Minutes

Minutes of the Interagency Autism Coordinating Committee Full Committee Meeting

January 13, 2017

The Interagency Autism Coordinating Committee (IACC, also referred to as "the Committee") convened a meeting on Friday, January 13, 2017, from 9:00 a.m. to 4:08 p.m. at the National Institute of Mental Health, 6001 Executive Blvd, NSC, in Rockville, Maryland.

In accordance with Public Law 92-463, the meeting was open to the public. Joshua A. Gordon, M.D., Ph.D., Director, National Institute of Mental Health (NIMH) and chair of the IACC chaired the meeting.

Participants:

Joshua Gordon, M.D., Ph.D., Chair, IACC, Director, National Institute of Mental Health (NIMH); **Susan Daniels**, Ph.D., Executive Secretary, IACC, Office of Autism Research Coordination (OARC), (NIMH); **David Amaral**, Ph.D., University of California (UC) Davis MIND Institute; **James F. Battey**, M.D., Ph.D., National Institute on Deafness and Other Communication Disorders (NIDCD); **Diana W. Bianchi**, M.D., *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHHD); **Aaron Bishop**, M.S.S.W, Administration for Community Living (ACL) (attended the afternoon session); **Josie Briggs**, M.D., Director, National Center for Complementary and Alternative Medicine, National Institutes of Health (NIH) (representing Francis S. Collins, M.D., Ph.D.); **Samantha Crane**, J.D., Autistic Self Advocacy Network (ASAN); **Geraldine Dawson**, Ph.D., Duke University (attended by phone); **Ruth Etzel**, M.D., Ph.D., Director, Office of Children's Health Protection, Environmental Protection Agency (EPA); **Tiffany 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, Centers for Medicare & Medicare Services (CMS) (attended by phone); **Jennifer Johnson**, Ed.D., Administration for Community Living (ACL) (representing Commissioner Aaron Bishop, M.S.S.W. during the morning session); **Laura Kavanagh**, M.P.P., Deputy Associate Administrator, Maternal and Child Health Bureau, Health Resources and Services Administration (HRSA); **Walter J. Koroshetz**, M.D., National Institute of Neurological Disorders and Stroke (NINDS); **Cindy Lawler**, Ph.D., National Institute of Environmental Health Sciences, (representing Linda Birnbaum, Ph.D.); **David Mandell**, Sc.D., University of Pennsylvania; **Shui-Lin (Stan) Niu**, Ph.D., U.S. Department of Defense (DOD) (representing Nicole Williams, Ph.D.); **Kevin Pelphrey**, Ph.D., George Washington University and Children's National Medical Center; **Edlyn Peña**, Ph.D., California Lutheran University (attended by phone); **Laura Pincock**, PharmD., M.P.H., Agency for Healthcare Research and Quality (AHRQ) (attended by phone); **Robert H. Ring**, Ph.D.; **Stuart K. Shapira**, M.D., Ph.D., Centers for Disease Control and Prevention (CDC); **Alison Tepper Singer**, M.B.A., Autism Science Foundation (ASF); **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)

Call to Order, Roll Call and Welcome

Joshua Gordon, MD, Ph.D., Director, NIMH and Chair, IACC; Susan Daniels, Ph.D., Director, Office of Autism Research Coordination, NIMH, and Executive Secretary, IACC

Dr. Susan Daniels called the meeting to order at 9:08 a.m. and took roll call. Dr. Joshua Gordon welcomed the Committee and thanked the public attendees. Dr. Gordon introduced two new Committee members. Dr. Diana W. Bianchi, the Director of NICHD, is replacing Dr. Spong. Dr. Laura Pincock from AHRQ is replacing Dr. Kato. Dr. Gordon announced several members who were leaving the Committee. Shannon Haworth is now working as a federal employee for HRSA and is stepping down as a public member. This is the last meeting for Commissioner Aaron Bishop (ACL) and tentatively for Dr. Francis Collins (NIH). Dr. Josie Briggs (NCCIH) will continue to represent the NIH Office of the Director on the IACC during the interim period.

The draft minutes from the October 26, 2016 meeting were approved with no comments or corrections and will be posted on the IACC website as soon as possible after the meeting.

Welcome and Introductions

Dr. Gordon reviewed the agenda for the day. Dr. Daniels welcomed Dr. Thomas Novotny to provide an update from the HHS Office of the National Autism Coordinator.

Update from the HHS Office of the National Autism Coordinator

Thomas E. Novotny, M.D., M.P.H., National Autism Coordinator & Deputy Assistant Secretary for Health (Science and Medicine), Office of the Assistant Secretary for Health, Department of Health and Human Services.

Dr. Thomas Novotny provided an update on the report that the U.S. Department of Health and Human Services (HHS) is providing on the transition of youth and adolescents with ASD into adulthood. This report is required by the Autism Collaboration, Accountability, Research, Education, and Support (CARES) Act of 2014. He acknowledged his appreciation for the input that HHS has received from federal members and other stakeholders. Dr. Novotny believes work on the report will be supported and continue after the presidential transition. The Department has recruited subject matter experts and staff to produce the report. The Department has created a working group that consists of members across the federal government including several agencies within HHS, the U.S. Department of Labor, the U.S. Department of Housing and Urban Development, DOD, and the U.S. Department of Justice. The data call to working group members gathered a lot of information for the report. The goal is to have a draft prepared by the end of January which would then go through agency clearance processes. He noted that the presidential transition could slow down the clearance process.

Dr. Novotny emphasized that the report will focus not just on challenges and gaps in the federal system, but also challenges to individuals with ASD, their families, and caregivers. The report will address gaps in services and research. They will invite stakeholder input into the product later in the process. Dr. Novotny is optimistic that the report will be completed in a timely manner.

Dr. Novotny reported that they have provided a fair amount of information about the working group on autism for the presidential transition team but have not had any response yet. Dr. Novotny met with Representative Chris Smith (NJ), who authored the Autism CARES Act. He described the meeting as cordial and supportive, and felt it was a good opportunity to share what they have accomplished.

There were no questions from the Committee for Dr. Novotny.

Dr. Gordon thanked Dr. Novotny for his update and is looking forward to reviewing the report.

Update from Autism Speaks

Angela Geiger, President and Chief Executive Officer, Autism Speaks

Ms. Angela Geiger commented that she was brought on board to craft a vision for the next 10 years of Autism Speaks. Autism Speaks has changed their mission statement to reflect their goals for the future (https://www.autismspeaks.org/about-us/mission): "Autism Speaks is dedicated to promoting solutions, across the spectrum and throughout the lifespan, for the needs of individuals with autism and their families through advocacy and support; increasing understanding and acceptance of autism spectrum disorder; and advancing research into causes and better interventions for autism spectrum disorder and related conditions." This reflects the organization's desire to continue raising awareness while also moving toward an increased emphasis on understanding and acceptance, as well as a focus across the spectrum and throughout the lifespan. Autism Speaks will continue to be committed to research to understand the causes of ASD and to develop better interventions. Ms. Geiger shared that their "quick impact statement" is to *enhance lives today and accelerate a spectrum of solutions for tomorrow*. The Autism Speaks Board has approved a 3-year strategic plan. Ms. Geiger reviewed the 5 mission objectives in the strategic plan:

- Increase global understanding and acceptance
- Be a catalyst for life-enhancing research breakthroughs, with a focus on near-term results
- Decrease the age of diagnosis and the time from diagnosis to intervention, with an emphasis on lower socioeconomic status populations
- Improve the transition to adulthood and successful transition outcomes
- Ensure that people on the spectrum and families have access to reliable information and services throughout the lifespan, making it easier to navigate and be more proactive.

Questions/Discussion:

Ms. Alison Singer asked how Autism Speaks plans to pursue research and science (opportunities for short-term wins, their commitment to basic science) and what opportunities existed for partnerships.

