



## **Minutes of the Interagency Autism Coordinating Committee Full Committee Meeting**

**July 19, 2016**

The Interagency Autism Coordinating Committee (IACC, also referred to as “the Committee”) convened a meeting on Tuesday, July 19, 2016, from 9:00 a.m. to 4:45 p.m. in Building 31 on the main National Institutes of Health campus in Bethesda, Maryland.

In accordance with Public Law 92-463, the meeting was open to the public. Bruce Cuthbert, Ph.D., Acting Director, National Institute of Mental Health (NIMH) chaired the meeting.

### ***Participants:***

**Bruce Cuthbert**, Ph.D., *Chair*, IACC, 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 Ball**, Ed.D., B.C.B.A.-D., JB Autism Consulting; **James F. Battey**, M.D., Ph.D., National Institute on Deafness and Other Communication Disorders (NIDCD); **Linda Birnbaum**, Ph.D., D.A.B.T., A.T.S., National Institute of Environmental Health Sciences (NIEHS); **Samantha Crane**, J.D., Autistic Self Advocacy Network (ASAN); **Geraldine Dawson**, Ph.D., Duke University; **Ruth Etzel**, M.D., Ph.D., Environmental Protection Agency (EPA); **Tiffany Farchione**, M.D., U.S. Food and Drug Administration (FDA); **Amy Goodman**, M.A., Self-Advocate; **Shannon Haworth**, M.A., Association of University Centers on Disabilities (AUCD); **Laura Kavanagh**, M.P.P., 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 (NIEHS); **Brian Parnell**, M.S.W., C.S.W., Utah Department of Human Services; **Edlyn Peña**, Ph.D., California Lutheran University; **Louis Reichardt**, Ph.D., Simons Foundation Autism Research Initiative (SFARI); **Robert H. Ring**, Ph.D.; **John Elder Robison**, College of William and Mary; **Alison Tepper Singer**, M.B.A., Autism Science Foundation (ASF); **Stuart Shapira**, M.D., Ph.D., Centers for Disease Control and Prevention (CDC); **Catherine Spong**, M.D., Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD); **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**

Dr. Susan Daniels called the meeting to order at 9:00 a.m. and took roll call. The draft minutes from the April 2016 meeting were approved with no comments or corrections and will be posted to the IACC website as soon as possible after the meeting.

## **Welcome and Opening Remarks**

Dr. Bruce Cuthbert, Acting Director, NIMH, and Chair, welcomed participants to the meeting and said he was looking forward to all the presentations and discussions. He noted that the Committee would hear from Dr. Thomas Novotny, the Deputy Assistant Secretary for Health in the areas of science and medicine and HHS National Autism Coordinator. Dr. Cuthbert introduced Dr. Stuart Shapira of the Centers for Disease Control and Prevention, a new member of the Committee. Dr. Shapira replaces Dr. Cynthia Moore, who is working on the Zika virus. He asked Dr. Shapira to briefly describe his background.

## **Update from HHS Office of the Assistant Secretary for Health**

Dr. Thomas Novotny commented that the U.S. Department of Health and Human Services (HHS) is in the process of mobilizing resources to coordinate preparation of the report on the transition of youth and adolescents with ASD into adulthood required by the Autism Collaboration, Accountability, Research, Education, and Support Act of 2014 (the CARES Act). The Department has assembled a group of experts on autism care, which will meet on August 29 to determine the contents of the report. The goal is to draft the report by the end of the calendar year. An IACC Working Group will provide a robust analysis on transition issues and gaps to address at the federal, non-federal, and state levels. This work is moving as quickly as possible given current resources. Dr. Cuthbert added that NIMH has been working to find resources to help with the report.

## **Updates and Presentations**

### **Autism Policy Update**

***Samantha Crane, J.D., Legal Director and Director of Public Policy, Autistic Self Advocacy Network***

Ms. Samantha Crane explained that the Autistic Self Advocacy Network (ASAN) is the Nation's largest advocacy group by and for autistic people. She described a range of common policy-related complaints among adults with ASD—including a lack of access to quality health care and transition and employment services. There is a need for long-term services and supports, especially those that enable people with autism to live outside of a group or family home.

The [Home and Community Based Services \(HCBS\)](#) Settings Rule of Medicaid implements quality controls for services receiving HCBS funding from the Centers for Medicare & Medicaid Services (CMS). Regarding the Settings Rule, the goal is to require access to non-disability-specific

settings so that individuals have maximum autonomy, respect, and choice. Another goal is to ensure that day services focus on the actual interests, schedule, and needs of the person (i.e., eliminate “mall therapy”). Finally, an aim is to achieve accountability so that service providers cannot simply self-certify as “community-based.”

More than 2 years after CMS issued the rule, the first plans are being approved to help states transition to compliance with the new rule. Tennessee’s plan provides a good example of what will be approved in future. This state did an extensive site evaluation, worked with stakeholders, partnered with other agencies, and created good accountability guidelines. Facility-based day services are time limited and must include training or fulfilling a person-centered plan to achieve community-living and employment goals. The state requires documentation that people with ASD are choosing facility-based services. Ms. Crane also reported developments in supported decision-making legislation (a supplement to guardianship), habilitation services under the Affordable Care Act, the Transition to Independence Act, the Home Care Rule, and Avonte’s law.

