience. It is challenging in all areas of medicine to make sure that you get the care that you are entitled to.

There were several comments about the public comments. I am wondering if any committee members had any thoughts or comments in response to requests for either increased public comment or opportunities for individuals to come back more than once a year, et cetera.

DR. DANIELS: As background, I know that this was discussed at a committee meeting before you joined. We were having issues over the last year with the public comment sessions going over schedule consistently. I tried a number of different approaches to try to keep things on schedule and it was not working. The committee asked me to try to come up with a solution. That is the solution we came up with. It would limit any individual to commenting once a year.



They also mentioned hoping that we would have less duplication of comments like the same comment coming in multiple times. But we are of course open to changing it again if you do not think it is working well.

DR. BATTEY: I think it is working pretty well. I think once a year is often enough. We are smart people and we remember.

DR. GORDON: I think that the summary of written comments actually works quite well as well, at getting things across. I think our discussions about the issues raised in written comments say that.

I would suggest one thing which is we have had opportunities for three speakers per session. Because of various things, we have had less than three for the two sessions that I have been at so far. I think last time we had and this time one. One thing that we might want to consider going forward would be having alternate speakers so that we give as many as we can accommodate the

opportunity to speak before us orally. I do not know if there are any other opinions. Again, I was not here for the times where we had difficulty keeping on time. I certainly do not want to speak for the rest of the committee, but it is one observation that I had that I think we could make a quick fix to that would allow more comment.

DR. DANIELS: Just also to clarify about this time, we only had one commenter come in. The new calendar year has started so it was open to anybody who wanted to come in. We only had the one. It probably is partially with the holiday. Maybe people were not able to get that organized and everything ahead of time.

The last two sessions were the ones where we had the fewest people asking to give public comment except the last time we had eight people come in, three of whom had just spoken within the last couple of meetings. We turned those three down and had five on the schedule and then two

dropped out at the last minute. That is why we ended up with three, but we had originally scheduled five to speak last time.

DR. GORDON: We will close the discussion of the public comments. Susan, I will make a decision about how to handle the oral comments going forward if there are more than three requested.

We are now back to committee business and back to Susan, who is going to resume our discussion of the Strategic Plan update. There are a few more items to complete and then we will go to the summary of advances discussion.

DR. DANIELS: We are going to talk about the budgetary requirements. The last time we met I discussed a little bit about the budgetary requirements for the Strategic Plan. The Autism CARES Act requires that the IACC Strategic Plan include proposed budgetary requirements. That is the exact language of the law, which as usual is a little bit open ended for us to interpret as to

what types of things we would do for proposed budgetary requirements.

The previous Strategic Plan provided estimated budgetary requirements for each objective and those objectives were based on projected projects that we thought would be done and we had experts in those fields estimate how much they thought those projects would cost.

You have seen the objectives we have for this Strategic Plan, which are much broader. The one drawback of having broad and ambitious objectives as we do now is, for example, putting a dollar amount on reducing disparities might be a little bit hard to do. It might not be as feasible. Also, if we are mixing research and services estimating, I do not think is really possible. We need to come up with some different way to do budgetary requirements. Objectives in my opinion are a little bit difficult, but you are free to give your ideas.

DR. BATTEY: I agree with you. I think especially now that we have broadened it out of the research arena, it was not easy when it was just research where we have pretty good idea how much stuff costs. Now we are being asked to do it in an arena where we know even less than we did before. But I guess that is what the Congress tells us we have to do. We cannot say no.

DR. DANIELS: That is right. We cannot say no, but we can be a little bit creative about how we come up with a list.

DR. BATTEY: We can give a range, not a number, but a range, a broad range because they are broad goals.

DR. DANIELS: We could. That would be one possibility. We could do things with the objectives. We could go at the question level and try to do estimates there or we could do an estimate for all of the overall plan, keeping in mind the broad objectives and that we need to be

inclusive of both research and services activities.

We can do budgetary requirements around research budgets because we have that information. Through the portfolio analysis, we have been collecting that data. I just wanted to quickly show you the 2015 preliminary data. Those of you who have participated know that we have collected 2014 and 2015 and we have actually just started analyzing it. We had collected information from 18 funders. This analysis provides detailed information about the portfolio across both federal and private organizations.

What we have here is in 2015, the total funding was \$314 million across 1300 projects. The proportion of federal to private research stayed roughly the same. The federal portion has increased over time. At one point, it was more like 75 percent to 25 percent. That is the proportion. Overall funding has decreased since 2012 from \$331.9 million and at that point, the

federal was \$260 million and the private was \$71 million.

This just gives you another picture of where funding has gone over the last several years. You can see that it has sort of flattened out in the last few years.

You do not need to read in detail, but this is the proportion of the total research portfolio that is funded by various funders. You can see that NIH is a large funder. There are some other large funders and small funders across the strategic plan.

The percent of 2015 funding by IACC Strategic Plan questions is as follows. There have been some changes since the 2013. I had a few notes that Questions 5 and 6 increased by 1 percent each and that meant Question 6 doubled, but it was very small to begin with and the smallest. Question 4 decreased by 3 percent. Question 3 decreased by 1 percent. And Question 2

stayed the same by both percentage and dollars.  
That is a quick rundown.

And then we have some information about the amount of money that was spent by federal agencies across these questions too in case you want to use that for any budgetary requirements.

Some possible options. You could base proposed budgetary requirements on the questions. You could base them on the objectives. You could base them on the entire research budget, for example, sort of like the NIH doubling saying we are at \$314 million. Where do we want to be in five years from now in terms of the overall research budget? Or we could set a target amount to reach each year. Those are some options. And then Jim placed another on the table. I wanted to get your feedback.

I think there is something very direct we could do about research and then I have some discussion on the services piece as well. Open for discussion.



DR. MANDELL: I think there is some value in placing some kind of dollar amount or dollar amount range by question. I think part of the way that this document has been used in the past and probably will continue to be used is to think about where we are putting our money, not just broadly in the category of autism and to the extent that we are supposed to advise or play any kind of watch dog role. That is a particularly helpful level of granularity for us to have.

I would argue that we provide data or propose targets at the question level. I am kind of agnostic about whether it should be a range, whether it should be a target, how we decide that.

DR. WEXLER: I am wondering if we cannot think a little differently about the dollar amount. Many of us have participated in assigning dollar amounts to things that are virtually pulled from the air because it seems like a good idea. I think it might be a little more genuine

if we somehow tied the investment that we would like to the increase in prevalence rate and maybe use that slope as a way of addressing what the investment ought to be. I am not saying that is what it ought to be because without using the assumption that the \$300 million or whatever it is. When Tom Insel testified in front of Congress and they were badgering him about this, he asked the congressman how much are we investing in AIDS research, for instance. They did not know of course, but he knew down to the nickel. It was in the billions. The assumption that that \$300 million is a good place to start, but maybe somehow looking at slope of increase, maybe tying it to something along those lines to come up with a ballpark figure that it could at least be tied to some type of metric might be a way to think of it.

DR. AMARAL: I agree with you. Absolutely. It seems to me that these numbers in the Strategic Plan has always been a convenient

fiction. I think in part they are drawn from thin air. You guys do a good job trying to put together data on what goes into research. When you are trying to anticipate what needs to be done for research, I think that is really difficult.

But I do think maybe in terms of communicating the need if we were to have a big number like you suggested doubling the funding for autism research or whatever and perhaps tied to the economic cost of the three or four billion people with autism in the United States. What is the economic cost and how could we try and reverse that through an investment and not worry so much about the details, but the big number? I think that that would be speak better to Congress if we said we are only investing \$300 million. Maybe draw analogies. \$300 million. What do we put that into? Increasing potato crops. I do not know what it is. We need to invest more in autism.

DR. PELPHREY: I think I am seconding what David just said. The experience of the insurance legislation that I spoke of earlier. For five or six years the law was put forward and we always had parents testifying and very upset and crying. Everyone agreed that it would be great to fund it and that it would cost the state X amount of dollars and then it always failed after the parents went home and the doors were closed and the vote happened.

The only way it passed was by making the argument that it would save money ultimately. I think that setting it to this is what autism costs in the United States. This is the investment. This is our track record of being able to address this problem or saving you X dollars with the money we spent. This is what we propose to do. If our committee could have that kind of influence and say this is how we would organize this sort of a bidding process for the projects across the different universities, which

we would personally love to see. Which university could do the same project the cheapest? By posing to the Congress that we have what we could save them, I think the argument could be much better made rather than the wishful thinking of let's double it because we do not have the money to double it.

DR. BATTEY: I think that is a really good idea. The tricky part with that idea is determining the cost of autism. What do you value the parent's time? Does somebody have a good idea about how to do that?

DR. DANIELS: We are really fortunate to have David Mandell on the committee. I see his workload potentially doubling.

DR. MANDELL: People are referring to a 2014 article in which I was a co-author, which we did exactly that. We worked with a group from the London School of Economics and we looked at both those indirect and direct costs associated with autism in the UK and the United States.

DR. BATTEY: You have at least a formula for how you have done it in the past.

DR. GORDON: I have a suggestion to make because I am hearing the comments and I think there are some different elements to it that can be pretty easily united. I think there is enthusiasm in the committee of continuing to provide at least question-level estimates. And there was also enthusiasm from members of the committee about making a statement that discusses overall perhaps with a goal of doubling the annual budget, but putting it in the context of the cost of autism and the fact that investments now will pay off in the future.

My synthesis for a moment of those and I do not mean to close discussion, but at least to advance it would be to say let's have a small group perhaps including David since he knows more about the cost than anything else, draft a brief, a couple of pages, maybe less, statement that would go in the beginning about the overall cost.

Then have each working group come up with an estimate. Yes, we understand that it is not going to be based upon knowledge of the cost of each pipette that is going to be used or each behavioral intervention and each therapist that is required for it, but an overall global cost that will hopefully add up to something on the order of doubling the current spending, given a certain - let's say ten years or something like that do that we can make some estimates that address the question level and then make a recommendation that is global and takes into account the overall cost.

DR. CRANE: I have two points on that. One is I would hesitate to try and rhetorically tie the cost of autism to the cost of research because unless your goal is there is zero autistic people left at the end of your research, which I would hope is not our ultimate goal, there is going to be costs. We are not reducing it to zero.

DR. GORDON: But my guess is although David can correct me that the bulk of the cost to society is not in the care of individuals. I know that is high. But it is in their lost contributions to society.

DR. CRANE: That is going to be tied to each other because a person who needs supported employment is going to need supported employment.

DR. GORDON: Remember two things. Our lofty goals, which are really full integration and success and number two is again the cost of appropriate effective care is much less in just about every disease than the gains in productivity you get when you effectively remediate.

