

## **PIPC/AAPD Roundtable Summary**

### **Participants:**

- Tony Coelho, Partnership to Improve Patient Care
- Sara van Geertruyden, Partnership to Improve Patient Care
- Mark Perriello, American Association of People with Disabilities
- Henry Claypool, American Association of People with Disabilities
- Colin Schwartz, American Association of People with Disabilities
- Mary Andrus, Easter Seals [via telephone]
- Mary Lou Breslin, Disability Rights Education and Defense Fund [via telephone]
- Kelly Buckland, National Council on Independent Living, [via telephone]
- Diane Coleman, Not Dead Yet [via telephone]
- Connie Garner, United Cerebral Palsy
- Donna Meltzer, National Association of Councils on Development Disabilities
- Theresa Morgan, ITEM Coalition [via telephone]
- Rhonda Neuhaus, Disability Rights Education & Defense Fund
- Angela Ostrom, Epilepsy Foundation of America
- Clarke Ross, American Association on Health and Disability
- Lili Siegel, Senate HELP Committee
- Anne Sommers, National Council on Disability
- Andrew Sperling, National Alliance on Mental Illness
- Julie Ward, The Arc
- Julia Wartenberg, American Foundation for the Blind
- Romana Hasnain-Wynia, Patient-Centered Outcomes Research Institute
- Chad Boulton, Patient-Centered Outcomes Research Institute
- Alexis Estomin, Patient-Centered Outcomes Research Institute

### **Background:**

In August, 2012, the Patient-Centered Outcomes Research Institute (PCORI) began convening a series of meetings with disability patients and advocacy groups. At the third most recent meeting held by PCORI in January, 2013, the group of people with disabilities and their advocacy organizations met with researchers from the disparities and health systems priority areas at PCORI. The conversation resulted in agreement that the individuals in the disability community

would collaborate to develop recommendations that PCORI could use to develop research contracts beneficial to the disability community.

The Partnership to Improve Patient Care (PIPC) and the American Association of People with Disabilities (AAPD) decided to convene a roundtable representing people with disabilities in an effort to provide PCORI with consensus recommendations. In that effort, roundtable attendees convened on June 10, 2013 at the offices of AAPD to explore potential areas of consensus. PCORI researchers were present to outline the parameters for the research projects that PCORI can fund, as well as the process for working with PCORI.

### **Introductions:**

In the introductory session, roundtable participants were given an opportunity to describe the past participation of their organizations with PCORI, and the issues they perceived as being most important for comparative clinical effectiveness research related to people with disabilities. The following general areas were highlighted as important to people with disabilities:

- Integration of acute services and long-term services;
- Promoting research looking at outcomes for people with disabilities in the context of leading productive lives in the community, with a focus on patient needs and preferences, rather than just biomarkers;
- Information access;
- Access to health care services;
- Long-term services and supports, and accompanying quality measures;
- Dissemination
- Medical comorbidities for people with serious mental illness;
- Challenges of designing effectiveness studies, particularly randomized clinical trials when that may not be feasible or ethical;
- The connection between access to the right device or intervention and improvement in health outcomes and maintaining or improving functional abilities for people with long-term disabilities; and
- Withholding of lifesaving and life-sustaining treatment from people with disabilities and the need for more informed consent procedures and civil rights protections in medical settings, as well as self-direction over the choice and implementation of services and supports.

Henry Claypool provided the group with a description of the activities of the Office of Disability at the Department of Health and Human Services (HHS). He noted HHS success in securing

nearly \$6 million in research funding for integrated care. He further highlighted the work of Mathematica. Subsequently, Mr. Claypool worked with Howard Koh on an action plan to address health disparities, and quickly discovered the challenge of using a disparities framework for such a heterogeneous population. While using a disability health disparities analysis is important in understanding gaps in care and defining health outcomes for people with disabilities as compared with the general population, the advocacy community should take on more discrete activities rather than combining them together under the disparities framework. Therefore, he suggested a focus on access to services and barriers to care, particularly related to issues such as mobility impairments, mental health, sensory and communications impairments, and access to dental care for people with intellectual and developmental disabilities.

### **PCORI Presentation:**

Dr. Romana Hasnain-Wynia began PCORI's presentation by describing the institute's activities. She noted that PCORI is a funding agency uniquely focused on comparative effectiveness research that truly focuses on patients and patient engagement, while also focusing on methodology so that research is credible to be disseminated. She highlighted the importance of focusing on outcomes that matter to people with disabilities, and how to integrate people with disabilities into all of the research funded by PCORI. She described PCORI's work in health disparities as not identifying disparities, but rather in addressing and reducing disparities. And she noted the broad view of disparities embraced by PCORI so that it addresses all populations at risk and recognizes that the categories of disparities are not mutually exclusive (for example, a person can be Hispanic living in a rural community with a disability). She then noted it is difficult to monitor what you cannot measure, which is a barrier to making the health system accountable.