Ms. Geiger reported that they are conducting a search for a Chief Science Officer (CSO) which they hope to have filled during the first quarter of this year. When that positon is filled, the organization will create a new Medical and Scientific Advisory Committee that consists of board members and outside experts. This committee will be responsible for determining the scientific priorities that will address the strategic goals. Autism Speaks will continue some basic science research investment, but they have not established what the ratio/percentage of their portfolio that will be. Once the Chief Science Officer and Medical and Scientific Advisory Committee are in place, they will begin to address partnership opportunities.

Dr. Gordon commented on Objective 3 (decreasing age of diagnosis and time to intervention) and noted NIMH efforts to address research issues related to screening. Dr. Gordon suggested introducing screening that targets socioeconomic classes which have a higher age of diagnosis. He asked Ms. Geiger her thoughts on this and how to reduce the time from diagnosis to intervention.

Ms. Geiger believes there are two levers to address diagnosis issues: 1) increase parent demand and 2) increase physicians' willingness to diagnose ASD. Ms. Geiger suggested developing campaigns that target segmented parent audiences in novel ways. As an example, they could identify the most used diaper by parents with lower socioeconomic status and partner with those diaper manufacturers to include "signs of autism" on packaging/products. This would offer greater visibility and constant reminders to parents. Ms. Geiger indicated that one barrier to diagnosis by doctors is a lack of knowledge about available resources. It is important to educate doctors about how to work in partnerships.

Dr. Gordon asked if Ms. Geiger had ideas for the near term about earlier intervention. Ms. Geiger indicated that Autism Speaks would like to work on more public advocacy but also work to increase parent self-efficacy and engagement in interventions.

Dr. Larry Wexler introduced Dr. Sam Odom. Dr. Wexler noted that the U.S. Department of Education has funded Dr. Odom's research for many years.

Translating Science into Practices: Autism Focused Intervention Resources and Modules

Sam Odom, Ph.D., Director, Frank Porter Graham Child Development Institute, University of North Carolina-Chapel Hill

Dr. Sam Odom began his presentation by disclosing that the Frank Porter Graham Child Development Institute has two grant funded randomized controlled trials (RCTs) that are funded by the Institute of Education Sciences at the U.S. Department of Education. Dr. Odom briefly discussed the movement toward evidence-based practice in education, psychology, and medicine, which dates back to the 1960s and was spurred on by the fact that healthcare was not based on the most current medical evidence. He also noted the distinction between a meta-analysis and a systematic review. A meta-analysis takes a deductive approach by identifying a single practice and looking for the research/studies that underlie this practice. A systematic literature review uses an inductive approach by looking broadly to identify evidence-based practices (EBP) that emerge from the literature.

Dr. Odom described two systematic reviews of intervention literature for evidence-based practices. One was completed by the National Standards Project (NSP)/National Autism Center (2009) and the other by the National Professional Development Center (NPDC) (Odom, Collet-Klingenberg, Rogers, & Hatton, 2010: http://dx.doi.org/10.1080/10459881003785506). NSP Phase 1 was released in 2009 and focused on interventions targeting core characteristics of ASD in children, adolescents, and young adults below 22 years old. NSP Phase 2, released in 2015, updates the phase 1 intervention literature and also includes studies evaluating interventions for adults (22+). NPDC reviewed literature from 1997-2007. Given the rapidity at which research on intervention practices was expanding, NPDC launched a second review which was designed to inform their professional development model. Dr. Odom described the results of this literature search, the iterative process used to identify and screen articles, and the inclusion criteria. From this process, 446 acceptable studies were identified and a content analysis process was used to sort practices into categories. NPDC's Criteria for evidence (Nathan & Gorman, 2007; Rogers & Vismara, 2008; Horner et al., 2002; Gersten et al., 2005; and Chambless & Hollon, 1998) was used to make a final determination on whether a practice met the necessary level of evidence to be classified as an EBP:

- At least two articles on high quality experimental group or quasi-experimental design studies conducted by at least two different researchers or research groups; OR
- At least five articles on high quality single case design studies conducted by at least three different researchers or research groups and having a total of at least 20 participants across studies; OR
- A combination of at least one article on a high quality group experimental or quasi-experimental design study and at least three articles on high quality single case design studies conducted by at least two different research groups

This updated review (Wong et al., 2014) identified 27 evidence based practices which were grouped into 6 practice categories: Fundamental Applied Behavior Analysis, Positive Behavior Intervention and Support, Social Communication Interventions, Broad Teaching Strategies, Cognitive Behavior Techniques, and Technology Oriented. NSP and NPDC's evidence-based practices were examined for overlap and they found that, for the most part, they were in agreement. Dr. Odom noted that the NPDC's parameters were birth to 22 years old.

NPDC will launch the National Clearinghouse for Autism Practice Evidence (NCAPE) in January 2017 which incorporates focused intervention practices research from 2011 to 2017. NCAP's goals, contingent on funding, are to develop a process for continuous literature updating and to conduct a review of psychopharmacological and behavioral/psycho-pharmacological interventions with the intention of making this useful, practical information available.

NPDC has also developed the AFIRM website (http://afirm.fpg.unc.edu/afirm-modules), which provides 27 free, multi-media, e-learning modules (based on the 27 evidence-based practices identified in the NPDC). These modules target special educators, early education teachers, early interventionists, and related service personnel. By February 2017, all 27 modules will be available on the site. Each module consists of four lessons (Basics of EBP, Plan for EBP, Use of EBP, and Monitor EBP), a description of key components of EBPs, and a step-by-step process for applying the practice. The modules are case based and include supplemental materials such as checklists, practice guides, parent guides, professional tips, data sheets, and lists of studies documenting existing evidence. Each module also has a pre- and post-test, an evaluation, and a certificate of completion. NPDC is collecting data on web-usage, which continues to increase over time. AFIRM modules are one tool that practitioners can use to implement EBPs in their programs for students with ASD. They found that they are being used frequently by universities in preservice training.

Questions/Discussion:

Dr. Robert Ring asked whether their scope expanded to include parent skills. Dr. Odom noted that one EBP was a parent-implemented intervention. Two areas that NPDC would like to grow are: 1) making information more visible for parents and getting their feedback and 2) developing more information for paraprofessionals.

Dr. David Mandell noted that there is evidence that online training does not change behavior and asked how other organizations could help increase the probability of behavior changes translating into practice. Dr. Odom agreed and shared that they have 2 RCT’s funded through the Institute of Education Science that are using a model providing teacher coaching across a year to determine both teachers’ uptake and students’ education/outcomes. Examining an eclectic model like this draws from different theoretical roots but is based on science and linking science to goals for students. Dr. Mandell noted that the Individuals with Disabilities Education Act (IDEA) requirement for EBPs was a great way to expand the use of EBPs and wondered how to emphasize the evidence base and impact/influence policy. Dr. Odom reported that three states use these EBPs to establish what should be funded. Dr. Gordon asked the Committee to share their plans and experiences getting states and boards of education to adopt EBPs. Dr. Wexler has found that policy is driven by demand from parents and advocates. Samantha Crane suggested that professionals should not be directed to a specific EBP but should be given guidance on a menu of evidence-based interventions from which they can choose. Dr. Gordon concurred and noted that NIMH would strongly state that any encouraged practice should have an evidence-base. Dr. Wexler agrees that parental demand is important, as is pre-professional training.

Ms. Crane asked if professionals can search AFIRM for an EBP by problem. Dr. Odom indicated that AFIRM only lists by broad outcome categories. Dr. Mandell agreed that this would be a great resource for people who would not know what terms to search for. Dr. Mandell also noted that over the past two decades, the majority of IDEA class action lawsuits are on procedural issues, with few on outcomes, and none on the use of EBPs. He wondered if they could rethink how to use IDEA to focus more on EBPs and less on procedural issues. Dr. Gordon commented that other areas of NIMH have dealt with a similar issue. He discussed the development of a set of EBPs for First Episode Psychosis Treatment (FEP). Advocacy groups lobbied Congress for funding for FEP. Congress funded SAMHSA to provide state block grants, but they required the use of EBPs for FEPs as well as consultation with NIMH to identify the EBPs. Dr. Gordon wondered if this model could be used for ASD, with the AFIRM website as one resource for EBPs.