DR. CRANE: I do not think that that is necessarily going to be true for a lot of people on the autism spectrum, but just to move on to my second point, I think that we need to also have transparency. When we have question level budget proposals, we need to have transparency about



what we anticipate that paying for because a lot of the time when we talk about disparate spending on different objectives, there will be a lot of confusion. Well, maybe we are spending more on certain objectives because each study costs more for a biomedical study versus a naturalistic intervention study. Depending on the biological study and the naturalistic intervention study and how many subjects you have in each one, which might not always be true. But we need to make those assumptions transparent so that it is not just like we think that we should do more money's worth in this question than that question. That we really make it clear that we think that this question. We are not prioritizing it over another question, but we believe that the research is of the kind that will cost a lot more so we are going to bump that up a little bit.

DR. MANDELL: I think to speak to Sam's first point, I think it is a mistake to conceptualize the purpose for medical, biomedical

treatment research as economic. That may be a fortunate consequence of successfully treating and supporting people with a particular condition, but I do not know that that is what we ultimately value and where we should be putting all of our energy. That is the first thing.

The second thing is that one of the things Ari Namon(phonetic) has talked about is we should not be talking about the cost of treating autism. We should be talking about the cost of not treating autism. That is what we have. That is the cost that we have.

I do think that you can say if you look at the inability of people to enter the workforce, the opportunity costs associated with parents having to leave the workforce and inappropriate housing options for people. Those are the three biggest drivers of cost for people with autism. We could probably add to that inefficient or ineffective early intervention services.

I think you guys are on the same page because when I look at the matrix of what is driving the cost, the issue is not getting rid of people with autism. The idea is ameliorating the disability that comes from care delayed and denied.

DR. KOROSHETZ: I just offer a parallel situation that we might want to think about that happened in Alzheimer's disease. There was a group like this and they had a strategic plan. They developed a series of recommendations for research. They put numbers around them. Lo and behold, they got the money. Then the research plan turned into a bypass budget that went to Congress.

The reason why you put these numbers down. There are two reasons. One is in case that you get lucky like that and the money comes because you make the strong argument that this is what it is needed for and this is what it is going to cost. People who put this together really thought

about this. This makes a lot of sense. It actually leads to funding. I think that is one thing to be more prescriptive about what the money is going to be used for in these different questions and objectives and really fine tune it more.

The other reason is to let people know how much this stuff really costs compared to what is available. That is more of a messaging type of thing.

I am more for putting the money next to the - this is the kind of research we need to do. This is what it will cost and do it for each of the objectives. It is always slim, but it is more likely it is going to persuade somebody to bring money in.

DR. PELPHREY: I think we have an opportunity to put forward even though our goal is not to necessarily save money, but to put forward a very clear level-headed plan of exactly what we would need if we really wanted to address

the problems that we outlined in our strategic plan would be perhaps the most important element of our service to Congress because ultimately that is what they want to know. It is how to distribute limited resources.

And then related to that - I think I have been here a full year at this point. In reading all of the written comments and the oral comments as well, the two themes that come up over and over again are more studies of adults, more services, and more treatment development. Adults and the issue of - treatment. Question 4. I was stunned by the comment earlier that Question 4 had gone down 4 percent because every set of comments that I have read since my first meeting is please do more treatment research and then more studies of adults. As we think about what we are going to do with the money that we are going to ask for, which does not really exist yet, we have to think about do we put more money into those efforts and what could we accomplish.

I did a back of the napkin calculation the other day looking at the demographics of who is becoming an adult and also eligible to vote and thinking about that. There is just a wave of people. Our cost estimates are going to be very different if those individuals continue to have unemployment rates of 70 and 80 percent. If you look at a minority population and a group of people and you had unemployment rates at that level for anything else there would be a national outcry. Here we have hundreds of thousands of people that we could be serving. And at the same time doing some very cool neuroscience around the transition into adulthood and trying to understand plasticity in early adulthood and lifespan development.

DR. BATTEY: I want to say how thankful I am that David is on the committee and knows how to do the calculation. I think one important thing though for total transparency is to describe exactly how the calculation was done. If anybody

comes back and asks where did this number come from, we would have a very good and defensible answer to that.

DR. MANDELL: We created an Excel spreadsheet that we could put online that anyone can put in there - any of our assumptions and see how it changes.

DR. BATTEY: That would be just superb. Absolutely superb.

DR. KOROSHETZ: People come from different viewpoints. I do not think anybody in this room thinks we need to make an economic argument for funding autism research. You just have to know people with autism to know that this needs to be done. I just wanted to throw that out there in case somebody is wondering.

The economic argument is often times I think something that influences people who are thinking about big budgets and that is where the money comes from.

DR. GORDON: Let's be clear. We are not doing the research to save them money. We are saying that with the investments now that the biggest - one big impediment to devoting the money to this is that it is a lot of money. If we can make the argument that investments now will save money down the road then we are saying you can help people and it will not cost you as much as you think. In fact, it will save you money.

Now I think we do need to wrap up this. Susan is pointing out quite rightly that we need to do work on this and it has to be done. We are at the point where it is time to put this document out. We need to figure out how we are going to proceed to get these cost estimates. Is that right?

DR. DANIELS: Right and also to -- it does not have to be decided in this room, but I heard a couple of different things. It sounded like a possibility of going from the bottom to the top or the other way.



DR. GORDON: That is exactly what I want to do right now. Let me revise my earlier statement. I think the first thing we have to decide is do we want the cost estimates at the question level to be at the questions or at the objectives because there were two opinions and I am not sure I have a read in the room about where I think they ought to be. There were initially some opinions and it should be the question level and then a couple of strong opinions later that we should really go to the objective level to give a little bit better accountability and relevance especially if this thing were to really get funded.

I am going to ask you to restrict your comments to the question level versus objective-level discussion.

DR. SINGER: As a person who is involved in assigning our studies and their expenses to the categories, I would say it is very challenging to do that. I think to try to figure out which of

the objectives under a question some of the studies fall into could be very arbitrary. I would suggest we do the budget at the question level rather than the objective level.

DR. KAVANAGH: A clarifying question. Are we working under the assumption that regardless of whether we pick objective level or question level for the sake of transparency we are going to say in order to achieve either this objective or this question, it would require X number of studies at X dollar amount?

DR. DANIELS: We do not have a number of studies. It would have to be dollars only. We do not know. This is a mix of services and research in the objectives.

DR. GORDON: As Susan said, we are given a vague commandment. If you wanted to we could do that, but we do not have enough time frankly or the administrative resources to do a study-by-study level dollar amount.

UNKNOWN SPEAKER: How are we justifying the number that we are going to come up with?

DR. GORDON: We are not getting there yet, but I guess you are saying if you need that information to make an informed decision, again, we do not have the time here nor do we really have the time overall to get into that level of detail. My thought on it - if there are strong opinions against it, we should probably discuss it. My thought on it is that it is going to have to be left to the work group level to come up with these estimates and to make some rough justification because I do not see how Susan's staff could do that. There are just not enough people with the right expertise. I do not see how this committee could do it. I do not think we want to get into the discussion with it at that level.

I think the work group is going to have to come up with these estimates whether it be at the question or objective level.

DR. DANIELS: I am not actually even seeing the path forward to doing it with working groups because if I just come up with some estimate, we need to have some sort of clearer way of calculating this that everybody is going to do it consistently, not just have apples and oranges and people guestimating all kinds of things and adding it up. We need a really clear logic. It would be nice if there were a small working group that wanted to work out a plan for something and try it on one of them. Make sure it works before we go to any trouble trying to do it and I think also getting a million opinions on it. If we just have a clear formula. That is my opinion. I just think throwing it out to a working group and say come up with an estimate will be very difficult.

DR. GORDON: The problem that I have is the timeframe that we need to produce this document.

DR. DANIELS: The timeframe is we are trying to put the document out after the April 26 meeting. We want a full draft of the document by

April, but we have a couple of months I think that we could do that.

DR. WEXLER: I would ask Walter. In terms of Alzheimer's, had you broken it out into categories we need X amount of dollars for this, X amount for that?

DR. DANIELS: But it depends on how you framed your objectives or if we are doing it by the question level to say how much do we need for diagnosis and screening research and services. How would we ever come up with that?

DR. LAWLER: -- to the question versus objective discussion. I think maybe Question 3 is a little bit different. There has been this continuing tension in the field about whether we are devoting most of our risk factor dollars to genetic studies. If we collapse those three objectives into one budget estimate, we are not going to be able to see whether there has been real progress in doing that. I do have some concerns for that.

DR. GORDON: Let me suggest because I do not think we are going to resolve this. I will riff off of Susan's idea. Let me ask for first volunteers for a small group of people to iron this out and bring it back to the committee via email because I think that might be the only way forward. Can I have some volunteers of a small group, let's say three or four of us that will make some recommendations about how to do the budgeting? Again, we are not going to do this to a pipette level. I have David, Walter, Kevin, and Alison.

DR. DANIELS: Just to clarify, we can do some work by email, but any decisions that are made have to be made in a public forum. We have to be either in a public phone call or in a meeting.

DR. GORDON: Let's be very clear. No decision is made until the document is prepared. They would make recommendations to the working group. The working group would come up with the

estimates. They would all be presented here in April. Would that be FACA okay?

DR. DANIELS: That would be. We would want to get into a draft. I have not gone through the whole timeline with folks yet, but I want to see drafts ready by the beginning of April so that we have a clear path to approval at the April meeting and we are not still considering changes.

DR. KOROSHETZ: It seems to me that you are going to have to come up with a budget. The objective versus question level. You could let it wait until later. To develop a question-level budget, you have to look at your objectives and figure out what would go in which one and then you would get a question-level budget. We could try that and then see if we --

DR. GORDON: I am going to ask. Let's get that granularity and that committee of four that we just got listed. What I suggest is you guys come up with a plan that takes into account question and objective level and how we are going

to make these estimates and what the overall budget goal is going to be. We can email around just to get agreement about how we are going to move forward with it at the work group level and give assignments to work groups to come up with the money and build that into their chapters. Obviously, when we come back in April, we will have to make sure that - we will have to hash out. We should spend some time on this. Hash out whether that meets the approval of the committee as a whole in order to vote on it publicly.

DR. BATTEY: How much time do we have after the April 26 meeting before this thing starts to go forward?

DR. DANIELS: If for some reason you are not able to get it approved April 26, we have a July meeting. I was hoping to get this out the door by end of the April, but if it is not possible, we can always keep working on it and then come back in July.



DR. BATTEY: Or do an intervening teleconference.

DR. DANIELS: We will be doing intervening teleconferences.

DR. BATTEY: We could actually do the approval process by teleconference or is that not legal?

DR. DANIELS: We could. Say it is after April that we have a draft and we are going to basically just take a vote on the public phone call or something, we could do that.

DR. BATTEY: That sounds like a good way forward to me.

DR. GORDON: Budget is not the last issue in regard to the update. Is it?

DR. DANIELS: We had the services budget estimate discussion as well unless we do not want to go into that today. I have been talking with David. The committee asked for us to come up with a way we could estimate the services budget.

Maybe this is mute if we are going to do some overall --

DR. MANDELL: I would not have a lumped services and research budget. I would keep them separate because your strategies for calculation, the potential for them to dwarf each other.

DR. DANIELS: This is a proposal basically that David and I discussed. I would like David to talk about how we might be able to form recommendations around the services budget. David, if you would like to talk, I put a few points on the slide for you.

