

## **Conference Call for Interagency Autism Coordinating Committee (IACC) Scientific Workshop Panel Four**

Strategic Plan Questions IV: *"Which treatments and interventions will help?"*

Tuesday, September 22, 2009

**Call Participants:** Dr. Thomas Insel (Co-Chair), Dr. Stephen Shore (Co-Chair); Panelists: Dr. Joyce Chung, Dr. Bryan King, Dr. Edwin Cook, Ms. Sharisa Kochmeister, and Dr. Robert Hendren; Dr. Susan Daniels (Office of Autism Research Coordination (OARC) Staff)

### **Summary:**

Dr. Insel, co-chair, began the conference call by informing the panelists of the items to be covered in the call. This included the following five areas; 1) comments from the previous phone call (September 18, 2009), including discussion of the notes distributed by Dr. Eric Samstad, a panelist who was not present; 2) review of the Request for Information (RFI) comments; 3) discussion of items deferred from the 2009 version of the Strategic Plan; 4) review of modifications to the text of the Strategic Plan; and 5) comments on the draft slide presentation.

The panel discussed the previous phone call and noted that many of the points raised there were mentioned in the RFI comments. One issue the panel needed clarified was how to address the cross-cutting nature of many of the themes found in Question IV. Dr. Daniels informed the panel that the Scientific Workshop would be the best place to address this area, as all 30 panelists (1-5) would have an opportunity to discuss each of the presentations in a designated session immediately following each panel slide presentation.

The panelists remarked that an excellent job had been done in assembling all the materials, especially the RFI, and then began a discussion of a number of items that were highlighted in the public comments. The first prominent issue discussed was the diversity of opinion expressed in the RFI, and the difficulty of creating a strategic plan that incorporates the different viewpoints. The panelists noted a consistent voice throughout the RFI regarding inclusion in research studies of both non-verbal people with ASD and people with "low-functioning" forms of autism, as well as the development of interventions specifically targeting communication. Dr. Cook commented that the current Strategic Plan is viewed by many to be biased towards people with high-functioning autism in terms of its approach to research and interventions. The panel decided that the plan needs to highlight the unique needs and issues related to sub-populations of people with ASD who are non-verbal, and the people with ASD who are considered low-functioning. It was also emphasized that non-verbal is not synonymous with low-functioning – that communication disability and intellectual disability are separate issues that often get lumped together, but that are distinct from one another. The panel also agreed that communication and intellectual disabilities need to be distinguished during assessment, and that efforts should be made to assess the level of each type of impairment separately. The panel agreed that "low-functioning" and "non-verbal" are not adequately descriptive terms to describe these populations.

The panel discussed another theme found in the RFI, to add a metric to measure “real life” outcomes rather than just rating scale based outcomes. This topic was noted to be especially important in providing information on interventions, and how they function in the community. Ms. Kochmeister mentioned the term “Quality of Living Skills” as a possible moniker in labeling these outcome measurements.

Dr. Insel summarized several themes the panel noted about the RFI, including focusing on the inclusion of the non-verbal ASD population in research studies; providing interventions that target communication; developing interventions relevant across the entire ASD spectrum; replacing the term “Low-Functioning Autism” with “spectrum of functioning”; and addressing any issues related to assessment.

One other topic discussed was how to provide an up-to-date clearinghouse of information on ASD research and evidence-based interventions to the public. The panelists agreed that this is an important research area, but did not develop a proposed solution to include in the Strategic Plan.

Dr. Chung raised a concern that the deferred topic (from the deferred topics list provided by OARC) of establishing a tracking registry was unclear. Dr. Chung was also concerned that registries, in general, do not include background information on the subjects, thereby limiting their usefulness. The panel discussed the possibility that established databases/projects such as the National Database of Autism Research (NDAR) and Clinicaltrials.gov, could serve in this capacity. Dr. Insel noted that ClinicalTrials.gov will soon begin requiring the registration of all clinical trials and their results. Dr. Chung said that she felt that the deferred item was referring to something more like the IAN database. Finally, Dr. Insel suggested that this topic be included in the Research Opportunities, and that its utilization of data from Clinicaltrials.gov and NDAR be included parenthetically.

Dr. Insel informed the panel that he and Dr. Shore had produced a draft of the panel’s workshop slide presentation and had requested feedback. It was noted that topics discussed in the present call were missing from the draft. The panel decided to add bullets to Slide 3: Noted Gaps in the Strategic Plan, on the inclusion of the non-verbal ASD population in research studies, the development of interventions that assist in communication, the need to capture real-world outcome measures, and the use of registries to aggregate data across ASD studies.

Dr. Chung noted that Slide 4: New Opportunities, Bullet #1, should be expanded to include technology that is not related to communication, such as the use of virtual reality or robotics to teach social skills, etc. She also said that Slide 4, Bullet #3 should include markers beyond the biological such as cognitive skill and working memory, and Slide 4, Bullet #4 should not be limited to just Fragile X, but just use Fragile X as an example in parentheses. The panelists also discussed that Slide 4 Bullet #2 needed more detail, specifically to provide examples of treatment comparisons in real-life settings, as well as the use of database mining in outcomes assessment. The panel decided that these points should be incorporated in to the bullets as parenthetical statements.

In their discussion of the Slide 5: Prioritizing the Short and Long Term Objectives, the panel debated the use of the term biosignatures versus predictors, as well as inclusion in all clinical trials to assist in the

development of personalized care. Other measures mentioned were real-life outcomes, such as quality of life and functioning. The panelists recommended that Slide 5, Bullet #1 be rewritten, to strike the word “collapse” in favor of “integrate”, to change the term “biosignatures” to “predictors”, and to add the outcome measurements of quality of life and functioning. They also emphasized the need to write out the objectives in the slides rather than refer to them by number, as the audience at the Scientific Workshop may not be able to follow the numbering scheme easily.

The panel’s other recommendations included the addition of an outcomes measurement to Short-Term Objective #2: randomized control trials (RCT) for interventions for co-occurring medical conditions, and the grouping of Short-Term Objectives #2, #3: RCTs for interventions for infants/toddlers, and #4: RCTs for interventions for school-aged children/ adolescents/ adults, under a single heading of “Launch RCTs in the following areas...”.

Dr. Daniels informed the panel that it was not the panel’s responsibility to provide appropriate budgetary figures for the new objectives. The panel did note that if Short-Term Objective #4 is modified to include adults, as is recommended, that the number of desired studies listed (3) might be too few.

The panel concluded their review of the draft slide presentation by recommending the inclusion on Slide 6: Summary and Discussion Questions, of a focus on the heterogeneity of ASD across the lifespan, and the inclusion of a quality of life metric as the outcomes assessment. The panelists nominated Dr. Shore to be their panel presenter at the Scientific Workshop.

The meeting closed with thanks to the group for their participation, an encouragement for the panel to continue to think about issues related to any question of the Strategic Plan, and that all panelists would have an opportunity to share any new ideas at the Scientific Workshop. The Scientific Workshop is scheduled to take place at the North Bethesda Marriot (Bethesda, MD) on Wednesday, September 30, 2009 and Thursday, October 1, 2009. The Panel 4 discussion will begin at 9 a.m. on Thursday, October 1, 2009

#### ACTION ITEMS:

- Revise draft slide presentation from the meeting summary and distribute to all panelists (Dr. Insel, Dr. Shore)
- Review draft presentation (All Panelists)
- Submit final presentation to Dr. Susan Daniels no later than 12:00 p.m., Monday, September 28, 2009 (Dr. Insel, Dr. Shore)