Dr. Odom noted that the early leaders of EBPs emphasized that the process of EBP requires an evidence base **combined with** professional skill.

Committee Business

IACC Strategic Plan Update
Materials related to IACC Strategic Plan Update:

- Draft: Statement Regarding Duplication of Effort (PDF – 268 KB)
- Draft: Question Titles, Aspirational Goals, and Objectives (PDF – 277 KB)
- Question 1 Outline (PDF – 288 KB)
- Question 2 Outline (PDF – 304 KB)
- Question 3 Outline (PDF – 245 KB)
- Question 4 Outline (PDF – 249 KB)
- Question 5 Outline (PDF – 403 KB)
- Question 6 Outline (PDF – 329 KB)
- Question 7 Outline (PDF – 220 KB)

Dr. Gordon turned the meeting over to Dr. Daniels, who presented on IACC Committee Business and provided an update on the development of the IACC Strategic Plan. The IACC Strategic Plan provides a blueprint to guide autism-related efforts across federal agencies and partner private organizations. The first IACC Strategic Plan was launched in 2009 and its focus was on research efforts. Under the Autism CARES Act, the IACC Strategic Plan is being expanded to address both research and services activities. The IACC Strategic Plan is organized around seven consumer-based questions. The Committee formed seven working groups to address each of the seven Strategic Plan questions.

Update on Working Group Activities/Chapters and Objectives: Dr. Daniels reported that the seven working groups have been meeting by conference call to discuss updates to the Strategic Plan. Transcripts and summaries of each call are available on the IACC website. Each working group has drafted a chapter outline (progress, gaps/needs, barriers, and opportunities), proposed revisions to the titles and aspirational goals, and identified three broad objectives for each question. Dr. Daniels and the Committee reviewed each question. Four slides were reviewed and discussed for each of the seven questions: 1.) Key Topics; 2.) The Title; 3.) The Aspirational Goal; and 4.) The three Objectives.

Question 1 Discussion/Comments:
Dr. Julie Lounds Taylor commented that there needs to be coordination between Question 1 and Question 6 on the issue of adult diagnosis

Dr. Gordon commented that the first Question 1 objective on early detection is important, as here are gaps in the evidence base for universal screening in the general population. NIMH is working on how to address these gaps.

Dr. Stuart Shapira found the proposed title for Question 1confusing since none of the objectives focus on "what are the signs." Dr. Briggs suggested clarification of the language in the objectives. Dr. Taylor suggested replacing the phrase "that will" with "in order to" in Objective 3. The Committee agreed with that change.

Question 2 Discussion/Comments:
Dr. David Amaral suggested including a stronger link to immune dysregulation early on. Dr. Daniels suggested incorporating the phrase "physiological systems" Into the Aspirational Goal to capture this concept.

Dr. Wexler questioned whether the objectives allow for studies of sibling groups not affected by ASD. Dr. Walter Koroshetz clarified that those types of studies would fall under Objective 1.

Dr. Bianchi commented that Question 2 blurs mechanisms and natural history, and she suggested clarifying the difference between lifespan and mechanistic-type studies. Dr. Koroshetz responded that there are relevant sub-bullets under Objective 1.

Dr. James Battey commented that there was strong feeling among the working group members that a long term longitudinal study would yield very good information. Dr. Geraldine Dawson commented that Objective 3 supports the idea of large longitudinal study. Dr. Dawson asked whether it would be better to frame this not by the study's design but by what they are trying to understand. Dr. Dawson suggested supporting a study that can answer questions about the biology of autism, rather than specifying the design; that scientific question could be examined in many different ways, and other types of studies could be relevant. Dr. Dawson commented that she is not precluding a longitudinal study to understand the mechanism of development from pregnancy through the lifespan, but that there are several ways to do this besides through a longitudinal study. Dr. Koroshetz commented that everything Dr. Dawson mentioned could be accomplished under Objectives 1 and 2. Dr. Koroshetz commented on the importance of standards. The community needs to develop standardized methods of comparable data collection over long periods of time in order to see the spectrum across the lifespan.

Dr. Amaral commented that the Question 3 working group found a disconnect between genetic and environmental approaches and that a large scale longitudinal approach would bring it all together. Dr. Amaral thinks it is important to endorse a longitudinal study at this point.

Question 3 (Risk Factors) Discussion/Comments:
Ms. Singer commented that there was no reference to resilience and suggested adding it to Objective 2 or 3. Dr. Gordon noted that the objectives are incredibly ambitious, difficult, and long-term; he felt this was particularly true for Objective 3, and this should be acknowledged in the chapter. Dr. Amaral and Dr. Battey agreed with addressing the need for integration of risk/resilience factors since so many studies focus on one. The Committee agreed to incorporate resilience factors everywhere the objectives mention risk factors.

Dr. Lawler commented that there has been a lot of focus on emerging technologies in the field. Dr. Battey commented that asking questions about environmental exposure could help determine what risk factors to look for. He commented that genetics cannot be the only explanation in light of the increasing prevalence; environmental factors seem likely to be involved in the increasing prevalence. Dr. Amaral commented that the Committee thought that researchers had missed opportunities but not asking about exposures when recruiting patients for genetic studies. Ms. Crane commented that this presupposes that ASD is growing faster than the human genome can change and that more children/youth are being diagnosed with autism than we would expect given the adult population. However, the difference in diagnoses in the adult population may relate to the rapid change in diagnostic criteria. Additionally, there has not been a comprehensive review of ASD in the adult population similar to what has been completed for the child/youth population. Ms. Crane commented that an adult survey should be prioritized.

Question 4 Discussion/Comments:
Dr. Gordon commented that the objectives, particularly Objective 1, are quite aspirational. He expressed support for inclusion of cross-cutting themes. Dr. Daniels commented that the objectives from the prior Strategic Plan were more project-based. For this Strategic Plan, the committee wanted the objectives to be broader and more ambitious.

Dr. Mandell noted that the focus on translation into community settings that was included in the cross-cutting themes fits well with Question 5. Dr. Mandel wondered how to work together on these “blurry lines/synergies.” Dr. Kevin Pelphrey suggested cross-reviewingQuestions 3, 4, and 5.

Dr. Taylor commented that she likes that Questions 4 and 5 take a lifespan approach. Dr. Dawson commented that Question 5 looks very strong and she is very comfortable with the draft materials for this question. Ms. Crane also likes the inclusion of the lifespan approach.

Ms. Crane suggested adding “mental health” to Objective 1, noting that there are a lot of psychiatric comorbidities that are not core symptoms, such as sleep and eating issues. After further discussion, it was suggested that “core symptoms and co-morbidities” be added to Objective 2 and that the reference to “cognitive, behavioral, and social” therapy be replaced with “psychosocial” in Objective 2.

Question 5 Discussion/Comments:

Dr. Gordon did not think there was too much overlap between Questions 4 and 5. Ms. Singer noted that the working groups for Questions 1, 3, 4, and 5 all raised the need for a highly skilled workforce and some of the discussion of that topic could potentially be addressed in Question 7.

Question 6 Discussion/Comments:
Dr. Gordon commented on the title, noting that “across the lifespan” is more inclusive but that Question 6 is primarily about adults. Dr. Bianchi favors “as they progress into and through adulthood.” Dr. Tiffany Farchione questioned whether the focus of Question 6 is specifically on adults. Dr. Daniels clarified that the working group did not want to lose the emphasis on transition to adulthood, which is included in Question 6. Dr. Mandell stated that this chapter was

included because of the paucity of services and research for adults, and they do not want to lose that focus, which includes transition to adulthood. The consensus of the Committee was to use the wording "as they progress into and through adulthood" in the title.