DR. MANDELL: The overwhelming bulk of services that are provided to people with autism are not through autism-specific programs. They are through existing programs, entitlements. The challenge in identifying the cost of services for people with autism comes in identifying services delivered to people with autism in those particular systems.

I have put up as an example and I think in some ways four of the most important and largest programs that support people with autism: Medicaid, private insurance, public education through the Individuals with Disabilities Education Act, and vocational rehabilitation, which is small relative to the others, but is one of the few programs that is explicitly for adults. There may be others and I would welcome people's thoughts about what other systems we could include.

In each of these, you can identify people with autism. In Medicaid data and in private insurance data, you could either do it at the claims level. Was the claim associated with the 299 ICD diagnosis or you could do it at the person level? Was this service delivered to someone who meets some a priori definition of autism based on their other service, use and diagnoses?

For public education and vocational rehabilitation, autism is a separate category. We can pull out people who are in that autism category. That is actually easy to do for VR. They are well set up to do that. Public education is challenging. We can identify people with autism. But the last time we tried to figure out the cost associated with children with autism was in 2001 when Senator Frist asked the GAO to commission a report on cost. We have no meaningful cost data for people with autism in the education system in that intervening decade and a half. Special ed data does not have cost associated with it. It does not really have services associated with it. The most you can get is the extent to which an individual is included in a general education classroom.

I think for the first one and the second one we have partners around the table who could make claims data available that would allow us to answer some of those questions. In fact, NIH

currently funds a lot of research where those data sets are used. We have a bevy of researchers who could probably do some of those calculations for us, myself included. Vocational rehabilitation data. You can get from the Rehabilitation Services Administration and do those calculations relatively quickly. There are researchers around the country who are doing that with recent data and we could call on them to do that.

The public education system is a tough one. But it is probably the second largest spender or perhaps even the first largest spender on services for people with autism in the country.

DR. WEXLER: 622,000 kids, 3 to 21 in the school year 15-16.

DR. MANDELL: You do not have any idea though about the money spent on it.

DR. WEXLER: None whatsoever. It is not a collection that we do nor anyone else that I know.

DR. MANDELL: We could go back to the American Institutes for Research, which is the group that did that report and ask them about their methodology and whether we could borrow it or we could punt on that one. They found that the cost for kids with autism were three times that of kids in general education and two times that of other children in special education. We could use that metric to try and ballpark a cost. We have strategies that are available.

DR. GORDON: Those are published estimates in the literature?

DR. MANDELL: Yes.

DR. GORDON: It seems reasonable then to use them. I think we can acknowledge in our calculation that those are very rough estimates because unless we are going to fund somebody to do deep dives, I do not know how we are going to --

DR. MANDELL: We can even weight them and do sensitivity analyses based on the percentage of

people who are fully included or partially included then versus now. I think there are strategies we could do. The question is is this a strategy we want to pursue. Are these the right four groups? Are there other groups and programs we should be considering?

DR. NIU: This is Stan from the Department of Defense. The major health system. This might be another system you want to look at. I was just at a meeting this week. We talked about the cost of ABA alone in the major health system. This year it will cost about \$250 million in ABA alone on the beneficiary major health system. There is very detailed data there. You might want --

DR. MANDELL: Is there someone working with Tricare?

DR. NIU: It is there from the Tricare system. I can point you to those people.

UNKNOWN SPEAKER: Let's add Tricare to that for sure.

DR. WEXLER: David, one other thing as a possibility is that we have pretty firm estimates that our federal formula grant pays about 16 percent, 17 percent of the excess cost of education for kids with disabilities. We know that that is about 11 and a half billion dollars that we formula out to states. I think the math is not too complex in that sense. That might give you - those are numbers used as part of congressional justification's own budget. They are fairly solid numbers.

DR. GORDON: That could be a check. You could divide that by the number of kids with autism and other disabilities. Use your 2X, 3X figure and compare that to the numbers that you get from school expenditures the same way and give you a sense of how much error there is going to be. Okay. So if we add Tricare. Anyone else to add to this list?

DR. SINGER: I do not have one to add. I just wanted to point out that the purpose of the



plan is to talk about what needs to be done, not necessarily what has been done or is currently being done. And the way we are looking at calculating the spending on services is calculating what is currently being spent. I do not know that there are that many parents who would say that their children are getting everything they need for a meaningful education. I think we just need to point out when we are writing up the budget that this is the current spend, but not necessarily the needed spend.

DR. KOROSHETZ: Certainly, it would help to understand what the required expenditure will be to know it is going to be built off of what is already being spent.

DR. SINGER: I agree, but I am just saying that that is not the end. This is the beginning of the analysis.

DR. GORDON: David, how long will it take to get numbers and who will we need to involve and

how can we get them to do so when we have no budget to do so?

DR. MANDELL: Until you said the last thing, we possibly could have a plan. I cannot answer that in a meaningful way right now. I need the train ride home to figure it out.

DR. GORDON: That is fair. You can be in touch with Susan and me about it. Basically what it comes down to is will we be able to include reasonable estimates of care costs in our budgetary recommendations to Congress. I do not know that we are explicitly asked to do that. We are asked to provide budget recommendations for what we think things will cost. We could punt if we need to in this update and say we do not have enough information on current costs let alone future ones to make estimates regarding to care. We are going to make estimates regarding to research. Or if we could get these estimates in time that the work groups could use them to build budgets off of then we could include it.

DR. DANIELS: Just to add to that, I think that with the way the law is it says proposed budgetary requirements including services to the extent practicable. But it does not mean that we would be in violation of anything if we cannot put everything into this version. We could just say that we are working on that and we will do it in a future version.

DR. WEXLER: In support of what Alison raised and Stewart knows more about this than I do. There was a case in the Supreme Court yesterday. And based on the arguments, it appeared that there is a possibility that the definition of educational benefit is going to be increased from a de minimis standard to a something else standard in between, which is going to mean increase demand for services and increased responsibility on school districts to provide those services. The costs are likely to spike if that happens. We need to keep that in

mind let alone whether the level of service they are currently getting.

DR. GORDON: I think we have a plan moving forward on the budget whether it includes these services piece or not. You will let us know, David, what sort of support you might need in that regard.

Susan has one last question regarding the Strategic Plan.

DR. DANIELS: With the portfolio analysis that we conduct, we collect research project data from all the agencies and organizations. We have thought about it in OARC to be able to collect information about services, programs in federal agencies. I just wanted to verify with the committee if that is something that you would like to see. We could collect, for example, lists of programs that are being run through the federal agencies that address various services issues. We would have some type of budgetary requests around it. Would that be useful? It

could be useful on a qualitative basis to know what kinds of programs exist, limiting it to only autism specific ones so that we are not looking at the whole realm of everything for disabilities. Or if you do not think it is that useful, of course we should not do things that are not going to be useful for you. If that is something you want, I wanted to know about it so that we could include it in our next data call.

Or if you want more time to think about it, we might not need to do it in 2016. We could leave it for another year. I anticipate the 2016 data call going out this spring. We are going to be preparing it fairly soon. Do you think a list of programs that the federal agencies have on various service areas would be useful to you in some way to know what types of things are being offered?

DR. MANDELL: It would be useful especially if we knew who the ultimate payer is. Where do those dollars show up?

DR. DANIELS: For example, I know that ACL has a program for legal assistance that is in our report to Congress. We listed in the report to Congress, do you want us to be collecting more budgetary information about individual programs like that or is that really just not useful to have. It is not the same as the grant-level stuff that we collect for research. There is really not an equivalent. Laura, what do you think?

DR. KAVANAGH: I think the difficulty is it is really hard to get that level of information for only children with autism. For example, the MCH Services Block Grant to states. Thirty percent is required to serve children with special health care needs, but we do not have data on the number of children with special health needs that are being served who have the diagnosis of autism. That is an investment that folks should know about. But for analytic purposes, it is not going to be helpful.

DR. DANIELS: The other option is we continue with - our report to Congress is due in 2018 from HHS and our office heads that up. We always collect qualitative data about all these programs. We could just put that information there and then the committee in 2018 can refer to it when that report comes out. That sounds like you are happy with that. Then we will not add anything to the new data call.

DR. GORDON: Next up is the summary of advances. Susan will remind us of our charge and then we will figure out how to proceed.

DR. DANIELS: The summary of advances especially for new members on the committee is an annual public - the law does not say it is a publication, but it is a requirement that the IACC prepare a summary of research advances that is sent up to Congress. It does not say what type of summary and how many advances. What the committee has done in the past is it has selected what it felt were the top 20 most significant

advances in ASD biomedical services research for the previous year and trying to cover all the areas of the strategic plan. What we have done is with each article that was chosen as a significant advance, we have written up a lay friendly summary of it and put it into a volume for the year.

We are at the point now where we have collected information about advances that people have submitted throughout the year, articles that members of the committee feel are significant. We are at a point now where we would normally be trying to narrow this down and make a selection. In the past, we have made our final selection by a paper of an electronic ballot after the meeting in January, but we are going to talk about this here. We have been sending out monthly solicitations to all of you on the committee to get you to submit nominations. In the past, we always used to collect all the nominations in January, but now we are doing it on a monthly



basis throughout the year. We have been discussing them at these quarterly meetings at the IACC.

Today, we would like to talk about the top articles that you may feel are important among those that have been nominated and then to make a decision on the remainder of the process on whether you would like to basically from today's meeting go on with the process we have had in the past or if you want to do something differently.

I also wanted to get your feel on does the committee want to accept other organizations' lists as en bloc nomination submissions. We did have one of those nominations this time around which was sort of a review of the previous year and it had 70 citations on it. All 70 got added in, but they did not have individual justifications. The regular process is each article is submitted with an individual justification. If we are doing this, should we be accepting lists from all different organizations

or would you prefer to be doing individual nominations?

DR. AMARAL: I think that getting en bloc nominations before was part of what caused the problem. I think if we have a process of these committee members and invited individuals making contributions, that is what we should do because we do not know the process for how that en bloc - it could be good. It could be not so good.

DR. DANIELS: One way around that is I guess if we see some of those types of reviews or lists for individual members to just look at the lists and find the ones that they think are really the best and then submit those individually instead of maybe the whole list. We could do that in the future, but for now, I have an entire list.

DR. SINGER: I just want to point out that I am not the one who submitted the ASF list. But the process was that our chief science officer Alycia Halladay in consultation with our

scientific advisory board reviewed all of these articles. That was the process.

DR. DANIELS: And the different organizations may have different philosophies or thoughts about what they are putting forward whether they think it is a top advance or just an interesting new piece of incremental science that happened or something that is an important advance in a small field versus an advanced for the overall field.

DR. AMARAL: I have no concerns about ASF doing this. If this becomes widely known, there could be all kinds of organizations that will say these are our top ten. Again, I think just having that ad hoc process is not a good idea. We should have one process.

I like the suggestion that ASF or anybody else could submit to this committee a set of nominations. But some committee member here or committee members should go through it and say

yes, I agree. That one is a good one. That would be very helpful.