## **Discussion**

Dr. Cuthbert asked how states are rewarded under the Transition to Independence Act. Ms. Crane explained that states must propose to be in the project and CMS must approve their applications. States in the demonstration project receive incentive payments if they meet certain benchmarks (e.g., show increases in competitive integrated employment). Incentive payments must be reinvested in community-based programs.

Mr. John Robison appreciated the focus on adult issues. He asked whether aging and younger adults faced similar challenges. Ms. Crane replied that generally, people need more supports as they age, but some concerns overlap (e.g., housing). Some older adults have never lived independently and need to find new housing when a relative dies, for example. Health care for older adults with ASD is also an issue, as is access to family-friendly housing for people with disabilities. Older people, especially those who have spent an extended period of time without paid work, need significant employment support as well as day activities.

Dr. Geraldine Dawson commented that ASAN is doing great work to support the needs of adults. She asked whether the organization partners with other advocacy groups. Ms. Crane responded that ASAN partners with the National Health Law Program, the Autism Society, and Justice and Aging.

## **Autism Society Lifespan-Based Strategy Update**

***Margaret Miller, Vice President of Strategic Advancement, Autism Society***

The Autism Society’s mission is to improve the lives of all affected by autism. Its vision is for individuals and families living with autism involves three key components: 1) to be able to maximize their quality of life; 2) be treated with the highest level of dignity; and 3) to live in a

society in which their talents and skills are appreciated and valued. These three keys are essential to improving the lives of those affected by autism.

Ms. Miller briefly reviewed the Autism Society's strategic planning process. The overall goal was to define how best to assure opportunity and measurable outcome success in quality of life throughout an individual's life. The process was comprehensive, highly inclusive, and transparent. Autism Society staff members examined how best to assure that each person with an autism diagnosis would be able to maximize his or her quality of life every day. Each of the 15 outcomes of the [Strategic Plan](#) supports one of the three keys.

The Strategic Plan strives for consistent outcomes nationwide. It maintains autonomy among the Affiliates to serve their local communities through programs and provides clear language on what the group does and why it matters. The Autism Society will apply the outcomes model to its five Core Services—advocacy, education, information and referral, support, and community. Programs and services are tailored to best serve local communities, provide one of the five Core Services, and advance at least one of the quality of life outcomes.

Lifespan planning is an ongoing cradle-to-grave process in which an individual's needs are anticipated and proactively planned for. It is a vital element in influencing positive outcomes for families and individuals living with autism. Ms. Miller described how the Autism Society supports people with autism and their families through five critical stages of life. She particularly focused on the transition to adulthood, which involves a shift from federally mandated services provided through the school system to adult services. The Autism Society is currently working to build a lifespan planning model that is sustainable, accessible and scalable, and that leverages community partnerships.

## **Discussion**

Mr. Robison commended the Autism Society for taking a more active role. Ms. Miller acknowledged the efforts of Dr. Jim Ball, the former chairman of the Board of Directors of the Autism Society, who helped develop the strategic initiatives. The Autism Society has a committee for each of its strategic initiatives, with priorities including the transition to adulthood, employment, and housing.

Dr. Cuthbert noted that it is helpful to know the Autism Society's particular priorities and asked whether those were nationwide across all affiliates. Ms. Miller commented that affiliates are very autonomous, which is good. Moving forward, the national organization will create programmatic supports and service frameworks that affiliates can implement locally. Affiliates everywhere report that transition, employment, and housing are key issues. The national organization will provide program support in these three areas.

Ms. Shannon Haworth inquired about the Autism Society's collaborations with other non-profits. Ms. Miller remarked that the organization works with Autism Speaks, ASAN, and the

Arc. The Autism Society is entering a more collaborative space to develop milestones and is looking for partners with strong capabilities in outcomes research.

**Simons Foundation Powering Autism Research for Knowledge (SPARK) Update**  
***Pam Feliciano, Ph.D., Scientific Director, SPARK and Senior Scientist, Simons Foundation Autism Research Initiative (SFARI)***

Dr. Pam Feliciano briefly described the new [SPARK](#) initiative, which will develop an ASD research cohort. The team is engaging families and asking them whether they would like to be re-contacted to participate in future studies. Any scientist who wants to recruit from the SPARK cohort in the future will be able to do. Individuals with a professional diagnosis of autism can enroll and provide informed consent online. Participants complete a medical history and describe their diagnosis. They can choose to participate in the genetic component by having a saliva kit mailed to their home to return for sequencing. The goal is to recruit 50,000 participants, and SPARK is working with 21 sites across the country. Recruitment is also taking place through the community via social media. SPARK was launched in April and has consented 17,000 participants to date. About 7,000 have ASD and 80 percent of these participants are under 18 with about a 4:1 male to female ratio. The next steps for SPARK include the return of behavioral and genetic results and the sequencing of thousands of ASD trios. SPARK will begin data releases at the end of 2016.

**Discussion**

Mr. Robison expressed disappointment with the focus on young children and suggested a greater focus on adults. Dr. Feliciano emphasized that SPARK is making significant efforts to recruit adults, and the project is pleased to have already enrolled 1,500 adults. Often, this population is not recognized and difficult to involve in studies. To address this issue, SPARK is working to enroll older adults with ASD, including those in longitudinal cohorts. Dr. Feliciano noted that individuals who are participating in other studies are not excluded from SPARK, but the team does not want to duplicate efforts. So if individuals have provided genetic data elsewhere (there are unique identifiers for this), then SPARK will not re-sequence them.