Dr. Amaral commented that Objective 2 is very vague. He stated that it is important to recognize the health crises experienced by adults with ASD and asked the working group to consider adding wording that emphasizes this, such as by stating "understanding the health challenges" instead of "improving the health." Dr. Taylor concurred and noted that health outcomes and mortality are worse for adults with ASD. She suggested the objective be edited to "better understand and implement methods to improve…"

Question 7 Discussion/Comments:
Dr. Mandell applauded the expanded view of this question compared to the version in the previous Strategic Plan. He is excited about the potential of this question area, but concerned about the appearance of redundancy between chapters. Dr. Gordon asked whether they need to rethink the structure of the Plan or how chapter topics are presented so it is clear that overlap in questions reflects partnerships among the working groups. Dr. Daniels commented that it is possible that chairs could plan to exchange completed drafts of chapters to help streamline the content. The committee had already agreed to keep the 7 question structure at a previous IACC meeting.

Duplication of Effort Statement: Dr. Daniels reported that the Autism CARES Act requires the IACC to provide recommendations to ensure that ASD research, services, and support activities are not unnecessarily duplicative. During the October 2016 IACC meeting, Ms. Singer volunteered to draft a duplication of effort statement. This draft was disseminated to the Committee in advance of the meeting. Dr. Battey commented that it is important to remind non-scientists that reproducibility is the hallmark of good research, and indeed NIH has worked recently to address possible problems with reproducibility. He thinks the statement is very well written. Based on committee feedback, Dr. Daniels indicated that the statement will be accepted as is for inclusion in the IACC Strategic Plan.

Dr. Pelphrey suggested that there should be a system/method for tracking and following studies, crediting Fred Shic who has argued strongly for a system to tag studies. He commented that it could increase the usefulness of NDAR to require or encourage registration of studies as well as a method for following a study from beginning to end. Dr. Gordon noted that the new NIH clinical trial rules require registration of strategies, measures, and numbers of participants, etc. Dr. Pelphrey commented that many in the ASD field believe that NDAR is an important effort but it is an unfunded mandate. He suggested either developing an infrastructure to fund NDAR submission or helping individual investigators by providing a free/open-source tracking system.

Oral Public Comment Session

Patricia Swanson is the proud parent of 26-year-old twin boys: Andrew, who is an adult with autism, and Ben, who is neurotypical. Ms. Swanson shared her and her husband's efforts as parents to support Andrew throughout his life and the difficult decisions they have had to make. She discussed how they came to accept the realities of his disability and limitations. Andrew will need help to live day-to-day for the rest of his life. While she recognizes not all with ASD are as disabled as her son, Ms. Swanson feels it is important to hear all voices of those with ASD. She is her son's voice. While she would love total inclusion for her son, she recognizes his limitations. Currently, he works in a hospital but needs a support person beside him in order to do that. She is concerned about who will know how to give a voice to his desires when she and her husband are no longer living. If he were to be housed in an intentional residential community focused on the needs of people with disabilities, she feels he would have more independence than if he were alone and isolated in an apartment, where he may not feel comfortable being in the surrounding environment. She asked the Committee to target efforts that offer solutions and opportunities, such as appropriate housing choices, to support meaningful lives for all individuals on the autism spectrum regardless of their level of ability or disability. The goal of full inclusion for all, or only providing federal support to housing options serving 4 or fewer people with disabilities in s ingle site, may isolate and exclude many who could benefit from larger disability group settings.

Summary of Written Public Comments

Dr. Daniels introduced Karen Mowrer, Ph.D., Health Science Policy Analyst, Office of Autism Research Coordination, NIMH, who presented a summary of written public comments. The IACC received written comments from 11 commenters. The Committee was provided with copies of the written public comments in full. The full text of the oral statement and written public comments are available on the IACC website.

Link to written public comments: https://iacc.hhs.gov/meetings/iacc-meetings/2017/full-committee-meeting/january13/written_public_comments_011317.pdf

Link to statement of oral public commenter: https://iacc.hhs.gov/meetings/iacc-meetings/2017/full-committee-meeting/january13/oral_public_comments_011317.pdf

IACC Committee Member Discussion of Public Comments

Dr. Pelphrey shared that a bill in Virginia has come forward to require health insurance companies to cover behavioral interventions at any age. Previously they won coverage for 2-5 year olds, then the law expanded to include 5-10 year olds, and now the legislature is considering any age.

Ms. Crane reported that the Autistic Self Advocacy Network (ASAN) monitors a lot of these bills and ASAN consistently observes that bills focus exclusively on behavioral interventions or lump other interventions as behavioral interventions. She cautioned people to remember to discuss insurance coverage for the **full range** of evidence-based interventions.

Dr. Gordon responded to commenters asking about environmental risk factors, reporting that there are efforts funded by NIH, NICHD, and the National Institute of Environmental Health Sciences (NIEHS) to look at these factors in neurodevelopmental disorders including ASD.

Dr. Mandell noted the number of comments on the availability of services and state mandates. He noted the difficulty parents have with taking advantage of the services available to them. He asked whether there is a federal role in enforcing state mandates. Dr. Gordon suggested following up with Dr. Novotny on that issue. There have been discussions about strengthening enforcement of federal insurance mandates such as mental health parity, but he does not know the status of those discussions.

Ms. Crane mentioned ASAN's *Guide to Medicaid Coverage for Individuals*, *Guide for Medicaid Plan Administrators*, and *Guide for Private Health Policy Holders* (http://autisticadvocacy.org/home/policy-center/policy-advocacy-toolkits/healthcoverage/), and indicated that ASAN is developing one for private plan administrators. These guides discuss the state mandates and mental health parity, and describe ways to use those to get ASD services and support through mental health parity. Ms. Crane noted that there is limited discussion of essential health benefit requirements from the *Affordable Care Act* (ACA) which include habilitative services (to gain new skills) compared to rehabilitative services (to regain skills that had been presnt previously). States are defining these habilitative and essential health benefits and this is a development to continue to watch.

Dr. Daniels asked if there were any Committee comments on the current process for public comments. As background, the Committee asked OARC to develop a policy to help address the issue of the public comment sessions going over the scheduled time allotment. Dr. Daniels indicated that solutions that did not involve changes to the policy had not worked. The new policy issued in October 2016 states that a limited number of slots for oral comments is available for each meeting and limits individuals to one oral comment per calendar year in order to ensure that as many different individuals as possible have the opportunity to give oral comment. Those who are not accepted for oral comments due to space limitations still have the option to provide written comments or to comment at future meetings. Dr. Daniels mentioned that the committee could revisit this policy in the future if they feel it is not working well. Dr. Battey and Dr. Gordon said that they think this process and the summary of comments are working well.

Committee Business

- **IACC Strategic Plan Update (continued)**

Budgetary Requirements: The Autism CARES Act requires that the IACC Strategic Plan include "proposed budgetary requirements." The prior Strategic Plan had budgetary requirement estimates for each objective. Since the objectives are much broader in the new Strategic Plan, it may be more difficult to estimate budgetary requirements for each objective. Dr. Battey agreed that this is difficult, so he suggested giving a broad budgetary range for broad goals versus providing a specific number. Dr. Daniels stated that the Committee could develop budgetary estimates based on the objectives, the questions, or the overall Strategic Plan. The Committee could also base the proposed budgetary requirements on the entire research budget or on the federal research budget. The Committee could target the amount of funding to reach by a certain year or a percentage increase for each by a certain year. Dr. Daniels shared preliminary data from the 2015 IACC Portfolio Analysis. Data was collected from 18 funders. The analysis provides detailed information about federal and private funds supporting ASD research and helps the IACC monitor progress towards fulfilling the IACC Strategic Plan objectives. In 2015, Federal funds accounted for 79% of the research funding portfolio. Overall funding has decreased since 2012. NIH was the largest funder of ASD research in 2015. The information shared by Dr. Daniels included the percentage of funding (federal and private) received by each IACC Strategic Plan question.

Discussion:

Dr. Mandell suggested it would be valuable to indicate a budget amount or range by question. If the Committee is meant to advise or play a watchdog role, that would a helpful level of granularity. Dr. Wexler suggested that the Committee think differently about the dollar amount. He suggested tying the investment to the increase in prevalence rate and use that slope to address what the investment ought to be. He suggested looking at the slope of increase in prevalence to come up with a ballpark figure tied to a metric. Dr. Amaral agreed with Dr. Wexler and suggested tying that number to the economic cost (number of people with ASD) and emphasizing the need to invest more in order to reduce that cost. Dr. Pelphrey agreed with Dr. Amaral and noted that the insurance law he spoke about earlier only passed when they made the argument that it would save money. The argument is more powerful if you can show what you will save.