DR. GORDON: I want to add one other thing into the mix here, which reflects our discussion last meeting about the need to ensure that the ones that we eventually select for the summary of events is be rigorous and genuine advances as opposed to exciting but perhaps incremental findings.

We have time now to discuss first the process. We have eliminated one aspect of the process, which is to make sure that nominations come in individually with brief write ups by committee members. And then the second one is these questions up here that Susan mentioned. There are a number of reviews and commentaries, let's start with that, that were recommended. There was some discussion amongst our staff about whether we thought that was appropriate and whether we want to make a blanket statement

against them or whether we wanted to allow them and re-nominate it.

DR. BATTEY: My suggestion is that we do not nominate them because I think we should talk about original work and discovery, but I would not make a statement specifically against them. I would say these are articles on original research and just leave it at that.

DR. DANIELS: And the committee started there years ago and I think over time there were some reviews that people got very excited about. We did allow them to be considered and sometimes they were selected. The same thing for reports and even some of these clinical roundtable type publications. I just wanted to get clarity because that might simplify the list for you if we are sticking original research findings and not including these other types of things that will streamline your list.

How do you feel about it?

DR. FARCHIONE: Sometimes when you have those other kinds of things, that in itself can be an advance because you are pulling together a lot of information from different sources and really consolidating it in a way that has not been before. Now, it causes people to say - to make those connections and say if I look at this, this, and this, this is what it means for the field. In that kind of a situation, I would say that maybe it could be considered an advance. But I think we should be very rigorous in how we define whether non a new research paper would be considered in advance or not.

DR. DANIELS: That would suggest leaving these things on a list and just letting you decide at selection time whether you think that they are significant enough to count as an advance.

DR. FARCHIONE: Again, with some guidelines or a criteria for why they would count as an advance.

DR. DANIELS: Which would be part of the justification I would assume.

DR. KOROSHETZ: Clinical guidelines I think oftentimes are important and indicate that the research led to something that is clinically actionable - report to Congress.

DR. DANIELS: Yes and reports are the same way. Sometimes there is a compilation of findings that people feel is a significant advance for the field. It sounds like around the room people would like to keep these things on the list for consideration and then for you to make individual decisions about whether you want to vote for them. That helps. Thank you.

Now, we have a list that you have to consider. You have the list of everything that was submitted calendar year 2016. You have also the ASF list. You are free to discuss. If you would like to question by question, what is on the list, things that you thought were excellent. And if you have any concerns about things that

you think should be removed from the list of consideration for final voting.

DR. GORDON: Why don't we start with Question and the first group on your list starting with the McPheeters' article and ending with the Jones' article? The reason why we organized the questions we like to try to have one or two at least or at least one from each. Are there any candidates here that anyone would like to particularly note for either being nice advances or perhaps a little too preliminary to include?

I have one comment and that is on the Miller et al. article, School-Aged Outcomes of Infants at Risk for Autism Spectrum Disorder. This is I think a reasonable candidate for an advance given that we do not have that many good long-term studies of effectiveness on outcomes. We already talked about the need for longitudinal follow-up studies. This isn't exactly one of these large-scale longitudinal studies, but it did follow



both younger siblings of children with ASD and typically developing children and the numbers are reasonable in the 60s and 70s. It is one that we think - whether it comes up with profound new observations, it is a nice carefully done study that gives us understanding of outcomes in this population of high-risk kids.

Any other comments on any of the other articles in there?

DR. FARCHIONE: We are trying to pare down the lists a little bit now?

DR. GORDON: Paring it down would probably be a good idea. Basically, articles that are not thrown out here will go around for a vote by email after the meeting.

DR. FARCHIONE: My suggestion would be the one at the bottom of the first page, the diagnostic model generated by MRI-derived features. In a previous life, I was a neuro imager. I am really excited whenever I see neuroimaging research, and the idea that this one

was longitudinal, had 85 kids. To have something that is based on data mining and not a prospective kind of analysis and to have it be not replicated yet, I would be cautious about putting that in as an advance because a lot of the neuroimaging stuff when it first comes out it is all very exciting and then trying to replicate it becomes problematic. I would just hold off getting excited until we see a follow up.

DR. DANIELS: What I could use is clarity about whether you think something should be removed from consideration or you are just making a comment. Leave it on the list and let people vote.

DR. FARCHIONE: I think if we are trying to pare down the list then we could take that one off.

DR. GORDON: And then in view of the comments on reviews, what do people think about the McPheeters et al. article, which is a literature review, screening for autism spectrum

disorder in young children. Admittedly a high priority area for this committee and in general. A systematic evidence review for the US Preventive Services Task Force.

UNKNOWN SPEAKER: (Inaudible)

DR. GORDON: I do not know. It does not look like it was. It looks like it is a report.

UNKNOWN SPEAKER: Based on that criterion, I would take it off.

DR. GORDON: We will take off McPheeters.

DR. DANIELS: Should we check to make sure whether it was peer reviewed or not before we remove it and leave it if it is peer reviewed?

DR. GORDON: It is an Internet document and it is a review. My own recommendation speaking just personally and not as a committee member, would be to remove it. Anyone disagree with that?

DR. BATTEY: I would support that.

DR. FARCHIONE: The Preventive Services Task Force. Even though it was controversial, it was very impactful.

DR. GORDON: But was it an advance?

DR. DANIELS: This is not the report. This is the systematic review. This is not the USPSTF report. This is the literature review that supported the report.

DR. FARCHIONE: Then take it off.

DR. GORDON: We are going to take off McPheeters, unless there are any objections. Are we taking off Xiao as well? We are taking off those two. I endorse Miller. There are two others. Those three will go on the ballot.

DR. CRANE: Are we definitely taking off the MRI one?

DR. GORDON: That was the request.

DR. CRANE: I am not sure that I understand exactly the point that Tiffany was trying to - I do not see that it is about prevalence data. It seems like it is just a background thing. The background comment was about prevalence data.

DR. FARCHIONE: I was not talk about the prevalence. I was talking about that it was the

approach - they did data mining approaches to try to generate their diagnostic models.

DR. CRANE: Are we looking at the same one?

DR. FARCHIONE: At the bottom of the first page, the diagnostic model generated by MRI -

DR. CRANE: I was already on Question 2. I was really confused. Thank you.

DR. GORDON: Sorry about that. I jumped the gun in moving to Question 2. We have eliminated McPheeters. We have eliminated Xiao. There are three others for people to choose from when we send around the ballot.

Let's move forward now to Question 2, which is understanding biology. There are a number of - there are 14 recommended studies and open to comments on any of those 14, positive, negative, or neutral.

DR. CRANE: I was just going to say that the MRI study on the bottom of page 2, I think looked very exciting, not only because it could help with research, but it could also potentially help

with treatment and dealing with the health needs of kids on the autism spectrum.

DR. GORDON: This is the follow-up Werling study. Is that correct?

DR. FARCHIONE: I would agree actually.

DR. CRANE: I was looking at the Nordahl et al. study.

DR. GORDON: I have a different version of it because I have scribbled all over it. If you could use the first author's name to describe the paper then I will know which one you are talking about.

DR. FARCHIONE: If you could do neuroimaging without sedation in these kids that would be huge.

DR. PELPHREY: I would second that.

DR. GORDON: Given the poor reputation of the last author, I would like to know actually about the size of that. I think Tiffany's comment about the earlier MRI paper about reproducibility in fMRI is really important. One of the reasons

we have discovered about poor reproducibility typically is that numbers are not sufficient.

DR. AMARAL: This was a preliminary study that was done on 12 subjects, but we have now done 53 all with equal success. It is just describing the technique.

DR. BIANCHI: This is not a biology study. Should this paper be in another category? That was the question that I had.

DR. FARCHIONE: I would say even if it is not about biology specifically, it is about a means through which we can evaluate biology. That is one of the things that is very difficult in kids with ASD is trying to get them in a scanner in the first place. If you could do that without sedation then that opens doors that worked previously.

DR. CRANE: You could have them doing a task or --

DR. GORDON: In the interest of time, I think there is enough interest in the paper. We

will leave it. We had a bunch of comments. We will leave it certainly in the vote. Other comments, positive or negative?

DR. KOROSHETZ: I thought there were very impactful papers in this group and particularly struck by the two studies by Geschwind. One I missed, which was picked up by Alison's group. He looked at transcriptome in brain tissue from people with autism. One is Werling, sexually dimorphic pathways. That is in Alison's group. And the other one is Neelroop Parikshak, genome-wide changes in long coding RNA splicing, regional gene expression patterns in autism.

I think the main take-home points are that he has really pulled out a series of pathway abnormalities in autism brain and actually sees it in sporadic autism and also in one of the duplication syndromes that causes autism.

And then interestingly, he looked at sex differences and found that the ASD risk factors are not increased expression in males versus



females, but the pathways that are affected in autism that are downstream from the risk factors are differentially expressed and much higher in males than females. It is a really interesting study there.

And the other one, which is really interesting, is the study by Orefice and Ginty, where they show that actually in the Mec2 model, a Rett syndrome model, that the abnormality if it is induced in the dorsal root ganglion cells causes hypersensitivity, which then in the developing mouse causes the mouse to develop abnormal behavior. But if you actually turn it on in the adult mouse, you do not see anything. It is a very interesting - hypersensitivity sensory overload is common in autism, 50 to 70 percent. And the question is whether or not that actually sets up things, pathways that should not be set up so it is coming from the periphery which is kind of a new idea.

I think Kevin mentioned this in our group, that some of the problems in autism may actually be compensatory to something that is the origin, but the compensation actually is causing problems too.

DR. GORDON: I note that you are suggesting that we move the Geschwind and Werling et al. paper from the Autism Science Foundation list to the main one, so that it be nominated. You are also speaking well of Orefice and of Nordahl.

Other comments about other papers?

DR. PELPHREY: I was going to recommend taking off the one where I am the senior author because it is not about autism. The Libertus article. It is a cool paper, but it is not about autism at all.

And then also take off the motor noise as a rich signal in autism research. I watched the coverage of that. It is the second most over interpretive article in all of autism history.

DR. GORDON: Can you say a little bit more about that?

DR. PELPHREY: You cannot actually measure motion via MRI. You can estimate it. If one group has more motion than the other, it disrupts your estimates of the motion. It kind of starts there. And then they did not control for sight as a variable, which this was the ABI(phonetic) database, so it had at least 14 different sites.

DR. GORDON: I have heard enough. Anyone object to removing Torres et al. or - I do not know which one is the first author here - Libertus et al. No objections. We will remove those from the list.

Any other comments about other papers in Question 2?

DR. AMARAL: I think we both nominated the Marchetto et al. paper. This is the iPSC cells from individuals that had brain overgrowth early on and they found a potential mechanism for why the brain overgrowth. I think it is a neat paper.

DR. GORDON: Then along those lines, the one before that. We are having a lot of positive comments about the biology, which reflects the excitement in this area as we learn more and more about the genetics and develop new tools. The Yi et al., which is looking - I would say very carefully controlled study of the effects of one particular autism SHANK3 in human neurons.