Mr. Brian Parnell asked whether SPARK accepts Diagnostic and Statistical Manual-IV diagnoses and how diagnoses are verified. Dr. Feliciano commented that the team cannot manually confirm cases, but previous studies using self-report have shown that a high proportion of diagnoses are validated by follow up. Self-report diagnoses are helpful for scaling up the cohort; SPARK will do a diagnosis validation study. Ms. Crane asked whether SPARK has a plan for re-consenting children when they reach adulthood and about notification of genetic markers for associated conditions. Dr. Feliciano remarked that the team is developing a plan for re-consenting young adults. Participants are notified for genetic markers linked to autism only, and the team does not actively look for incidental findings. Ms. Haworth asked about the demographics of the current cohort (e.g., race/ethnicity and socioeconomic status). Dr. Feliciano explained that in order to achieve a high completion rate, SPARK does not ask for this information. The team will distribute a follow-up survey to obtain this information. SPARK

wants to reach underserved communities and plans to reach out to increase enrollment among these groups (including Spanish-speaking individuals).

### **National Autism Indicators Report: Vocational Rehabilitation**

***Anne Roux, M.P.H., M.A., Research Scientist, Life Course Outcomes Research Program***

***A.J. Drexel Autism Institute, Drexel University***

Ms. Anne Roux noted that the National Autism Indicators Report series was supported by the Health Resources and Services Administration (HRSA). Rates of employment for people with ASD after leaving high school are 58 percent. One in four adults with ASD who were disconnected from jobs and education after high school also had no access to services. Vocational rehabilitation (VR) is a major funder of employment services in the United States that is supported by federal and state funds. Grants are given to state VR agencies to implement services for transition-age youth and adults with disabilities. Ms. Roux described the nature of VR services and noted that this is a good area for research because it is associated with a large, national public dataset. Counselors complete standard questions across states about clients, and there is a system for addressing user concerns. However, there is no information directly from people with ASD.

Currently, there is an ongoing national experiment with VR and employment. The Department of Labor is promoting Employment First. Under the 2014 Workforce Innovation and Opportunity Act (WIOA), 15 percent of state VR funds are directed to transition-age youth and there is an extended length of time that youth may receive services. WIOA also addresses sub-minimum wage pay. With WIOA's youth focus, the field needs baseline information to determine whether changes in VR alter outcomes.

Ms. Roux described the data source (Rehabilitation Services Administration RSA-911 2014). Analysis indicated that only 3 percent of people receiving VR services have ASD. Two-thirds of eligible VR applicants with autism received services through VR. On average, VR participants with autism received almost \$5,900 per person in services through community rehabilitation programs. More than half of VR service users with autism exited VR with a job. Almost one-third of workers with autism had on-the-job supports when they exited VR. There is significant variation in the gap between hourly wages for workers with autism exiting VR and all workers across states. Ms. Roux noted that future research will examine service use patterns—particularly the “churn” in and out of VR services—and the interaction between VR and Social Security benefits. The team also plan to study state-and local-level variation and the impact of WIOA state plans.

### **Discussion**

Dr. Cuthbert thanked Ms. Roux for her presentation and stated that it was great that HRSA funded this work addressing an important issue. Mr. Robison noted that some states limit the amount of time in training programs (6 to 8 weeks). People with mild to moderate autism may think that is an unrealistic time for training and opt out of VR. Additionally, finding a living wage is an issue. Programs do not have the type of training that would qualify people for full-time

work. Ms. Roux agreed and commented that WIOA should help improve the situation. A key issue is that there is no national model, and this is an area that warrants research consideration.

Ms. Alison Singer asked whether there were VR data for people with autism and intellectual disabilities. Ms. Roux replied that the analyses reflect people for whom autism is the primary or secondary cause of impairment but do not include those with both conditions. People with both conditions participate in VR services, but it is difficult to track this group. Ms. Laura Kavanagh asked what happens when a VR case closes. Ms. Roux remarked that at the end of 90 days, individuals may receive community rehabilitation services. However, data collection stops when people leave VR programs. Ms. Crane commented that Medicaid home and community based services include supported employment, so there are opportunities for blending funding. Ms. Roux added that VR datasets can be linked with Social Security and Medicaid data to provide more information, but that longitudinal data are needed so that outcomes can be tracked.

**Parents' Perceptions about Supporting Students with Autism to Transition to College**  
***Edlyn Peña, Ph.D., Associate Professor of Educational Leadership and Director of Doctoral Studies, California Lutheran University***

As young people with autism are accessing college more than ever, Dr. Peña, an IACC member and researcher, stated that the purpose of her study was to obtain in-depth information from parents and caregivers about the college transition process. Her research team conducted interviews with 38 parents of people with autism who were either in college or planning for college. The study did not include students with autism themselves, as these individuals were difficult to recruit. She noted that the findings are not meant to be representative of all families, as most participants in this study were white, well educated, and had a high income. This brings up the question: Among young people with ASD, who is getting access to college?

Qualitative data revealed that parents were highly involved and exercised cultural and social capital to assist students with the transition to college. For example, they helped students research postsecondary options, navigated policies for transition and admission, and advocated for access to resources to support students' college success and retention. Parents coached students to navigate college and worked behind the scenes to help their children (e.g., made telephone calls to manage financial aid process). They experienced difficulty finding a balance between supporting their children and encouraging them to be independent. Major challenges included navigating the Federal Educational Rights and Privacy Act (FERPA) and finding supportive faculty. Faculty wants to be supportive but do not have the appropriate training in ASD.