Dr. Battey commented that determining the cost of ASD is tricky. Dr. Mandell mentioned that a formula for determining this cost was developed as part of a 2014 article he co-authored with the London School of Economics that looked at direct/indirect costs of autism in the United Kingdom and the United States. Dr. Gordon suggested establishing a small working group including Dr. Mandell that would draft a brief about overall costs of ASD and then each working group could develop an estimated budget at the question level over a specified time period (for example, double the budget over 10 years). Ms. Crane stated that she is hesitant to tie the cost of ASD to the cost of research. The bulk of ASD costs are not in the care of individuals with ASD but are in their lost contribution to society. Dr. Gordon noted that the cost of appropriate effective care in most diseases is less than the gains made in treatment. Spending for each Strategic Plan question may vary by type of study, but it should be clarified that the greater cost of certain types of research does not mean it is more important. Dr. Mandell commented that they have methods for determining the cost of **not treating** ASD, not the cost of treating ASD. Dr. Koroshetz commented that a similar group on Alzheimer's disease developed a plan, linked specific proposed budgets to their plan, and received the funding from Congress. Dr. Koroshetz suggested being more prescriptive about what the recommended budgets will be used for in each objective/question. Dr. Koroshetz suggested that estimating budgetary requirements for each objective is more likely to result in increased funding.

Dr. Pelphrey commented that the Committee's opportunity through the Strategic Plan to provide a clear plan to address problems could be the most important element of IACC's service to Congress. He was stunned to see that Question 4 dollars had gone down given the consistent theme in the public comments that there needs to be more treatment research and more studies of adults.

Dr. Battey commented that it is important to describe how the budget recommendation calculations are created. Dr. Mandell developed an online excel spreadsheet that could be provided as an explanation. Dr. Koroshetz commented that the economic argument often influences people's thoughts about budgets. Dr. Gordon noted that asking for a lot of money can be an impediment, so the Committee needs to demonstrate that the investment will save money down the road.

The Committee had further discussion about how to develop cost estimates and at what level: the question level or objective level. It was clarified that the working group will have to develop the estimate whether at question/objective level and that they need a clear logic for the calculation. Dr. Daniels clarified that they would like a full draft of the Strategic Plan completed by April but could move that until July and do approvals of the recommended budgets by teleconference on a public phone call. Dr. Pelphrey, Dr. Mandell, Ms. Singer, and Dr. Koroshetz volunteered to participate in a small working group to develop a plan for determining whether to use question/objective level estimating the overall budget, and determining how to calculate budget recommendations at the working group level. This small working group's findings can then be shared by email.

Dr. Mandell commented that services and research budget calculations should be treated separately. Most services for people with ASD are provided through existing programs/entitlements. The challenge is to identify the services delivered to individuals with ASD in these programs/entitlements. Dr. Mandell proposed measuring the number of people served within Medicaid, private insurance, public education, and vocational rehabilitation services since people with ASD can be identified in each of these four programs. Dr. Mandell suggested that partners at the table could provide some of the data and do some of these calculations. Dr. Shui-Lin Niu suggested adding the military health system (Tricare) which has detailed data. Dr. Wexler commented that the federal formula grant pays 16-17 percent of the excess cost of education for kids with disabilities and these numbers are used as part of the congressional justification on budgets. Ms. Singer pointed out that the purpose of the Strategic Plan is to focus on what needs to be done, not what has or currently is being done/spent. Most parents will say that their kids are not getting all they need. Dr. Mandell will need to think about how to accomplish this (for example, consider including reasonable estimates of care costs in their budget recommendations). Dr. Gordon commented that they do not have enough estimates on current costs to develop estimates of care. Dr. Daniels commented that they are asked to include services estimates to the extent practicable: so these could be included in a later version if necessary. Dr. Gordon stated that the plan is to move forward on some level of research budget requirements whether or not this version of the Strategic Plan includes services estimates.

Dr. Daniels asked if the Committee wanted to expand the Autism research project data call to try to collect data on federal programs covering various ASD services/service delivery programs; she inquired if it would be useful, for example, to know that ACL has a legal assistance program and have that as a part of a list. Dr. Mandell said it would be useful to know the payers, but did not comment on the usefulness of project data as described. Ms. Kavanagh commented that it would be difficult to get that level of data on services for children with ASD because most services projects and programs do not have breakdowns based on diagnosis. Overall, the committee decided not to request services projects data to be collected in the same manner that data on the research portfolio is collected. Dr. Daniels noted that there is an Autism Report to Congress from HHS due in 2018, and her office could plan to include qualitative data about service programs in that report, as had been done in previous years, in order to provide the committee with more information and updates on services programs.

- **IACC Summary of Advances**

Materials related to Summary of Advances:
ASF: This Year in Autism Research (2016) (PDF – 206 KB)
2016 Summary of Advances Nominations (PDF – 266 KB)

The IACC is required to prepare a Summary of Advances publication that is shared with Congress. The annual IACC Summary of Advances publication identifies the top 20 scientific advances from the year and provides lay-friendly summaries of each study. Throughout the year, the Committee has submitted a number of articles for nomination, and now the Committee needs to begin narrowing down the selections to determine the top 20 articles for 2016. Typically, there is an electronic ballot after the January IACC meeting to identify the 20 advances. The goal for this meeting is to discuss the full list of nominated articles and make additional decisions regarding the selection process. The Committee briefly discussed how to handle “en bloc” nominations from organizations that did not include individual justifications and decided not to include these types of nominations in the future, but instead to encourage members to identify specific articles of high interest and rigor from these lists created by other organizations. It was acknowledged that the rationale for inclusion of articles on other organizations’ lists may not be the same as the criteria used by the IACC, so IACC members should vet further.

The Committee discussed how to handle reviews/commentaries. It was decided to keep them on the consideration list for now and make individual decisions on whether to vote for them.

Summary of Advances:
Question 1: Dr. Gordon suggested keeping Miller et al.[1] on the list since there are not many long term studies on the effectiveness of outcomes and this article includes reasonable numbers.

Eliminate: Dr. Farchione suggested eliminating Xiao et al.[2] because it used data mining to generate their diagnosis model and there are issues with replicability. Dr. Pelphrey suggested eliminating McPheeters et al.,[3] because it is a literature review.

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[1] Miller M, Iosif AM, Young GS, Hill M, Phelps Hanzel E, Hutman T, Johnson S, Ozonoff S. School-age outcomes of infants at risk for autism spectrum disorder. Autism Research. 2016 Jun. [PMID: 26451968]

[2] Xiao X, Fang H, Wu J, Xiao C, Xiao T, Qian L, Liang F, Xiao Z, Chu KK, Ke X. Diagnostic model generated by MRI-derived brain features in toddlers with autism spectrum disorder. Autism Res. 2016 Nov 22. [PMID: 27874271]

[3] McPheeters ML, Weitlauf A, Vehorn A, Taylor C, Sathe NA, Krishnaswami S, Fonnesbeck C, Warren ZE. Screening for Autism Spectrum Disorder in Young Children: A Systematic Evidence Review for the U.S. Preventive Services Task Force [Internet]. U.S. Preventive Services Task Force Evidence Syntheses, formerly Systematic Evidence Reviews. Rockville (MD): Agency for Healthcare Research and Quality (US); 2016 Feb. Report No.: 13-05185-EF-1. [PMID: 26985520]

Question 2: After some discussion of the Nordahl et al.[4] study, the Committee decided to leave it on the list. Dr. Farchione noted that ability to scan children without sedation opens doors for further research. Dr. Koroshetz suggested moving the Werling et al.[5] article from the ASF list to this Summary of Advances Nomination list. He also suggested keeping Parikshak et al.[6] and Orefice et al.[7] Dr. Amaral recommended keeping Marchetto et al.[8] Dr. Gordon recommended keeping Yi et al.[9], which is an exciting study and represents a significant technological advance although he is not sure if it will be a significant advance for autism.