The question I have with that and the other iPSC, is they are very exciting and I think they represent significant advances in technology and approach. Like many basic neuroscience studies, we do not know yet whether they will represent significant answers for autism. But I think they are very exciting and important and I would certainly support their inclusion in the summary of advances.

UNKNOWN SPEAKER: They are new and fresh though. Their ideas, approaches and tools that we have not had at our disposal before. I think

highlighting them for Congress to see the payoff of their investments is really important.

DR. GORDON: Any other comments on this group?

DR. KOROSHETZ: Parenthetically, just the issue of the Geschwind paper, I do not know how this is going to come down. To understand brain development, I think it is probably very important that we study fetal tissue. There has been some pushback recently on the use of fetal tissue for research. I think it is more how it is obtained so maybe not critical. I think it would be great for this group to realize and maybe state that at some point the importance of fetal tissue research in autism.

DR. GORDON: That is the Parikshak paper that uses gene expression during development.

Moving on then to Question 3, comments about papers in Question 3. There are seven of them dealing with risk factors.

DR. LAWLER: I just want to chime in that the last one was a late addition. It was published in mid-December. The reason that I liked it was it is a very nice example of a gene environment interaction. If we remember back to the strategic plan of group three, we really wanted to get beyond identifying gene by E and observational studies to try and think about the underlying biology. This is focusing on epigenomics, which is a reasonable candidate to bring those together. It uses postmortem brain and also culture models and the duplication syndrome together with one of the PCB congeners or the two exemplars of genetic risk. There is convergence on some of the genome wide methylation patterns as well as some of the molecular players that are more intimately involved in transcriptional regulations, some of the histone codes as well. It is just a great example. Very thorough, systematic, nice.

DR. GORDON: Very good. Thank you.

DR. CRANE: I thought that the Erickson et al. study was particularly good because it came to a conclusion that I think wasn't what people would expect. I think it is the type of thing that can really help advance the sciences when we are challenged on an assumption.

DR. GORDON: I agree. I wanted to point out that there is some controversy about one paper amongst some of the scientific staff at NIMH and that is the Bennett et al. paper - sorry, not the Bennett et al. paper. That is a different issue. The Julvez et al. paper on the maternal consumption of seafood in pregnancy. Although it is a large study, the findings were pretty weak statistically. It would have potentially important policy impact in that the result of the study would be to encourage consumption of actually large amounts of fish, which potentially could lead to problems of mercury and goes against the recommendations to avoid large

amounts. Small amounts of fish are fine, but large amounts of fish for pregnant women.

The combination of the fact that we are not sure about the wisdom of the potential policy implications, not with respect to autism, but with respect to other neurodevelopmental conditions. We are a little concern if this was put forth as an advance given the weakness of the statistics. If there are no objections, I would say that we should eliminate that.

DR. AMARAL: I wanted to speak to the Zerbo et al. It is the one right after that one. It is a new one. There has been mixed evidence on whether influenza exposure during pregnancy increases risk for autism. This study was done at the Northern California Kaiser Foundation so lots and lots of patients. The bottom line is that they find no increased risk for autism.

There was a little signal of influenza vaccinations during the first trimester, but it turns out with statistical corrections that do



not actually prove to be reliable as well.

Neither flu nor vaccinations against flu, which I think is probably going to be an ongoing issue, but I think this is a well-done very large study.

DR. GORDON: And in fact, one of the public written comments was about vaccination during pregnancy and we should investigate that so highlighting the fact that this study is out there would also be good.

I have another study that I would ask whether we might want to eliminate and that is the Bennett et al. because it is not a study. It is a consensus report about the need to target neurodevelopmental risks. I do not think we disagree with the consensus, but I do not personally see it as an advance. Others might.

Any objection to eliminating the Bennett et al.? We are eliminating Bennett. We are eliminating Julvez. Positive comments were made about Erickson, Zerbo, and Dunaway.

DR. KOROSHETZ: Just a point of clarification. My understanding - I have not read it recently, but seafood and pregnancy paper - the effect on autism is very small like you said. The effect on development was actually quite big.

DR. GORDON: In what way?

DR. KOROSHETZ: They looked at intellectual development. There was a fairly large effect on improved intellectual development in that paper. The effect on autism was very small. And the importance of it is - I think they did control for the mercury in some fashion, but the mercury -

UNKNOWN SPEAKER: Walter, was it methylmercury?

DR. KOROSHETZ: What is ever in the fish.

UNKNOWN SPEAKER: I thought so.

DR. LAWLER: It is actually consistent with a pretty large body of data that any time you see mercury exposure with fish consumption, it is a balancing act between the protective effects of

some of the fatty acids. I think in general the studies that I am more familiar with are coming down on more of the beneficial effects. This would not be at all out of line. I think there was a study published last year in cognitive decline in aging that was pretty similar too. In that case, it had looked at just one fish meal a week. They could not find any effect of mercury, but they did find this protective effect of eating even small amounts of fish each week.

DR. GORDON: Is there sentiment that we should restore to consideration for those reasons or leave it off still because of the inconsistent statistical signal with regard to autism? Anyone think it should be restored? We will move on.

Question 4. Treatments and interventions. There were a large number in this category as well, which is wonderful.

DR. PELPHREY: This is another one where I am the senior author, the one about oxytocin by Gordon. It is on the same data, but a different

task than we published in proceedings of the National Academy a couple of years ago. That was highlighted as an advance. I think we should strike that one because it was an advance a few years ago. Now, it is just a replication.

But the one I would highlight in saying something positive about - I am an author, but Pam Ventola is the senior author. She identified an imaging-based biomarker that is a stratification biomarker to determine for which kids an evidence-based behavioral intervention work, pivotal response training. Not only was she able to predict for whom it would work, but mechanistically show why at the level of neuro systems it worked for those kids, which then provides a target for subsequent intervention. If there is going to be two fMRI papers there from our group, I would want Pam's to be highlighted and the other one stricken.

DR. GORDON: That is the Yang et al. Is that correct?

DR. PELPHREY: Right.

DR. GORDON: Yes. I had that highlighted as well as one of the ones that I thought deserved to be considered strongly.

Any other comments about other papers?

DR. MANDELL: There are a lot of reviews. Are we just going to strike those --

DR. GORDON: Let's say let's strike the reviews, but please look through them and if you think there is any that would meet criteria, we could consider including them.

My staff had some concerns about a couple of meta-analyses, which are not reviews, but the Mirza and Park. I am sorry. I take it back about Park. That was not a negative comment. Mirza considered moving because my staff did not feel that it was actually that strong of a meta-analysis and had a relatively small number of studies reviewed. Any objections for removing Mirza? No. We will remove Mirza.

One of the articles that my staff highlighted is being particularly good was the Chang et al., which was a preschool deployment of evidence-based social communication intervention, which was described by the proposers as one of the true effectiveness trials of preschool intervention for children with autism. Why are we smiling?

UNKNOWN SPEAKER: This is exactly where group 4 is moving and what is needed. It is a strong paper.

DR. BIANCHI: Quick clarification. You said remove reviews, but then we could still consider them. Do you want me to remove them from the list or keep them on the list?

DR. GORDON: Remove the reviews, but I want anyone here who sees one that they think ought to be included. Let me just raise one of them, which is part review and part meta-analysis, which is the Hampton et al., intervention effects on spoken language outcomes from children with

autism. My staff noted that this was a large meta-analysis study and adds new information on the effects of parental involvement, which is something that has come up today. I think we might want to keep that on the ballot at the very least. This is Hampton and Kaiser.

Any other that we want to highlight for discussion or for potential removal?

DR. MANDELL: I also thought that Pickles article on the long-term follow up for the PACT's intervention, the one that was in the Lancet, is very worthwhile, not just because of their findings, but also because of the study design and the idea that we should be moving towards maintaining contact with these treatment cohorts and examining outcomes over time very carefully.

DR. GORDON: This is another parent involvement study.

DR. MANDELL: The PACT's intervention is focused on parent responsiveness.

DR. GORDON: We heard that we are going to remove the number of reviews. We heard positive comment, with the exception of the Hampton and Kaiser, which is a large meta-analysis and right in the area where we should be. We heard positive comments about Chang, which is the preschool, Yang, which is the MRI prediction of treatment study, Pickles, which is the parent-mediated social communication therapy. I feel like I missed one that somebody said something positive about.

DR. CRANE: I think the Almirall. I was wondering - I was waiting to see if someone else suggested it. I like Almirall et al. study in part because we do not see that many studies on minimally verbal children. It is a population under researched.

DR. GORDON: And the sample size is pretty good at 60. I will just emphasize. There were others that were not specifically commented on. We are not taking them out, but we are going to



remove the reviews. Thank you very much. Again, we will try to compile a list just as fast as possible afterwards so you can do this. You might jot down notes of ones that you would like to vote for.

Question 5. Services. We only had four. The fourth one does not have a justification, but it is four. My staff picked out the Mandell et al. article. Their comments were large sample, rigorous design, which addresses an important services research question. This basically looks at the effects of insurance mandates on treatment use and points out that it does enhance. It identifies more kids with autism, but not so many that it is going to cause an economic disaster.

Any others for comment? Any for removal?

Question 6. Lifespan issues. Now, I think we should put in there adult. That is really what we are focusing on here. Adult and transition.

DR. TAYLOR: I think there are a few that we may want to think about taking off from here. I

will start with the ones I like. The Hirvikoski T study. That is the one that the people when they came from Autistica last time, were referencing in terms of premature mortality in autism. I think that is probably an important one to at least consider.

DR. GORDON: I think it is a big advance because it really changes how we think about our need to focus on adults from a physical health perspective.

DR. TAYLOR: The Wehman study. That is a randomized controlled trial of young adults with autism. Half of them were randomized to do project search, which was sort of an employer intervention. The other half to business as usual. They saw massive employment effects, big enough that it - it is a little concerning, but I think what is happening is that the people are being employed then where they did internship. But regardless of that it really one of the first RCTs to show benefits to employment. I think it

is worth considering on that alone even though I think some of the conclusions that we draw are a little narrow, but I still think it is important to consider.

DR. GORDON: I would add that my staff felt it was a really wonderful, but preliminary study, because of the relatively small 60 people, but still recommended it be considered.

DR. TAYLOR: And again because conclusions I think can be limited. They do not say where the people are employed per se, but I am pretty sure they are all - specifically --

DR. GORDON: It is a huge effect size. Even if the truth is somewhat less, it is a major advance.

DR. TAYLOR: I would be interested to see what everybody thinks about the Drexel report, which I read it over pretty closely. I know Anne Roux came and spoke here at the meeting. My impression is that a lot of the data that is presented in it is not new. None of it is new.

DR. GORDON: Are you talking about the Roux report?

DR. TAYLOR: Is it not peer reviewed as far as I can tell. It is actually a really beautiful presentation of what we know about voc rehab and how people with autism are affected. I think that is important, but I do not know that I think it is a scientific advance in the way that we are thinking about that.