The findings suggest that high school and college professionals should involve parents and their students from marginalized backgrounds to develop cultural and social capital that will enable students to access and succeed in higher education. Colleges should develop proactive partnerships with parents to define relationship boundaries (e.g. FERPA) and implement

professional development for faculty. In their future research, Dr. Peña and her colleagues plan to include the perspectives of people with ASD. More information on this topic can be found on her [website](#).

## **Discussion**

Mr. Robison pointed out that autistic parents may be disadvantaged and unable to help their students to transition into college. Dr. Peña thanked him for bringing this issue to her attention. The study described looked at families that had experienced a successful transition, but future research could include parents on the autism spectrum. Dr. Julie Taylor remarked that the struggle to balance a student's developing independence while providing support is common to all families. This balance involves some complex issues. Research is needed on why in some cases students do not use or take full advantage of supports set up by parents. Dr. Peña remarked that although her study did not explore this issue, other research confirms that students do not always initiate and follow through with campus services. Executive functioning may play a role. Additionally, parents have no role in the faculty-student relationship, and students have difficulty attending office hours or asking for help. Ms. Crane added that students may not want or need the particular supports arranged in advance by parents. She asked whether Dr. Peña's study compared students who lived in dormitories with those living in the community. Dr. Peña responded that the team did not ask specifically about dormitory accommodation, but about two-thirds of participants lived at home. Research is needed on the campus climate for autistic students.

## **Committee Business**

***Susan Daniels, Ph.D., Director, Office of Autism Research Coordination (OARC), NIMH and Executive Secretary, IACC***

## **Update on the IACC Strategic Plan Working Groups**

Dr. Daniels reported that IACC Strategic Plan Working Groups have been formed (see website for roster). Working Groups will meet by telephone between now and October on development of the Strategic Plan Update. All calls will be announced in advance and open to the public for listening. Ms. Julianna Rava from the Office of Autism Research Coordination summarized findings from the analysis of the 2013 ASD research portfolio data collected by the office. The analysis provides detailed information about the ASD research projects funded by both federal agencies and private organizations (19 funders). It informs the IACC and stakeholders about the research funding landscape and trends and helps the Committee monitor progress in fulfilling the objectives of the IACC Strategic Plan. In 2013, total funding on the ASD research portfolio was \$308,850,948 for 1,291 projects (76 percent of funds were from the federal government). About 75 percent of the funding was for projects related to the Strategic Plan objectives, with the remaining directed toward core/other projects.

Analysis of the overall progress in Strategic Plan objectives through 2013 indicates that 44 percent of objectives were fulfilled, 51 percent were partially fulfilled, and 5 percent of



objectives were inactive. Dr. Daniels explained that an “inactive” status means that no projects and no funding are associated with a particular Strategic Plan objective. In some cases, inactive objectives were assessed by the previous committee to be due to reasons such as objectives that were rapidly outdated by progress of the science, or that were not areas that could easily be addressed through funding initiatives. If the recommended budget for a given objective was met and the specified number of projects were completed, then the objective was categorized as fulfilled. If an objective met one condition but not the other, then it was categorized as partially fulfilled.

Dr. Daniels stated that OARC will provide the Strategic Plan Working Groups with the following items to assist in their assessment of progress: a table of objectives, funding, and status of each objective; a full listing of projects for each objective that can be used to identify trends and gaps; and a breakdown of funding and projects according to research subcategories. Dr. Daniels asked the Committee members whether there are any other breakdowns of data that would be helpful to the Working Groups.

Dr. Daniels reported that on behalf of the IACC, the OARC issued a Federal Register Notice soliciting public comment on the research, service, and policy priorities for the topics addressed by the current strategic plan. The Request for Public Comment was issued on June 15, 2016 and is scheduled to close on July 29, 2016. The comments received will be provided to Working Groups by Strategic Plan question and will be made publicly available on the IACC website within 90 days of the closing date. As of July 18, 2016, 827 comments have been received. Dr. Daniels summarized themes from these comments for the committee.

### **Discussion on the IACC Strategic Plan Working Groups**

Dr. Walter Koroshetz recommended that the OARC examine the “other” category of projects not related to Strategic Objectives. Dr. Daniels explained that the data provided in the project listing as well as the subcategory analysis provides information on all projects, including those that fall outside the Strategic Plan objectives. Dr. Dawson suggested that each Working Group should receive a mini-report on progress in the area it is reporting on, including a discussion of barriers to progress. Dr. Daniels explained that there will be a template to guide the committee’s discussion about the data, and it will include those types of issues. Dr. Singer suggested that the chapter chairs meet via telephone mid-way through the process. Dr. Daniels remarked that OARC could schedule a call for the chapter chairs if needed.

Dr. Koroshetz asked whether there was a list of publications attached to ASD grants. Dr. Daniels responded that such a list was not available, and that in the past, though the team had tried to gather such information in 2010, it proved to be difficult for reasons including the low rate of citation of grants in research papers. She said, however, that each Working Group will have the summary of advances documents available and can conduct its own literature search. Dr. Daniels requested that Committee members email her with specific comments on gaps in Working Group expertise. Regarding public comments, Ms. Crane was concerned about the potential for miscategorization of issues. Dr. Daniels commented that OARC staff moved

comments to the appropriate category if they were submitted to the wrong category. IN addition, comments relevant to more than one question were duplicated.