Eliminate: Dr. Pelphrey recommended removing Torres and Denisova[10] because he felt the results of the study are over-interpreted. He also recommended removing Libertus et al.[11] because the study is not focused on autism.

Question 3: Dr. Lawler recommended keeping Dunaway et al.[12] which focuses on epigenomics, and is thorough and systematic. Ms. Crane recommended keeping Eriksson et al.[13] since the results challenged an assumption and can help advance science. Dr. Amaral recommended keeping Zerbo et al.[14] which found no increased risk for autism. It was a very large, well done study.

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[4] Nordahl CW, Mello M, Shen AM, Shen MD, Vismara LA, Li D, Harrington K, Tanase C, Goodlin-Jones B, Rogers S, Abbeduto L, Amaral DG. Methods for acquiring MRI data in children with autism spectrum disorder and intellectual impairment without the use of sedation. Journal of neurodevelopmental disorders. 2016 May 5;8(1):1. [PMID: 27158271]

[5] Werling DM, Parikshak NN, Geschwind DH. Gene expression in human brain implicates sexually dimorphic pathways in autism spectrum disorders. Nat Commun. 2016 Feb 19;7:10717. [PMID: 26892004]

[6] Parikshak NN, Swarup V, Belgard TG, Irimia M, Ramaswami G, Gandal MJ, Hartl C, Leppa V, Ubieta LT, Huang J, Lowe JK, Blencowe BJ, Horvath S, Geschwind DH. Genome-wide changes in lncRNA, splicing, and regional gene expression patterns in autism. Nature. 2016 Dec 15;540(7633):423-427. [PMID: 27919067]

[7] Orefice LL, Zimmerman AL, Chirila AM, Sleboda SJ, Head JP, Ginty DD. Peripheral Mechanosensory Neuron Dysfunction Underlies Tactile and Behavioral Deficits in Mouse Models of ASDs. Cell. 2016 Jun 9. [PMID: 27293187]

[8] Marchetto MC, Belinson H, Tian Y, Freitas BC, Fu C, Vadodaria KC, Beltrao-Braga PC, Trujillo CA, Mendes AP, Padmanabhan K, Nunez Y, Ou J, Ghosh H, Wright R, Brennand KJ, Pierce K, Eichenfield L, Pramparo T, Eyler LT, Barnes CC, Courchesne E, Geschwind DH, Gage FH, Wynshaw-Boris A, Muotri AR. Altered proliferation and networks in neural cells derived from idiopathic autistic individuals. Mol Psychiatry. 2016 Jul 5. [Epub ahead of print] [PMID: 27378147]

[9] Yi F, Danko T, Botelho SC, Patzke C, Pak C, Wernig M, Südhof TC. Autism-associated SHANK3 haploinsufficiency causes Ih channelopathy in human neurons. Science. 2016 May 6;352(6286):aaf2669. [PMID: 26966193]

[10] Torres EB, Denisova K. Motor noise is rich signal in autism research and pharmacological treatments. Sci Rep. 2016 Nov 21;6:37422. [PMID: 27869148]

[11] Libertus K, Greif ML, Needham AW, Pelphrey K. Infants' observation of tool-use events over the first year of life. J Exp Child Psychol. 2016 Dec;152:123-135. [PMID: 27522041]

[12] Dunaway KW, Islam MS, Coulson RL, Lopez SJ, Vogel Ciernia A, Chu RG, Yasui DH, Pessah IN, Lott P, Mordaunt C, Meguro-Horike M, Horike SI, Korf I, LaSalle JM. Cumulative Impact of Polychlorinated Biphenyl and Large Chromosomal Duplications on DNA Methylation, Chromatin, and Expression of Autism Candidate Genes. Cell Rep. 2016 Dec 13;17(11):3035-3048. [PMID: 27974215]

[13] Eriksson JM, Lundström S, Lichtenstein P, Bejerot S, Eriksson E. Effect of co-twin gender on neurodevelopmental symptoms: a twin register study. Mol Autism. 2016 Jan 19;7:8. [PMID: 26793297]

[14] Zerbo O, Qian Y, Yoshida C, Fireman BH, Klein NP, Croen LA. Association Between Influenza Infection and Vaccination During Pregnancy and Risk of Autism Spectrum Disorder. JAMA Pediatr. 2017 Jan 2;171(1):e163609. [PMID: 27893896]

Eliminate: Dr. Gordon commented that the NIMH scientific staff have concerns over Julvez et al.[15] Although the study is large, the findings were somewhat weak statistically. The study results encourage consumption of large fish amounts that could lead to high levels of mercury exposure. Dr. Gordon also suggested eliminating Bennett et al.[16] which is a consensus report, not an advance.

Question 4: Dr. Pelphrey recommended keeping Yang et al.[17]. Dr. Gordon said his staff highlighted Chang et al.[18] as being very good. Dr. Mandel agrees it is strong and should be kept on the list. Dr. Gordon also recommended keeping Hampton and Kaiser,[19] which is a large meta-analysis and adds new information. Dr. Mandel recommended keeping Pickles et al.[20] due to the findings and study design. Ms. Crane recommended keeping the Almirall et al.[21] study which is a study on children and has a good sample size.

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[15] Julvez J, Méndez M, Fernandez-Barres S, Romaguera D, Vioque J, Llop S, Ibarluzea J, Guxens M, Avella-Garcia C, Tardón A, Riaño I, Andiarena A, Robinson O, Arija V, Esnaola M, Ballester F, Sunyer J. Maternal Consumption of Seafood in Pregnancy and Child Neuropsychological Development: A Longitudinal Study Based on a Population With High Consumption Levels. Am J Epidemiol. 2016 Feb 1;183(3):169-82. [PMID: 26740026]

[16] Bennett D, Bellinger DC, Birnbaum LS, Bradman A, Chen A, Cory-Slechta DA, Engel SM, Fallin MD, Halladay A, Hauser R, Hertz-Picciotto I, Kwiatkowski CF, Lanphear BP, Marquez E, Marty M, McPartland J, Newschaffer CJ, Payne-Sturges D, Patisaul HB, Perera FP, Ritz B, Sass J, Schantz SL, Webster TF, Whyatt RM, Woodruff TJ, Zoeller RT, Anderko L, Campbell C, Conry JA, DeNicola N, Gould RM, Hirtz D, Huffling K, Landrigan PJ, Lavin A, Miller M, Mitchell MA, Rubin L, Schettler T, Tran HL, Acosta A, Brody C, Miller E, Miller P, Swanson M, Witherspoon NO; American College of Obstetricians and Gynecologists (ACOG); Child Neurology Society; Endocrine Society; International Neurotoxicology Association; International Society for Children's Health and the Environment; International Society for Environmental Epidemiology; National Council of Asian Pacific Islander Physicians; National Hispanic Medical Association; National Medical Association. Project TENDR: Targeting Environmental Neuro-Developmental Risks. The TENDR Consensus Statement. Environ Health Perspect. 2016 Jul 1;124(7):A118-22. [PMID: 27479987]

[17] Yang D, Pelphrey KA, Sukhodolsky DG, Crowley MJ, Dayan E, Dvornek NC, Venkataraman A, Duncan J, Staib L, Ventola P. Brain responses to biological motion predict treatment outcome in young children with autism. Transl Psychiatry. 2016 Nov 15;6(11):e948. [PMID: 27845779]

[18] Chang YC, Shire SY, Shih W, Gelfand C, Kasari C. Preschool Deployment of Evidence-Based Social Communication Intervention: JASPER in the Classroom. J Autism Dev Disord. 2016 Jun;46(6):2211-23. [PMID: 26936161]

[19] Hampton LH, Kaiser AP. Intervention effects on spoken-language outcomes for children with autism: a systematic review and meta-analysis. Journal of Intellectual Disability Research. 2016 May 1;60(5):444-63. [PMID: 27120988]

[20] Pickles A, Le Couteur A, Leadbitter K, Salomone E, Cole-Fletcher R, Tobin H, Gammer I, Lowry J, Vamvakas G, Byford S, Aldred C, Slonims V, McConachie H, Howlin P, Parr JR, Charman T, Green J. Parent-mediated social communication therapy for young children with autism (PACT): long-term follow-up of a randomised controlled trial. Lancet. 2016 Nov 19;388(10059):2501-2509. [PMID: 27793431]

[21] Almirall D, DiStefano C, Chang YC, Shire S, Kaiser A, Lu X, Nahum-Shani I, Landa R, Mathy P, Kasari C. Longitudinal Effects of Adaptive Interventions With a Speech-Generating Device in Minimally Verbal Children With ASD. J Clin Child Adolesc Psychol. 2016 Jul-Aug;45(4):442-56. [PMID: 26954267]

Eliminate: Dr. Pelphrey recommended eliminating Gordon et al.,[22] which is a replication. Dr. Gordon suggested removing Murza et al.,[23] a meta-analysis that his staff had concerns about (small number of studies reviewed). Dr. Mandell commented that there are a lot of review articles and suggested eliminating all the review articles.