DR. GORDON: I also think peer review is pretty important.

DR. TAYLOR: I do not know for sure that it was not peer reviewed, but it may not have been.

DR. GORDON: Are there any dissents to removing Roux? We will remove Roux.

DR. TAYLOR: I nominated a study that I might want to un-nominate mostly because I was looking through before the meeting. I was thinking there has to be some adult studies to nominate to go on this form here. I nominated the Fernandez study about sexuality, mostly because I

thought that it was a really important topic for us to be knowing a little bit more about. I liked that they had a self-report sample and a parent report sample because I think there are some limitations of both.

But I would say the methodology is not particularly strong. At the end of the day, it gives us a little bit of new information, but I do not know if it gives us enough that it would be on par with some of the other advances that we are talking about in other areas and other questions.

DR. GORDON: Since you nominated it, we can let you withdraw it. But are there any dissents to that? Any other comments on Question 6? We picked up the Koegel et al. for the first one listed, at least in my version, Improving Empathic Communication Skills in Adults. It has very small sample size. We thought that would be inappropriate even if it was a major effect.

DR. TAYLOR: I was just looking it up. I think it is three.

DR. GORDON: It is three people. We will remove Koegel unless there are any objections. Removing Koegel. We had positive things to say about the Wehman et al., the Hirvikoski et al. We are removing Roux and we are removing Hernandez. We are removing Koegel.

DR. KOROSHETZ: The Hewitt study is kind of interesting.

DR. GORDON: Which one?

DR. KOROSHETZ: Hewitt. We had discussions about autism in Somali immigrants particularly in the Minneapolis area and that led to the study, which is interesting.

DR. GORDON: Oh, you are on 7 already. Great, we are on 7. Go for it.

DR. KOROSHETZ: Interesting in that they did not see a difference in incidence, but the incidence is incredibly high in Minneapolis like 1 in 36 in non-Somali and 1 in 32 in Somali. That

is the highest incidence rates I have ever heard of.

DR. GORDON: Do we know what the study population was? I agree, that is pretty high.

DR. KOROSHETZ: I don't remember.

DR. GORDON: My staff also - they liked the Christiansen et al. mostly because it is a good sample size and updates the prevalence although it is interesting because I do not know how it will agree or not agree with Hewitt et al. I do not see the numbers listed.

Any other comments about those two papers?

DR. MANDELL: I do not know if this means we should take it off. I have written about the issues with the CDC current methodology for identifying autism.

DR. GORDON: And that is the Christensen et al.

DR. MANDELL: The Hewitt.

DR. GORDON: The Hewitt.

DR. MANDELL: They applied the same methodology when they did the Somali prevalence study. They used the same methods that they have been using since 1996 to do surveillance. It is in a smaller sample. It is single site. I think the potential for over identification is really high. I eagerly await the results of the CDC's success study that is going on in South Carolina that would validate their methodology. I worry about publishing a 1 in 30 something or highlighting a 1 in 30 something prevalence estimate before that methodology is validated by the CDC.

DR. GORDON: That is a good point. And it would also decrease your confidence in not finding differences. The main point of the paper is the lack of difference between the Somali and the non-Somali population, but you lose confidence in that if you are not confident in your ascertainment.



DR. MANDELL: You also lose confidence in the lower prevalence in black and Hispanic kids. Why? If there is something going on in the Somali community and that prevalence is higher, I get it. But why is the prevalence lower in African American and Hispanic communities. And the answer we get back from the CDC is because there is increased awareness in the community. Increased awareness should have nothing to do with the prevalence estimate. You are right. We have some kind of ascertainment bias.

DR. GORDON: I think that is important. You are recommending removing it. Anyone dissenting?

DR. KOROSHETZ: I am just saying that it just seems to me that you cannot - this is what CDC has been using for 20 years and now you cannot just say we do not care about any studies that use the CDC method. There are problems with it. I agree with. It is not perfect.

DR. GORDON: You know what we will do. We will leave it up to the vote of the committee

then. We will not remove it and people can weigh in by voting as to whether or not Hewitt is an advance.

Again, Susan is going to try to get out just as soon as possible a reduced list for your vote. How should they vote, Susan?

DR. DANIELS: I also wanted to ask. Do you want to pick anything else off the ASF list that you would like to see on the ballot? Do you mind just double checking?

DR. TAYLOR: I thought the camouflaging paper and for Question 6 was an interesting one. It is small. It is 30 men and 30 women, but they looked to see whether observed autism symptoms - the difference between that and how people report their autism symptoms, what that relates to and find when there is a big discrepancy there, it relates to depression and anxiety. I have not read it over really closely. I am not necessarily advocating for it.

DR. GORDON: I would be concerned about the numbers there. Only 30.

How should we vote?

DR. DANIELS: You will receive a ballot to vote from. We will send that out by email.

DR. GORDON: How many votes do you want to give each person? 20?

DR. DANIELS: We will look at whatever we have done in the past. I think it is less than that. I think it is ten. And then we do a tie breaker. If we get ties, we end up doing a tie breaker. We will just send those out via email.

DR. GORDON: Do try to distribute your votes amongst the different categories. I know that there were a lot of very good ones in biology. We can certainly over represent one category if there really are a number of good advances in it. But we want to at least try to get one in each of the other categories. I think we can do that. Let's try to distribute those.

DR. BIANCHI: When you send it out, can you give us instructions? Are we supposed to vote for all the ones that we favor or should we just pick the top one in each category?

DR. DANIELS: It is really up to you. Some people like to vote for things that are within their expertise and don't like to vote for things outside of their expertise. Other people like to just vote over the entire list. It is really up to you.

DR. GORDON: I would say you have up to ten votes and you can distribute them however you would like. I just want to encourage people to try to hit multiple categories. We can always come back and try to encourage some of the other categories. I think there were enough promising papers in each category that we should have a pretty good spread.

Susan, anything else?

DR. DANIELS: No. Staff, do you have any thoughts about that? That should be sufficient.

We will be sending you out a ballot and we will let you know as the process progresses. Once we have a top 20 or top whatever number it is - if it is somehow less than 20, we will do a write up for the summary of advances and be looking to bring it back to you in April. When we send out the draft for review, it is not really a serious line-by-line review. If there is somebody on the committee who is on author, we, as a courtesy, do send out the blurb that is written about your article to you so that you can just check it for accuracy. We would give a very fast turnaround for the review in order to beat the April deadline for publication.

DR. GORDON: For clarity, we choose ten. We do not have to rank them. We just pick ten.

DR. DANIELS: I believe so. I have not looked back at the emails. I think it is ten and then you do not need to rank them. I think on time breakers, sometimes we have had you rank them, but we may or may not need that.

DR. BATTEY: (Inaudible)

DR. DANIELS: On the camouflaging paper I think we decided not to include it.

DR. GORDON: We find ourselves in the enviable position of being slightly ahead of time, which gives us a little bit more than a ten-minute breaks. We will end earlier. It is now 3:10 basically. We will meet back at 3:20. We will try to get Dr. Farber down here. He is here. At 3:20, we will start with - Greg Farber is going to give us an update on NDAR.

(Whereupon, the Subcommittee members took a brief break starting at 3:10 p.m. and reconvened at 3:20 p.m.)

DR. GORDON: It has been a while since we heard from Greg or anyone for that matter, on the National Database for Autism Research, which has already come up a couple of times today. I am glad that we had this schedule so that we can hear what is new and what we are doing to try to

encourage people to share data and to use the data that is shared.

Greg Farber is the director of the Office of Technology Development and Coordination at NIMH. He has been shepherding this and many other data archives, since they found it, and also doing a heck of a job on lots of other initiatives for NIH in general and NIMH in particular. Greg, take it away. Tell us all about NDAR.

DR. FARBER: Thanks Josh. I want to thank you all for the opportunity to come and talk about NDAR and the NIMH data archive. Please ask questions as I am going along. Don't wait until the end necessarily. I think there should be plenty of time for a discussion. I understood that there were a number of issues related to data that have been raised today. I can try to go through some of those perhaps, but if not, we can have that at question time as well.

I want to start by giving you a sense that NDAR, the National Database for Autism Research,

was the starting point for the NIMH data archive. Perhaps I should not really paint NDAR as a caterpillar, but it was a great thing in and of itself and continues to be really great. But we have expanded quite a bit since then.

I should also thank a lot of the institutes sitting around the table in fact I think almost everyone contributes funds to NDAR from the beginning and continues to do so. We are greatly appreciative of that.

We will start by maybe - I always like to start by justifying my existence. Why should there be data archives in the first place? I think there are a variety of reasons for this. The first is that understanding complex conditions and almost all neurological disorders, conditions are complex. There are many diseases that are outside of the brain that are also complex, meaning that you have to understand the environment, genomics, perhaps a whole variety of things. Understanding complex conditions requires



data from large numbers of subjects. I think genetics has pretty clearly shown that we are talking about thousands or tens of thousands of subjects. It is pretty clear I think that when you add environmental influences on top of that that you are probably talking about numbers in the hundreds of thousands that you are really need.

You need to be able to really put these data together in some sort of meaningful way. That turns out to be difficult. It is pretty straightforward to take individual data sets from one laboratory and another laboratory and a third laboratory and just store them as buckets of data. It is much harder to actually put them all together and make an entire data archive that is searchable and where you can really do things. That is what the NIMH data archive, what NDAR and the NIMH data archive do.

The second reason is that aggregating data from different labs allows us to understand how

similar or how dissimilar the data really are. That is important because if you want data from 100,000 subjects, you really want everyone to be collecting similar data whenever possible. I think we have clearly shown and I will show you some of the numbers that that is not true today.

A third reason to aggregate data is that it actually helps people doing experiments. I will talk a little bit about our validation tool and how this ensures the data that are being collected are consistent with a particular data dictionary.

Finally, aggregating data allows the research community to do all sorts of evaluation types of things and to figure out what is going on. That is true for program staff. It is true for anyone else who wants to look at the archive.

The data that are in NDA come first from the National Database for Autism Research. In addition, we have the Legacy clinical trials that NIMH has funded, data from all applications that

are submitted to NIMH after May 1, Pediatric MRI Study, which was an older study, and right now we believe that there are around 550 NIH awardees who are expected to submit their data.

We also have data from the NIDA, NIAAA, NIMH, NINDS, and Child Health is part of this as well. The ABCD Project, data from the Human Connectome Project. We take in data from other awardees. The Stanley Foundation I believe has as a term and condition that all of their awardees will submit data to us. We have a fair amount of data from the Autism Science Foundation. And then in addition to actually holding these data, we also are federated with other databases, which are listed there so that when you come and launch a search at our site, the search goes across our data, but also across all of these other databases. You get all of it with a single search.

As a general overview, we are a federal data repository, which actually I think is usually a

good thing in this case. We only contain data from human subjects. That is an important point. We do not have preclinical data in general or anything like that. We make the data available to the research community. But even without formal access to subject-level data, to individual-level data, you can see all sorts of aggregate data just from your browser. I know that if you are bored and want to play around, you can go to [data-archive.nimh.nih.gov](http://data-archive.nimh.nih.gov) and start looking at all of this data.