Dr. Daniels noted that because of the Autism CARES Act, the IACC will need to expand the Strategic Plan to cover both research and service provision and policy-related issues. Dr. Dawson remarked that the treatment domain will be difficult to comment on and is distinct from access to treatment or screening. Dr. Daniels clarified that OARC tried to include experts on the Working Groups who could address this issue. Intervention service implementation and access are covered in Question 5, so Question 4 will focus more on the research aspect. The outlines could be revised if necessary, and chairs might identify gaps in expertise among the Working Groups. Dr. Ball suggested including a theory-to-practice section for each chapter in the template. Dr. Daniels responded that OARC had something similar in mind and will consider the suggestion. Mr. Robison suggested that the introduction to the Strategic Plan address the public's concerns about autism, particularly the biggest issues facing parents and families. Dr. Daniels noted that Mr. Robison is drafting an introduction and conclusion and asked other members of the Committee who would like to work on these sections to let her know.

### **Summary of Advances Process**

Each month, the OARC solicits nominated advances from IACC members. OARC compiles advances quarterly and they are discussed at IACC meetings. At end of the year, after the January meeting discussion, the IACC will vote on the top 20. Dr. Daniels asked whether the IACC wants to select a certain number per Strategic Plan Question area or the overall top 20. She also asked whether selected advances should be prepared in a summary format similar to the current document. Dr. Daniels thanked the OARC team for their work in preparing the updates.

### **Discussion on Summary of Advances Process**

Mr. Robison and others favored a simple top 20, as there might not be good results for each question. Dr. Cindy Lawler suggested that the Committee look for balance across topics. Could the Committee members select a bigger number of papers and then choose a smaller set so important areas are not omitted? Dr. Daniels remarked that this might lengthen the process. Dr. Dawson suggested that a group of papers with a similar impact could be written up as one. Dr. Etzel suggested that perhaps papers could be grouped as primary, secondary, or tertiary prevention. Dr. Daniels remarked that introducing a new categorization system might be confusing, as the current Summary of Advances follows the same categorization scheme as the Strategic Plan.

### **Discussion of Nominated 2016 Science Advances**

Dr. Walter Koroshetz nominated Orefice et al. from *Cell* (June 9), which focuses on disrupted sensory systems in mouse models. This paper raises the surprising possibility that people with autism are receiving altered sensory information, which may help guide treatment. Dr.

Cuthbert agreed that this is a good animal model. Dr. David Amaral commented on Nordahl et al. from *Journal of Neurodevelopmental Disorders* (May 5), which addresses methods for acquiring MRI data in children with autism spectrum. Dr. Larry Wexler spoke in favor of four papers related to practical educational matters. Dr. Taylor supported the Wehmann et al. study in *Autism* (May 5), which was a RCT showing that an intensive long-term internship boosts employment among adults with autism.

Ms. Singer nominated the Jokiranta-Olkonemi et al. paper from *JAMA Psychiatry* (June 1) on the risk for other psychiatric disorders among siblings of individuals with ASD. Dr. Amaral favored including a twin registry study on fetal exposure to testosterone and the risk of autism by Eriksson et al. in *Molecular Autism* (January 19). The study found a greater risk to siblings who were female rather than male, which goes against the prevailing hypothesis. Dr. Koroshetz nominated a paper by Yi et al. from *Science* (May 6), which found a connection between a genetic mutation and neuronal channel defects in human cells—perhaps suggesting a mechanism.

### **Oral Public Comment Session**

Ms. Katie Myers, a board certified music therapist and member of the American Music Therapy Association, spoke about the growing body of evidence for music interventions for people with autism. She noted that treatment programs designed and delivered by professionals have improved outcomes (e.g., increased attention, decreased self-stimulation, and enhanced socialization) among people with ASD. She asked for a recommendation to support music therapy researchers in multidisciplinary interagency collaborative work (including neuroscience research) to benefit basic, applied, and translational research as well as applied demonstration projects.

Mr. Albert Enayati, MSME, showed a clip of the 2016 film *Vaxxed*. This film alleges a cover up by the CDC of a purported link between the MMR vaccine and autism. He is the father of a child with autism and stated his belief of a link between the condition and childhood vaccinations. Having addressed the IACC with these concerns previously, he requested that the Committee include the National Vaccine Advisory Council recommendation as a part of its new strategic plan and recommend to HHS that vaccine-autism safety needs to be addressed immediately. Mr. Enayati remarked that the IACC, CDC, and U.S. Food and Drug Administration should work together to address this issue.

Ms. Lori Frome spoke as the parent of a child with ASD and an early intervention provider. She commented on the rapid developmental improvement among her son and seven other children when all electronic media were removed from their environments. Other therapies were continued and parents engaged with their children during time normally spent on screen. Ms. Frome cited research on the link between screen time and developmental problems among children. She recommended additional research on this issue as well as efforts to increase awareness among parents.

Ms. Carolyn Gammicchia spoke as the parent of a 25-year-old man living with autism. Ms. Gammicchia noted that she has addressed the Committee previously with concerns about vaccines and autism. Ms. Gammicchia requested that the IACC revisit this issue. She commented that the CDC's Dr. Coleen Boyle has testified to Congress that there are no studies comparing vaccinated and non-vaccinated children with autism. Ms. Gammicchia remarked that this study should be conducted and replicated. She also suggested that Dr. William Thompson, who alleges that the research on vaccines and autism he participated in at CDC was flawed, should testify before Congress.