Question 5: Dr. Gordon's staff recommended Mandell et al.,[24] which uses a large sample size, employs a rigorous design, addresses the effects of insurance mandates on treatment use, and identifies more children with ASD.

Question 6: Dr. Taylor recommended keeping the Hirvikoski et al.[25] study highlighted at the October 2016 IACC meeting as well as the Wehman et al.[26] study which had massive employment effects and is a first RCT to show benefits from employment.

Eliminate: Dr. Gordon recommended eliminating the Roux et al.[27] report which was not peer reviewed and was essentially a review and not a scientific advance. Dr. Gordon also suggested eliminating Fernandes et al.,[28] which examined an important topic (sexuality) but the methodology was not that strong and only provided a little bit of new information. He also suggested eliminating Koegel et al.,[29] which had a very small sample size.

Question 7: There was some discussion about whether to keep Hewitt et al.[30] (pros: high incidence rate, cons: small sample, single-site study) however it was decided to keep it on the

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[22] Gordon I, Jack A, Pretzsch CM, Vander Wyk B, Leckman JF, Feldman R, Pelphrey KA. Intranasal Oxytocin Enhances Connectivity in the Neural Circuitry Supporting Social Motivation and Social Perception in Children with Autism. Sci Rep. 2016 Nov 15;6:35054. [PMID: 27845765]

[23] Murza KA, Schwartz JB, Hahs-Vaughn DL, Nye C. Joint attention interventions for children with autism spectrum disorder: a systematic review and meta-analysis. International Journal of Language & Communication Disorders. 2016 May 1;51(3):236-51. [PMID: 26952136]

[24] Mandell DS, Barry CL, Marcus SC, Xie M, Shea K, Mullan K, Epstein AJ. Effects of Autism Spectrum Disorder Insurance Mandates on the Treated Prevalence of Autism Spectrum Disorder. JAMA Pediatr. 2016 Sep 1;170(9):887-93. [PMID: 27399053]

[25] Hirvikoski T, Mittendorfer-Rutz E, Boman M, Larsson H, Lichtenstein P, Bölte S. Premature mortality in autism spectrum disorder. Br J Psychiatry. 2016 Mar;208(3):232-8. [PMID: 26541693]

[26] Wehman P, Schall CM, McDonough J, Graham C, Brooke V, Riehle JE, Brooke A, Ham W, Lau S, Allen J, Avellone L. Effects of an employer-based intervention on employment outcomes for youth with significant support needs due to autism. Autism. 2016 May 5. [PMID: 27154907]

[27] Roux AM, Rast JE, Anderson KA, and Shattuck PT. National Autism Indicators Report: Vocational Rehabilitation. Philadelphia, PA: Life Course Outcomes Research Program, A.J. Drexel Autism Institute, Drexel University, 2016. [http://drexel.edu/autismoutcomes/publications-and-reports/publications/National-Autism-Indicators-Report-Vocational-Rehabilitation/#sthash.ZhrjVYEl.dpbs]

[28] Fernandes LC, Gillberg CI, Cederlund M, Hagberg B, Gillberg C, Billstedt E. Aspects of Sexuality in Adolescents and Adults Diagnosed with Autism Spectrum Disorders in Childhood. J Autism Dev Disord. 2016 Sep;46(9):3155-65. [PMID: 27401993]

[29] Koegel LK, Ashbaugh K, Navab A, Koegel RL. Improving Empathic Communication Skills in Adults with Autism Spectrum Disorder. Journal of autism and developmental disorders. 2016 Mar 1;46(3):921-33. [PMID: 26520148]

[30] Hewitt A, Hall-Lande J, Hamre K, Esler AN, Punyko J, Reichle J, Gulaid AA. Autism Spectrum Disorder (ASD) Prevalence in Somali and Non-Somali Children. J Autism Dev Disord. 2016 Aug;46(8):2599-608. [PMID: 27106569]

list. Dr. Gordon said his staff recommended keeping Christensen et al.[31] which had a good sample size and updates the prevalence rate.

Dr. Daniels asked if the Committee would like to add any studies from the ASF list to the ballot of scientific advances. Dr. Taylor asked the Committee to consider Lai et al.[32] for Question 6, which compares the autism symptoms of 30 men and 30 women, the difference between them, and how people report their autism symptoms, as it relates to depression and anxiety. Dr. Gordon was concerned with the small number of people in the study (60), so it was decided to keep it off the list.

Dr. Daniels indicated that Committee members will receive a ballot via email to vote for scientific advances. Each member is given up to 20 votes. If necessary, there will be a tiebreaker. Dr. Gordon asked people to distribute their votes across all the categories, if possible. After the final selections are made by the Committee, the selected articles will be summarized. Once prepared, the draft publication will be distributed for a brief Committee review, and the final publication will be prepared for release with a target date of April 2017. Nominated articles that are not selected will be listed in the appendix of the publication.

National Database for Autism Research (NDAR) Update

Greg Farber, Ph.D., Director, Office of Technology Development and Coordination, National Institute of Mental Health

The National Database for Autism Research (NDAR) (https://ndar.nih.gov/) is an NIH-funded research data repository that aims to accelerate progress in ASD research through data sharing, data harmonization, and the reporting of research results. Dr. Farber indicated that NDAR was the starting point for the NIMH Data Archive (NDA) (https://data-archive.nimh.nih.gov/). Dr. Farber provided four reasons for data archives: 1.) Data from large numbers of subjects are needed to understand complex conditions such as when exploring genetic and environmental influences; 2.) Aggregating data from different laboratories helps researchers understand similarities and differences in the data and can lead to agreement on common data elements; 3.) Data archiving helps the laboratory improve rigor and reproducibility of their experiments; and 4.) Data archiving allows the research community to evaluate costs and outcomes from different data collection methods.

Data in NDA comes from various sources including NIMH awardees (including NDAR), awards made by other funding agencies, and data from the Adolescent Brain Cognitive Development Study. NDA is a federal data repository. They only contain data from human subjects. The data

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[31] Christensen DL, Baio J, Braun KV, Bilder D, Charles J, Constantino JN, Daniels J, Durkin MS, Fitzgerald RT, Kurzius-Spencer M, Lee LC, Pettygrove S, Robinson C, Schulz E, Wells C, Wingate MS, Zahorodny W, Yeargin-Allsopp M. Prevalence and Characteristics of Autism Spectrum Disorder Among Children Aged 8 Years - Autism and Developmental Disabilities Monitoring Network, 11 Sites, United States, 2012. MMWR Surveill Summ. 2016 Apr 1;65(3):1-23. [PMID: 27031587]

[32] Lai MC, Lombardo MV, Ruigrok AN, Chakrabarti B, Auyeung B, Szatmari P, Happé F, Baron-Cohen S; MRC AIMS Consortium. Quantifying and exploring camouflaging in men and women with autism. Autism. 2016 Nov 29. [PMID: 27899710]

is available to the research community through an application process. Summary data are publicly available at: https://data-archive.nimh.nih.gov.