It is interesting to know how much data we actually have. At this point, we are holding around 800 terabytes of data. These data numbers are so big. It is really hard to get your head around. I have tried to provide a little bit of a translation here. A kilobyte is about the size of a word file, some sort of document file. There are a thousand kilobytes in a megabyte. A megabyte is the size of a Power Point presentation. A thousand megabytes in a gigabyte

and a gigabyte is the size of a movie, normal length movie. A terabyte is a lot of data. If you put all of the books in the Library of Congress into a single file, it would be 15, 20 terabytes big. A terabyte is a lot of data. There are a thousand terabytes in a petabyte. We actually hold just under a petabyte of data. And a petabyte is such a staggeringly big number that it is hard to find anything that makes sense in terms of comparison. If you had a file that contained a movie that played for 13 years, that would be about a petabyte. That is the type of data that we are currently holding, which is to say it is an awful lot of data.

The basic structure of the archive is - I think the best way to think about it is a pretty straightforward two-dimensional matrix with rows and columns. There are data dictionary elements and I will show you what these look like that are columns. And then there are rows, which are each subject that is in the database. We use the data

dictionary to describe each experiment and we use GUIDs, the Global Unique Identifiers system, to aggregate data that are measured on the same subject in different labs.

In addition to this two-dimensional matrix, you need to have clever ways to query through the data. That is quite a hard project, but we have spent a lot of time over the past four or five years building a variety of different query tools, which make it fairly straightforward to find data. But I have to rush to say it is not Google. The beauty of Google is that they figured out using all of the searches that we all make and how to actually find what it is most likely that you are looking for. We do not have a simple, single box where you type in cure for autism and answers pop up.

This is a graphic representation of what I just said where these are the subjects. Here are some made up questions. This might be a question where the allowable answers are A, B, and C. This

one might be the allowable answers 1, 2, and 3. The way the validation tool that I am going to talk about later works is that if the allowable answers here are A, B, and C and you try to send us a D or an X or a 42, we come back and say that is not an allowable answer. You need to fix that before the data come in. That turns out to be - even though I think PIs are generally unhappy to discover the first time when they try to submit to us that they have these sorts of problems, they do correct those problems pretty close to the time when they measured the data and that is clearly a very good thing.

Let's talk a little bit about data dictionaries. These are the columns in that last framework. We have at the moment over 1500 different data collection instruments. A data collection instrument might be the ADOS or an IQ test or something like that. In those 1500 data collection instruments at the moment, we have over 130,000 unique elements. Those might be a

question inside one of those particular instruments.

We use this data dictionary to define complex experiments as well as clinical experiments, which are a little easier to define. We can deal with any type of data or data structure.

They are curated by the staff at the NIMH data archive. The curation is the really hard thing. If male and female are coded M and F in one instrument and 0 and 1 in another instrument, you have to curate that so that you can launch a query across all of the instruments and figure out all of that. Male and female are pretty easier. Most of the time it is not nearly that easy. The curation takes a lot of effort and is made necessary because of this ridiculous number of data collection devices or dictionaries that we have.

Here is what they look like. Here are some of the categories of the data dictionaries. Here



are individual data dictionaries. If you go to the website, you can click into any of these and actually see individual-level questions and allowable values, all sorts of things. If you do click into one of them, here is an example. In the background, you have the individual-level questions. These are the data that come out of - the data distribution that comes out of one of those questions. You can get this level of data, this aggregate data just sitting on your browser anywhere in the world. I think that is really incredibly valuable because you could imagine that you did an experiment that was similar to this and you saw a little bump here and you can quickly come to our website and say they saw that same bump too and then you can change different age ranges. You can look at gender. You can look at whatever. Just bang and look at those types of questions without having access to the underlying data.

Of course, we would like you to do real science and that means getting access to the data and pulling this down and then really comparing what you have to what was in the database.

I think the other important thing to point out is that we have a lot of data. Each of these bars in this case ends in the hundreds. That is a lot of people.

I want to make the point that the data dictionary I think is really a key component in improving rigor and reproducibility. If you have tried to submit data and you have been told that you have a problem and you do not fix it then the blame is completely on you. If you do not run your data through a validation tool on a regular basis, you will not necessarily know about the problems.

The Global Unique Identifier, the GUID, is the other organizing principle. This is a really great piece of software where you put in some basic information from a birth certificate into

software that it sits at your research site. The GUID is generated at your research site and then that information is sent to us, the hash code derived from the data you put in. And then we just have a simple look-up table that compares that hash code to IDs that we have already given out.

If I were seen in a research study in two different laboratories and those two labs put in the same information, the same GUID would be a sign to both laboratories. You can aggregate the data easily and I think there were some questions earlier today about aggregating data in genomic studies. That is the way the GUID makes that happen.

It is always nice to prove that things work. This is one of these things that we implemented. It should have worked theoretically. Does it actually work? It does. This is an example of a query showing all of the data that we have that were in the interactive autism network. That is

usually a patient or a parent self-report database. Parents do not have neuro images. They do not have genomics. All of the people who are in these wheels were examples where there is clinical phenotypic data in IAN as well as these people are seen in neuroimaging studies funded by someone or in genomic studies funded by someone. We have done pretty careful analyses in terms of false positives, false negatives. The GUID is a really robust tool at this point.

Something that I always like to talk about is the NIMH data archive study. One of the nice things about a data archive is that you have data from all sorts of different labs. A user can aggregate data in a meaningful way that we call a study. I will show you an example of this, but the data could come from a single laboratory or from a variety of sources. We assign a digital object identifier to each of these studies. That is exactly the same identifier that the Library

of Medicine assigns to papers and widely used at this point.

You can then use the DOI as the reference for a particular group of data. It is becoming easier and easier to measure the number of clicks through a DOI and citations. We think that this is going to be the way that people will get credit for depositing data that are reused in a meaningful way.

Here is what the site looks like for studies. If you view into one of those studies, you see the DOI. You see the underlying laboratories that deposited data and how many subjects each of those labs deposited. This is a tool that we really do like.

I was tempted to give you examples of all of the many different types of queries and things we could do. I decided that that was not perhaps the wisest use of your time especially at the end of the day. I just take this as an example of some of the ways that we package and allow queries.

As I get close to the end here, I really do want to give thanks to the staff who work on this. It is a very dedicated staff. I feel incredibly fortunate to have these people working on this project. Two members of the project team are on the autism spectrum. There are I think at least five members of the team who are parents or who have close relatives who are on the spectrum. They are dedicated for a lot of reasons, but they are committed to them. They really are committed to helping to try to find effective ways to aggregate the data that we have.

In summary, the database really makes human subjects' data easy to find, discoverable, useful to others in a variety of ways, cite-able. I think those DOIs really are going to be important. And something I did not talk about, but linked to the literature, we have worked with PubMed so that if we have data that is associated with a paper that those links show up when you find that paper in PubMed.

I think with that, I will stop and I welcome any questions or comments that you have. If I did not cover things that were discussed earlier, please bring them up now.

DR. GORDON: Thank you, Greg. It is a great and thorough review of an incredibly valuable resource for the research community and for researchers in a lot of other fields of relevance to NIMH.

Do we have questions from any of the committee members? I was wondering how active the community is in using this resource and what we are doing to try to expand that.

DR. FARBER: It is a great question. I like to use the analogy and I think it is right that I think about databases like a swimming pool. The swimming pool is not too useful when there is not much water in the pool. You need to get enough water in the pool before you can really expect people to dive in.

It has probably been about two and a half years now since we have had enough data to really have a meaningful presence in the research community. In a variety of ways, you can measure usage. Probably right now there are 20 or 25 - actually, it might be a little more now. There are folks online who have found this by watching here. At any moment, there are 15 to 25 people who are online doing searches and things. We have a number of examples of papers that publish secondary data reanalysis from the archive.

We are still honestly waiting for the first Nature paper that makes a big wild discovery that was not unexpected, using data that was aggregated. We do not have that yet. In any other way, I think you have to argue that it is widely used.

(Applause)

DR. GORDON: We now set aside some time for the committee to go around and bring up issues that we might want to consider as a committee in



the future or make announcements or share updates from your own organizations. We have had a couple of people who asked to speak in advance. I think we will go ahead and start with Tiffany. You had something you wanted to bring up and then we had another person. And then we will open it up.

DR. FARCHIONE: Unfortunately, all of the exciting things that I was - all the details I was going to give for background are in my email that now just crashed.

DR. GORDON: I can give you some time. Aaron, you are going to provide us with an update.

DR. BISHOP: Good afternoon everyone. It is a pleasure seeing you. We have a few items that we would like to bring up that are taking place at the Administration for Community Living. The first one has to do with the President's Committee for People with Intellectual Disabilities. The committee met this past December and decided that the 2017 report to

Congress is going to focus on the needs of direct service staff and how can we do a better job at making sure that staff are reimbursed properly, making sure that individuals have proper training, and making sure that we reduce the unfortunate abuse and neglect situations that we see in community based and other settings. They are just starting to figure out what the format of the report is going to be like. The goal is for the report to be finalized and to start to go through the vetting process with federal agencies in April and for it to be finalized as it typically is sometime around August of 2017. That is the first one.

The second one is - this was not one that I am familiar with. I am going to read this to you. It is coming from the National Institute on Disability, Independent Living, and Rehabilitation Research, NIDILRR, and specifically the ICDR. I am blanking on what it is called.

UNKNOWN SPEAKER: The ICDR. The Interagency Committee on Disability Research.

DR. BISHOP: Agencies across the federal government are working to advance the science related to devices and assistive technologies for rehabilitation. Many devices developed face significant challenges when they move through the regulatory process, as we all know, and face even greater hurdles at the level of commercialization. A number of federal agency funding partners including the Department of Defense, the VA, NIDILRR identified this as a key challenge and translation and would like to engage the community to identify successful stories in which interagency coordination was successful in enabling the translation of devices or assistive technology.

There are three planned meetings that are taking place across the United States over the next few months. Unfortunately, the first one took place yesterday. We were not here so we

could not make that announcement at this time. They said that they are working on when and where the other two are going to take place in calendar year 2017. Please pay attention to the NIDILRR and specifically the ICDR website for additional details. That is it. Thank you.

DR. FARCHIONE: One thing that I know that people have asked me pretty much every time that I have come to one of these meetings for the past couple of years is when we are going to be scheduling a patient-focused drug development meeting for autism because it was one of the priority areas that was listed when these PFDDs were first announced. I can say that we do have a date set now for May 4 of this year for a patient-focused drug development meeting.

For folks who do not know what that is, when the latest round of prescription drug user fees was approved by Congress a couple of years ago, in that legislation, there was a commitment on the part of Center for Drug Evaluation and

Research and the Center for Biologics to do these disease-specific meetings that allow FDA to systematically obtain a better understanding of patient perspectives on the severity of the disease and available therapies and then also to help us learn more about what those affected by various conditions think are important. What are the most impactful symptoms? What things impair ability to just function day to day? If something were to be improved, what would be the most meaningful domain for improvement?