Ms. Heidi Scheer spoke as the parent of a son with autism. She discussed the need for research on biomedical treatments for autism. Ms. Scheer remarked that biomedical interventions have changed her son's life for the better, but not everyone can afford these treatments. She requested that research on biomedical treatments be included in the CARES Act.

Ms. Sheryl Melling is the parent of a high-functioning son with autism and a teacher. She pointed to the great need for more training on autism for general educators, as children with ASD are generally mainstreamed. She also remarked that children with ASD often are categorized as having emotional impairment or as defiant. Ms. Melling linked a lack of understanding among educators to punitive treatment of students with ASD. She requested enhanced training on ASD for teachers and aids.

Dr. Eileen Nicole Simon referred to an article in the October 1969 *Scientific American* on damage to the inferior colliculus caused by asphyxia at birth. As this region is part of the brain stem auditory pathway, it may be a plausible explanation for why some children do not learn to speak. Dr. Simon suggested that more research is needed on why the language circuits fail to develop in autistic children as well as why the prevalence of ASD began to increase during 1990s. She noted that her written comments presented ideas on these issues.

Ms. Chiara King, Esq., referred to a study at Johns Hopkins University on excessive folate and vitamin B12 in women's bloodstreams after birth and increased risk of having a child with autism. Current practice recommends folic acid throughout pregnancy, even after the critical period for neural tube defect has passed. Women with genetic mutations that impair folate and B12 metabolism may experience excessive accumulation, which may possibly affect fetal development. Ms. King also mentioned research on folic acid promoting estrogen-sensitive brain development and links with autism. She noted that 90 percent of American women take folic acid during their entire pregnancy and asked: Is this practice worth the risk?

Ms. Lisa Wiederlight, MPP, the parent of a child with autism and Executive Director of Safe Minds, commented that the IACC should be accountable to Congress for making a difference with real outcome measures each year. She noted the many challenges faced by people with autism and their families (e.g., lack of respite for caregivers). Given the rising prevalence of autism, the government response is inadequate, in her opinion. She listed areas for improved research and urged federal agencies to conduct studies on the environmental factors that may

relate to autism, citing report language from the Senate HELP Committee. She asked the IACC to tell Congress how it will address the issues faced by people with autism.

Ms. Adrienne McBride, Executive Director of Madison House, delivered remarks on behalf of the organization's president, JaLynn Prince. She commented that her organization's goal is to help adults with autism (e.g., housing network online resource and arts and employment initiatives). At age 21, people with ASD face many issues related to no longer receiving federally mandated services. Funding is scarce for the most vulnerable, and exiting services are inadequate. Her organization has declared April 21 as Autism Day, and she asked members of the Committee to please mark this observance. Ms. McBride asked the IACC to help change the way services are delivered.

### **Summary of Written Public Comments**

Full text of the oral statements and written public comments is available on the [IACC website](#).

### **IACC Committee Member Discussion of Public Comments**

Mr. Robison commented that the worrying crisis of confidence in the public health system should be addressed, as it makes implementing interventions difficult. Dr. Cuthbert suggested that the IACC should consider how it might present the latest science and in a way that would engender confidence. Dr. Amaral questioned how representative the public comments received are of concerns among the members of the public. He stated that the data suggest that vaccines affect a very small number of children if they are a factor at all. Yet, the field has not been able to successfully communicate these findings to the public in a way that resolves the issue. Members of the committee discussed addressing public concerns about this issue in the Strategic Plan introduction or in a separate document (e.g., white paper). Dr. Cuthbert commented that the clearance process for a white paper might be onerous but possible to complete. Dr. Daniels advised that IACC's work does not have to be approved by any agency because the IACC is an independent advisory body, but the Committee as a whole has to come to consensus or near-consensus on the content of any document that represents the opinion of the committee. Dr. Dawson disagreed that the issue was about communication. There have been many publications and documents on the issue of vaccines and autism, but nevertheless a segment of parents is not convinced. A new document would not necessarily alleviate their concerns. Public commenter Ms. Gammicchia expressed the view that there is a conflict of interest among some members of the Committee because their organizations have patents on vaccines. She also remarked that the current research is not satisfactory to address the issue. In her opinion, new research must be conducted. Dr. Dawson commented that Ms. Gammicchia's view suggests that another summary of the literature will not address the issue. She recommended addressing this issue and a range of other ones brought up in the public comments in the Strategic Plan. Dr. Cuthbert stated that it seemed unlikely that the issue would be resolved immediately and thanked members for their suggestions, which could be taken into consideration.

Members of the IACC also discussed the process for public comments, in response to a request from Dr. Daniels for feedback. As in recent months there were more requests for oral comments than allotted time, she noted that this segment ran over time, reducing time for consideration of written comments and discussion by the committee. She explained that a stricter time limit was communicated to commenters, but the time limits and requests by the chair to curtail comments were disregarded in some cases, resulting in the session going over its scheduled time. The committee discussed potential solutions. Members expressed interest in hearing as many oral comments as possible and getting commenters to stick to time limits, but it was noted that had not been effective. It was suggested that the chair/committee/management could be more aggressive about cutting people off if they passed their time limits, interrupting speakers or shutting off their microphones, but committee members also acknowledged how that can be difficult and seem insensitive when individuals are sharing very personal accounts and impassioned pleas. Dr. Daniels asked if the committee wanted to allow the session for public comments to be longer than one hour in order to accommodate the oral comments without reducing time for written comments and discussion, but the committee agreed that they want to keep the whole session at one hour. Changing from oral comments to submission of comments by video instead was suggested. Dr. Daniels remarked that this could be considered, but might be too labor-intensive to manage. She stated that she would explore the feasibility of options and try to implement a potential solution for the next meeting.