Dr. Farber reported that NDA houses a large quantity of data: 800 terabytes (1 terabyte is equivalent to the contents of the Library of Congress). The Archive is a two dimensional matrix. Dimension 1 consists of the data dictionaries. Dimension 2 consists of the Global Unique Identifiers (GUID). GUID allows the aggregation of data from the same subject seen at different laboratories without requiring any personally identifiable information (PII).

Data dictionaries are the building blocks of the repository. NDA has 1500+ data collection instruments freely available, and 130,000+ unique elements. These dictionaries are curated by NDA staff. The data dictionary is a key component to improve rigor and reproducibility.

The NDA GUID software allows researchers to generate unique identifiers using information from a birth certificate. The same information generated at different laboratories will generate the same GUID which allows NDA to aggregate data on the same subject even if collected at different laboratories. NDA assigns a Digital Object Identifier (DOI) to each study so authors can deposit data into the NDA and get a unique identifier that can be referenced in a publication.

Dr. Farber concluded that NDA is a useful data archive that makes human subject data discoverable, useful to others, citable, and linked to the literature.

Questions/Discussion:

Dr. Gordon asked how active the community is in using this resource and how is NDA trying to expand usage. Dr. Farber responded that it has taken about 2.5 years to compile enough data to have a meaningful presence in the research community. At any given moment, NDA has 15 -25 people online doing searches. They are waiting for the first paper to make a big discovery using the aggregated data.

Round Robin

Dr. Gordon asked IACC members to share updates from their agencies/organizations on issues of relevance to the Committee.

Commissioner Bishop provided two update from the Administration for Community Living (ACL). First, the President's Committee for People with Intellectual Disabilities' 2017 Report to Congress is focusing on the needs of direct service staff, making sure that they are trained, properly reimbursed, and reducing abuse/neglect in community-based settings (https://acl.gov/Programs/AIDD/Programs/PCPID/index.aspx). The goal is to finalize the report in August 2017. Second: the National Institute on Disability, Independent Living, and Rehabilitation Research (NIDILRR) and the Interagency Committee on Disability Research (ICDR) are working with a number of federal partner agencies to identify successful examples of interagency partnerships. Three planned meetings are scheduled across the United States. One meeting was held yesterday. No dates have been set for the others yet. Information is available on the NIDILRR and ICDR website for details. (http://icdr.acl.gov/ and https://acl.gov/programs/nidilrr/)

Dr. Farchione reported that the FDA will be hosting a Patient-focused Drug Development (PFDD) meeting for people with ASD on May 4, 2017 at the FDA campus. Details are available at http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm347317.htm. Online registration is required. These disease-specific meetings help the FDA develop a better understanding of the patient experience and issues that patients think are important. FDA has conducted 20 patient-focused meetings so far.

Dr. Stuart Shapira reported that the CDC has 3 "lanes" regarding autism. The first focuses on risk factors for the development of ASD through the Study to Explore Early Development (SEED). CDC has a number of studies poised to be published in the coming years to look at risk factors/associated health outcomes. SEED 1 children are now teens, so CDC will be conducting a follow up study (SEED Teen) to understand the trajectory of children with early identified ASD to explore their long term health and other needs, as well as the impact on them and their families. The second "lane" is tracking the prevalence of ASD over time to see how the numbers are moving. CDC will be comparing diagnosis of children (at 8 years old) with ASD using DSM-IV criteria compared to DSM-5 criteria to see the impact on diagnosis. This will be conducted using the Autism and Developmental Disabilities Monitoring Network (ADDM). The third "lane" is to improve the identification of those with ASD and other developmental delays by encouraging families and early providers to monitor developmental milestones through the CDC's "Learn the Signs. Act Early." program. The CDC has released a tool to help parents, educators, and early care providers identify developmental milestones. This tool is integrated into an app so parents can easily track their children's milestones, and the app will include alerts to parents if children are not meeting milestones. The CDC has trained 45 ambassadors in 44 states/territories to integrate Learn the Signs. The CDC is working with the Women, Infants and Children (WIC) program in Missouri to integrate Learn the Signs/Act Early into the WIC program. This is being expanded statewide in Missouri, and the CDC is developing tools for other states given this success.

Ms. Singer asked Dr. Shapira about the process for re-consent for SEED and when they can expect that to be completed. Dr. Shapira replied that part of the SEED project is to re-consent for participation in SEED Teen. The CDC will also receive consent forms to re-consent for the teens' biologics to be integrated into larger studies. They are waiting for final approvals. They should have all approvals by April and then begin enrollment in SEED Teen.

Dr. Taylor reported that they just had an online article published on the results of a small RCT parent advocacy training on how to access services on behalf of a son/daughter. The funding mechanism resulted from the last Strategic Plan.

Dr. Gordon reported that NIMH has a number of good applications for the SERV-ASD program round 2. He hopes to announce more at the next meeting.

Dr. Bianchi reported on an NICHD-funded study on MRI without sedation. This was a study of 600 infants at risk of ASD (having a sibling with ASD). It included early screening and more frequent scans between 3 and 20 months of age to allow better understanding of early brain development in at-risk infants/children.

Ms. Singer reported that ASF's fourth TED-style science conference will occur on March 30th and include TED style talks on a range of critical issues including best practices for housing, modifiable autism risk factors, autism research, and understanding of female protective effects. All talks will be made available as videos online after the event. Information about this year's presenters and topics is available at http://autismsciencefoundation.org/day-of-learning-evening-of-celebration/2017-2/

Dr. Niu, on behalf of Dr. Nicole Williams, reported that the DOD is in the midst of the FY 16 funding cycle and is beginning to roll out FY 17. This includes a small program that is shifting to more translational studies. Their mission now is to make an impact in the community. DOD is studying the military population and helping young adults transition to independence and dealing with employment topics. They are also collaborating on a study exploring ADA and applied behavioral therapy in the military system.

Ms. Kavanagh reported she will be presenting findings from the National Survey of Children's Health that has data about an autism transition research project that they have out in the field.

Ms. Crane reported that the ASAN held an international symposium on supported decision-making and integration into the community and will publish a white paper on this. It will not be a scientific evaluation but will provide a good overview of the types of interventions being used that researchers might want to study.

Dr. Daniels noted the GAO report, *Youth with Autism: Roundtable Views of Services Needed During the Transition into Adulthood*, which describes opinions of subject matter experts on what's needed for transition services, is available at http://www.gao.gov/products/GAO-17-109.She also mentioned the Advisory Committee on Increasing Competitive Integrated Employment for Individuals with Disabilities' September 15, 2016 Final Report was submitted to the Secretary of Labor, the U.S. Senate Committee on HELP, and the U.S. House Committee on Education and the Workforce. The Advisory Committee would like to report on this at a future IACC meeting. (https://www.dol.gov/odep/topics/pdf/ACICIEID_Final_Report_9-8-16.pdf).

Finally, Dr. Daniels shared that Spectrum News published an interview with Dr. Gordon on neural circuitry, *Questions for Joshua Gordon: Circuit Solutions for Autism*, on their home page. The article is available at: https://spectrumnews.org/opinion/q-and-a/questions-joshua-gordon-circuit-solutions-autism/

Closing Remarks

Dr. Daniels provided a recap of the meeting and action items. The working groups will draft Strategic Plan chapters over the next several weeks. Each chapter should be 10 pages or less. Dr. Daniels will follow up with the chairs. Dr. Daniels will be out of town for the next two weeks.

Upcoming activities:

- A budget work group will be convened and share their results with the full Committee.
- A ballot will be sent to the Committee for the Summary of Advances using the new/designated IACC Summary of Advances email address.

If IACC members have any suggestions about future meeting topics, it was requested that they please let Dr. Daniels know.

The next meeting will be held on Wednesday, April 26, 2017 at the NIH Main Campus, in Bethesda, MD.

Adjournment

The meeting was adjourned at 4:08 p.m.