We have had 20 meetings so far. You can look those up on the web. If you just Google, FDA, PFDD then you will find a whole collection of those meetings. You can get an idea of what has happened in the past. And then you will also see on there a spot where you can register for the upcoming autism meeting. Again, May 4. It starts at one. I think it is the whole afternoon, 1 to 5 p.m. It is on the FDA campus in White Oak.

UNKNOWN SPEAKER: We have it on the IACC website as well. You can find it there.

DR. GORDON: We will take any announcements, updates, queries, questions, comments from the rest of the committee now.

DR. SHAPIRA: I am Stuart Shapira from CDC. I thought since there were some new members of the committee, I would say some brief words about what we are doing at CDC with regard to autism. There are basically three lanes that we work in. We are working to understand the risk factors that make a person more likely to develop autism, which helps us learn more about causes. This study is called SEED, the Study to Explore Early Development. It is a multisite case control study.

The second area we work in is we study the number of people identified with ASD over time. This lets us understand if the numbers are changing, if they are rising or falling or staying the same. We compare the number of

children with ASD in different parts of the country and among different populations and with different characteristics. This is our autism and ADDM network, Autism and Developmental Disabilities Monitoring Network.

And the third area that we work actively in is improving identification of children with ASD as well as with other developmental disabilities by encouraging families and early child providers to do developmental milestone monitoring and to get children seen sooner so that they can get services earlier. This is through our Learn the Signs, Act Early program.

And just one or two sentences about each of these go back to SEED that the - we have investigators that are poised to publish a number of studies in the coming year. I have seen many papers come through our clearance process. At CDC, I know that there are submissions and papers coming out, looking at risk factors and health outcomes associated with ASD.

We are currently working toward getting approvals for a very exciting study that I have mentioned here before. The SEED program. We are beginning to enroll children in our third iteration SEED three. SEED one was long enough ago that the children who were 3 to 5 years at the time that they were originally enrolled are now teenagers. We are doing a follow up study called SEED teen, which will provide some unique opportunities to better understand the long-term trajectory of children identified at an early life age stage as having ASD and their long-term health and educational and services needs associated with their diagnosis of ASD and how this has impacted them and their families.

The second area, the ADDM network or the surveillance activities that the data collection analysis is ongoing for the surveillance year for 2014. One exciting thing that we will be looking at is comparing those diagnosed under DSM-IV criteria versus DSM-V criteria and sees what the



impact of the new diagnostic criteria have on the prevalence and the characteristics of 8-year-old children identified with ASD.

Then in our third area, Learn the Signs, Act Early. I mentioned previously that we released milestones in action free image library that features photos and videos of children that demonstrates developmental milestones from the age of 2 months to 5 years. And the tool was created to help parents and early care and education providers, identify developmental milestones in children and know whether there should be a concern. We are integrating that into an app that parents can utilize in order to track their child's development. It gives them alerts if the child does not achieve certain milestones and that they should speak with health care providers at the next visit.

In addition, Learn the Signs, Act Early has recruited, selected, and trained the largest cohort of what we call Act Early Ambassadors to

date. We now have 45 ambassadors in 44 states and territories, doing exceptional work of integrating Learn the Signs, Act Early into the systems and programs, serving young children and their families.

Finally, I had mentioned last time that we had been working with the WIC program in one area of Missouri to integrate Learn the Signs, Act Early into WIC, which is the Women and Children, the early clinics. This is now going statewide in Missouri and we are developing tools to support the project in other states because it has been so successful in this pilot program.

DR. GORDON: Thanks Stuart.

DR. SINGER: I think Stuart knows what I am going to ask. How goes the process of re-consenting all of the SEED 1 participants so that all that genetic data can go into the other databases and be shared?

DR. SHAPIRA: That is the same question that I have heard before -- that is part of the SEED

of the SEED teen project. When they are re-consented for participating in the SEED teen project, they are also going to be receiving the consent forms for re-consenting to use their biologics that it can be integrated into larger studies like into NDAR and dbGaP. We have all that in place. We are just waiting for the final approvals to launch that. I think it will go pretty smoothly.

MS. SINGER: When can we expect that? When will we have that data? It is a lot of data. We could really benefit. A lot of studies could benefit from that data. When can we expect it?

DR. SHAPIRA: Over the next year that the study will be going strong to find these families and to re-consent them and to collect the data for SEED teen project. Ask again. We should have all the approvals by then and begin the enrollment in SEED teen at that time.

DR. GORDON: Let's keep moving along.

DR. TAYLOR: Our group just had an article pre-published online that is looking at the results of the small RCT that is a parent advocacy training. It trains parents of transitioned age youth with ASD about the adult service system and how to effectively access services on behalf of their son or daughter. We are pretty excited about our initial findings.

But the reason I bring it up here is because at least to my understanding, the mechanism that funded this project was a direct result from the last strategic plan from the ASD R34 mechanisms.

The projects that have been funded from that round and there were three transition projects and three adult projects are now starting to make their way into the literature, which I think is exciting.

DR. GORDON: We will come back to Susan. We just went through pre-council and had a number of really good applications for grants particularly in the adult sphere, but also autism sphere. We

hope to be able to fund them and announce them and share with you the results of those at the next meeting, not the results of the studies, but just what we have going on in that sphere because I know it is a lot of interest to people.

DR. BIANCHI: NICHD. I just want to take credit for one of the papers that was highlighted. I think it was David's study on acquiring MRI data without the use of sedation. That was an HD-funded study.

Also, I wanted to make you aware of an Infant Brain Imaging Study Network, the IBIS Network. This is also an HD-funded study that is collecting longitudinal brain imaging of a combined sample of 600 infants who are at high risk for later developing autism by virtue of having an affected sibling. It is orally screening and diagnosis. It relates to Question 1.

The team is going to gather more frequent scans for visits between 3 and 24 months of age.

This will allow investigators to gain a greater understanding of early brain development in children at risk. Thank you.

MS. SINGER: I will just say briefly that the Autism Science Foundation will be holding its fourth annual TED talks on March 30. Everyone is invited. This year we are going to be looking at topics including best practices for housing for adults. We are going to be looking at best practices for communication between teachers and parents and therapists. We are going to be looking at modifiable autism risks. We will also of course be looking at advances, understanding the female protective effects. Registration will be opening in a few weeks. But for those of you who will not be able to attend, we make all of the TED talks available as videos online usually about a week after the TED talks. I hope you will tune in.

DR. CRANE: I was going to ask if there is an online link or something announcing the date and time for the talks that I can check out.

MS. SINGER: It is on our website on our home page. All of the presenters and their topics are there as well as the date and location.

DR. DANIELS: It is on the IACC website too.

DR. NIU: Hi. This is Stan. On behalf of Nicole, I spoke to her before I came here, we do not have particular updates. We are in the midst of the FY16 funding cycle. We are at the end of the review making new funding recommendations and also we are rolling out the FY17. Over the years, our program - it is a small program, but we are being shifted toward a more translational study as our mission is try to make an impact to the community now. In the last few years, we pretty much divided a significant portion of investment toward clinical trials. One of the studies - excited about the - project search by Wayman. This was done with the civilian population.

We actually funded a project that was a similar model, but this would be done in the military population. We try to help those young adults transitioning into independence to help them to deal with employment topics.

There is another thing. Nicole probably will be making an announcement. I will just give a quick overview. It is still in the developmental stage. Basically, our office in collaboration with the DHA would roll out a study looking at the ABA and applied behavioral therapy in the military health system. This will be development. She will have a more mature stage by April. That is all.

DR. KAVANAGH: We have an autism transition research project that is out in the field. It is open until February 13. I will be presenting at a future meeting some findings from our National Survey of Children's Health, which has data about autism.



DR. CRANE: I do not have many responses right now. I was just looking at the TED talks. I got a little distracted. Can we skip me and come back?

DR. GORDON: But it is a short skip.

DR. CRANE: I found my composure. I do not think there is anything specific. We did have an international symposium on supported decision making and integration into the community in which people from a variety of countries including the US, but also the Czech Republic, Bulgaria, Turkey, and many others. We are talking about how their countries help support people to make decisions relating to their return to the community from institutions. We will be publishing a white paper on that. It might be relevant to people who are interested in best practices and services. It is not exactly a scientific evaluation, but it is a good overview of the types of interventions that people are using that might want to be studied.

DR. GORDON: Thank you. Susan, you have a few things to say.

DR. DANIELS: I just wanted to for an update, draw your attention to a recent GAO report, Government Accountability Office, called Youth with Autism: Roundtable Views of Services Needed During the Transition into Adulthood. This is a paper that describes the opinions of a convening group of experts about what is needed for transition services. And especially for Question 6 working group, it will be useful when they are coming up with the strategic plan draft.

There is also a report that is out from our sister advisory committee, the Advisory Committee on Increasing Competitive Integrated Employment for Individuals with Disabilities, which is a longer acronym than our acronym. They would like to come and give a report about this report here at the IACC. They could not come this time, but will come at a future meeting.

I believe I also might have pointed out that Dr. Joshua Gordon had an article in Spectrum News that is also on our website and that I shared with everyone. It is on the carousel on our homepage. I would encourage people to have a look.

DR. GORDON: No further comments. We will adjourn for the day. Thank you very much.

DR. DANIELS: Besides round robin, I have a few closing items.

DR. GORDON: We will stop with the round robin. We will get to our closing items before we adjourn.

DR. DANIELS: I just want to recap what we are doing. The working groups are going to be working on drafting their chapters over the next several weeks. We will be in touch with you. Over the next couple of weeks, I will not be in the office, but our office is available if you need some help in the meantime. After I am back, I will be in touch with all the chairs to see how

everything is going and we will see if we want to convene the chairs together once their actual drafts to work with.

We will also work on convening the budget working group to help sort out some of the issues with the budget.

Third, we will be sending out a ballot for the summary of advances. This will come from that new email address, the summary of advances one so that it makes it easier for us to make sure we do not lose anything. If we do not hear back from you, we will send you a reminder.

And then just to ask if you have any suggestions about things you want to hear about at IACC meetings, please email us and let us know what you would suggest.

DR. KOROSHETZ: What is the page limit on the reports?

DR. DANIELS: We were trying to go for ten pages or less for each chapter because we have seven chapters. It will become a pretty long

report. Even if you come up with something longer, we will try to pare it down once you have it on paper. Sometimes it is a little bit easier.

DR. GORDON: And then you will work on getting the budget group as quickly as possible. It will help to get it sooner so that the working groups can take whatever recommendations they have and to run with.

DR. DANIELS: My plan is to get the working group together to talk about this. See what is feasible to do and then be in communication with the committee about what the working group came up with.

DR. GORDON: No further comments. We will adjourn for the day. I look forward to seeing you all at the next meeting, which is - do we have a date?

DR. DANIELS: April 26. I believe it is on the NIH main campus.

DR. GORDON: Just to keep you guessing. See you in April.

(Whereupon, at 5:00 p.m., the Subcommittee  
adjourned.)