## **Panel on Challenging Behaviors in Autism**

### **Behavioral Interventions for Anxiety and Irritability in Children and Adolescents with Autism Spectrum Disorder**

***Denis Sukhodolsky, Ph.D., Assistant Professor, Yale Child Study Center, Yale School of Medicine***

Dr. Denis Sukhodolsky reviewed the core symptoms and associated features of ASD. About 40 percent of children with autism have co-occurring anxiety. Although the assessment of anxiety in this population is difficult, people with ASD can have an anxiety disorder. A well-established treatment for anxiety is cognitive-behavior therapy (CBT). In the component of exposure and response prevention, people face what makes them anxious and learn to change their responses to it. This approach is also effective among children with autism. A literature review showed large effect sizes, and children self-report that the treatment is helpful. However, a sizable number of children with ASD and anxiety do not respond to this therapy for as yet unknown reasons. It is important to study the neural mechanisms of CBT for anxiety among children with ASD.

A study that used functional magnetic resonance imaging (fMRI) before and after CBT for anxiety among children with ASD found a reduction in amygdala activity during a task of viewing unpleasant images either passively or when considering them as fake. Dr. Sukhodolsky and colleagues also observed increased activity in the dorsolateral prefrontal cortex and anterior cingulate during emotion regulation. This may serve as a biomarker, and the team is

conducting a randomized controlled trial.

Some children with ASD also have disruptive behaviors (e.g., anger outbursts, tantrums, aggression, and self-injury) that are described as irritability and are related to noncompliance with parental requests. Dr. Sukhodolsky described the role of core ASD symptoms in the expression of irritability. He and Lawrence Scahill have developed a manual describing [CBT for irritability in children and adolescents](#) in typical development. In a recent small trial of this treatment, Dr. Sukhodolsky and colleagues found a 65 percent reduction in irritability and an increase in activity in the prefrontal area of the brain (which is associated with emotional regulation) among children with ASD.

The Research Domain Criteria (RDoC) approach offers a valuable framework for studying common and unique characteristics of children with ASD compared with children who have other forms of developmental psychopathology. The team is conducting a study of CBT for aggression/irritability that includes children performing neurocognitive tasks of emotion regulation and face perception during fMRI scanning. The team has identified neural targets of behavior therapy for irritability. Understanding the neural targets of CBT will enable improvement of existing treatments and the development of novel interventions for children with ASD. Dr. Cuthbert noted that this study reflects the new NIH principle of supporting research that determines the mediators of behavioral outcomes.

**James Bodfish, Ph.D., Professor and Director of Research, Department of Hearing & Speech Sciences, Vanderbilt University School of Medicine**

Dr. James Bodfish focused on a core feature of autism—repetitive inflexible behaviors—and how they drive challenging behaviors (e.g., “meltdowns,” wandering, self-injury, and aggression). He described two models for understanding these behaviors. Currently, Dr. Bodfish and colleagues focus on identifying aspects of repetitive behaviors that drive the core features of autism. On a daily basis, many parents report that preoccupations and intense unusual interests are among the most challenging ASD symptoms. These are common and unique to ASD and are not associated with social impairment or intelligence.

Dr. Bodfish proposed that an addiction-like model (i.e. the “co-opting” of adaptive reward processes) may explain circumscribed interests and challenging behaviors in ASD. Applying this model ASD, nonsocial interests develop early and increase in intensity with age. The intense interests narrow the range of potential other experiences (including social experience). This results in a “motivational toxicity” so that as the idiosyncratic interest grows, interests in other areas may diminish. Mood and behavior problems may evolve as a reaction to interrupting intense interest, which can further restrict experiences.

Because imaging is not a viable biomarker for preoccupations, the team has examined an exploration task with an imbedded eye tracker. This task involves showing the respondent social and nonsocial images. There are no instructions for the task—which is feasible for infants, toddlers, and minimally verbal individuals. The researchers have found that the attention of

people with autism is driven to nonsocial images and that this nonsocial bias increases with age. The researchers are working to develop a preclinical model based on these findings that will support genetic analysis and drug screening. The researchers are at the proof-of-principle stage for this idea. The researchers have also developed a family-implemented intervention that begins with the child's specific interests and gradually broadens them.

## **Discussion**

Mr. Robison said he appreciated some of the ideas presented, but encouraged Dr. Bodfish to consider that people with ASD have mixed disability and gift. Characterizing preoccupations as "broken" is unhealthy, and perhaps it is best follow natural interests. Dr. Bodfish replied that it was not his intent to categorize preoccupations; rather his interest is in quantifying this behavior. In response to Mr. Robison, Dr. Amaral noted that his point was well taken, but it is taking time for scientists to adapt their terminology (e.g., from "abnormal" to "altered" or "different" or "atypical"). Ms. Crane remarked that people with ASD will have a higher distress tolerance if told they can engage in their special interest later rather than simply taking it away. Dr. Cuthbert added that the focus is on developing better ways to measure and quantify repetitive behaviors to better understand ASD, just as we have gradations of blood pressure.

## **Frank Symons, Ph.D., Distinguished McKnight University Professor, Department of Educational Psychology, University of Minnesota**

Dr. Frank Symons commented that his team's research focuses on self-injury regardless of diagnostic category and that almost all of their study samples are non-verbal. Therefore, the research presented is not necessarily specific to autism. There are fundamental knowledge gaps regarding the pathophysiology of self-injury. Estimates of self-injury prevalence vary widely and the mechanisms are currently unknown. There is a lack of evidence on effective interventions despite the high cost and morbidity. Dr. Symons reviewed general conceptual models of self-injurious behavior.

A common assumption of the neurological model is that people who self-injure have an insensitivity to pain or increased pain thresholds. However, evidence suggests that self-injury is related to *increased* sensitivity. Self-injury is also associated with altered autonomic and immune activity. In their research, Dr. Symons and colleagues have compared the peripheral nerve morphology among people who self-injure *in non-self-injury sites*. They have observed an absence of peripheral innervation and altered epidermal nerve fiber density among people who self-injure. Other alterations included levels of substance P (which is important in the pain pathway), immune activity, and mast cell degranulation. People who self-injure also show modified quantitative sensory thresholds to a variety of stimuli. However, some individuals who self-injure show very dense innervation—so there seem to be extremes in epidermal nerve fiber density among this population.

## **Discussion**



Dr. Cuthbert asked about adolescents who self-injure, noting that this behavior is associated with borderline personality disorder and other psychiatric conditions. Dr. Symons remarked that the focus of his research is on adults. Dr. Wexler asked whether there was research to test the hypothesis that self-injurious behavior is enjoyable. Dr. Symons replied that there are neurochemical models of self-injury related to dopamine, serotonin, and opioids. There is also a reward/addiction model. Ms. Crane added that some form of self-injury is common throughout the spectrum and is believed to be a response to stress despite feeling the pain. Dr. Cuthbert noted that people with borderline personality disorder feel pain but often experience an increase in nervous tension that self-injurious behavior temporarily relieves.

### **Round Robin**

Dr. Cuthbert updated participants on the NIMH ASD-PEDS Network, which is comprised of five large-scale studies on early identification of ASD and linkage to treatment and services. The Network held its second annual in-person meeting on June 15 to discuss questions raised by the United States Preventive Services Task Force on ASD screening. Dr. David Mandell met with a group to discuss an implementation strategy and ASD services research. NIMH has reissued two ASD lifespan announcements and reviewed applications in the transition-age youth and adult services area. The Institute anticipates that several applications will be funded. Applicants who are not funded may revise and resubmit.

Dr. Dawson briefly reviewed the most recent International Meeting For Autism Research (IMFAR), which convened May 11 to 14 with more than 2,000 participants. IMFAR is sponsored by the International Society for Autism Research (INSAR). This year's program featured about 1,400 presentations and posters. The 2015 INSAR annual report can be downloaded from its [website](#). Dr. Dawson reported that INSAR's first meeting in China was a success. INSAR has recently reviewed its strategic initiatives, adding two new ones: (1) disseminate science-based knowledge to inform policy and practice and (2) foster communication between autism researchers and individuals affected by ASD. The 2017 IMFAR will be in San Francisco, California on May 10 to 13.

Dr. Alice Kau of the National Institute of Child Health and Human Development, updated the IACC on the [NIH Autism Centers of Excellence \(ACE\) Program](#). The Program released a Request for Applications with a November 17, 2016 deadline. Five NIH Institutes and Centers have collaborated to fund grants that will build on ACE's research progress. NIH intends to fund innovative interventions and services research across the lifespan, as well as studies on the neurobiological basis of phenotypic characterizations of ASD.

Dr. Shapira of the CDC spoke about the [Study to Explore Early Development \(SEED\)](#), a multi-site collaboration to examine the environmental and genetic risk factors for ASD. To date, more than 5,000 participants have been enrolled; several key papers have been published. CDC recently funded Phase 3, which continues ongoing work and will involve a follow up of children enrolled in Phase 1 (who will be in their early teens). In Phase 3, participants will be re-consented for genetic analysis.

Dr. Wexler reported that the U.S. Department of Education has developed 27 modules for professionals who work with students with ASD. The modules describe evidence-based practices, are designed for general and special educators, and apply to the full age span (infants through aged 22). They are free, and the modules and supporting materials can be downloaded from the Department website. A continuing education track is available for the modules.

On behalf of Ms. Laura Pincock of the Agency for Healthcare Research and Quality (AHRQ), Dr. Daniels provided an update on activities. AHRQ is conducting systematic review updates on medical and sensory therapies for children with ASD. There will be two reports. Ms. Pincock will notify the IACC when public comments are open in August.

Dr. Farchione reported that FDA will convene patient-focused drug development meeting on ASD. The date has not yet been confirmed, but it will most likely take place in May 2017. At these meetings, FDA hears the patient perspective on drug development research and writes a reference document for pharmaceutical companies and researchers.

### **Closing Remarks**

Dr. Daniels asked members of the Committee to send her ideas for speakers and topics for future meetings. Dr. Cuthbert thanked presenters for providing a diverse and interesting set of topics for discussion. He also thanked members of the public who submitted comments and remarked that the IACC hopes to address concerns. The next IACC meeting will be on October 26 on the NIH main campus.

### **Adjournment**

The meeting was adjourned at 4:45 p.m.