She was also questioned on the distinction between defining disparities based on prevalence versus defining disparities based on access to care, and her response demonstrated that PCORI recognized that access and quality of care is where the disparity takes place.

Dr. Chad Boulton noted that PCORI is statutorily mandated to compare one approach to another in terms of outcomes that people care about – such as quality of life. He specifically noted the following fields of research that fall under his area of improving health care systems:

- Optimizing health information technology;
- Workforce deployment;

- Incentives that drive behavior, which he described as potentially looking at how a patients’ quality of life or functional independence differs when their providers are rewarded for certain behaviors; and
- “Special programs” like care management for people that have particular difficulties navigating the health care system.

Dr. Boulton provided the group with a description of the broad funding announcement process for submitting funding applications to PCORI, also known as the investigator-initiated process. He then described the targeted approach to funding led by ad hoc workgroups and advisory panels appointed by PCORI.

PCORI was encouraged by the roundtable participants’ interest in bridging the gap between “person-centered” approaches and “patient-centered” approaches, because there are community-based interventions that are also effective in a manner consistent with the views of a clinical researcher. Dr. Hasnain-Wynia noted that the broad funding announcement for the disparities priority area expresses interest in qualitative research that is comparative. She described a particular project funded by PCORI related to people with disabilities that studied the development of an instrument that compares the quality of care for people with disabilities to people without disabilities to identify the triggers for lower quality of care.<sup>1</sup>

Dr. Boulton referred to five proposals funded by PCORI for people with disabilities; one in particular called Patient-Centered Approach to a Successful Community Transition After Catastrophic Injury<sup>2</sup> that engages patients and families to design an intervention, then evaluates the effects on self efficacy, self management, and satisfaction with care – compared to existing practices or usual care. If the study improves outcomes, PCORI plans on disseminating the findings nationwide.

Dr. Boulton went on to describe the “engagement awards” intended to match patients and researchers—known now as the “Pipeline to Proposals”—which PCORI formally announced in the days following the roundtable. He described the Pipeline to Proposals as a potential avenue for the community of people with disabilities to move forward a proposal for funding.

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<sup>1</sup> <http://www.pcori.org/pfaawards/researching-the-effectiveness-of-a-decision-support-tool-for-adult-consumers-with-mental-health-needs-and-their-care-managers/>

<sup>2</sup> <http://www.pcori.org/pfaawards/a-patient-centered-approach-to-successful-community-transition-after-catastrophic-injury/>

Dr. Hasnain-Wynia described past challenges with broad funding announcements, citing difficulties of identifying applications that were both scientifically rigorous and patient-centered. She emphasized her efforts to immediately look at the budget of a proposal to identify whether it truly engages patients. Chairman Coelho noted the past bias among research agencies to rely on researchers to decide the topics for research, as opposed to patients. Dr. Hasnain-Wynia assured the roundtable that PCORI was fully committed to patient engagement, without sacrificing its rigorous standards.

In discussing the process moving forward, it was made clear that the community of people with disabilities is supportive of connecting with researchers as long as those researchers are committed to meaningful patient engagement on topics that matter to the patients themselves. Dr. Boulton described the operational process for reviewing and funding applications to ensure patient engagement:

- Reviewers are trained to look for evidence of patient and stakeholder engagement in the applications;
- Proposals must outline how patients and stakeholders are engaged, including the engagements techniques being outlined in the project's budget; and If funded, PCORI has the ability to stop the funding if the applicant is not meeting milestones for engagement, such as evidence of stakeholder advisory committee meetings.

In response to a discussion about existing alliances that may want to submit an application to PCORI, PCORI assured the group that there are also webinars available online to educate potential applicants on the broad funding announcement process.

### **Outcomes that Matter to People with Disabilities:**

In discussing outcomes that matter to people with disabilities, independence and self-determination were key themes, as was the challenge of identifying employment as an outcome. Participants also expressed concern for the medical model's focus on the term "patient" as opposed to a more whole person focus. Throughout the roundtable discussion, there was criticism of the academic institution's bias and lack of appreciation for what matters to people with disabilities. An example was described whereby academic researchers conducting satisfaction surveys among people with mental illness preferred allowing the interviews to be conducted by a PhD researcher, as opposed to peer-to-peer interviews using consumer and family monitoring teams that are proven to be more effective. And while the issue of mortality was also highlighted as a typical focus for researchers, the non-consensual withholding and withdrawal of life-sustaining treatment from people with disabilities by surrogates and/or providers has not

been adequately researched, even though this particular cause of mortality has been identified in multiple states by the disability protection and advocacy system.<sup>3</sup> In addition, participants expressed the importance of focusing on quality of life, including the ability to live in the housing and community of the person's choice, underscoring the need for better recognition of outcomes that matter for people with disabilities, as well as the need for better data development.

The roundtable participants focused in large part on the outcomes that matter to people with disabilities as developed by Mathematica<sup>4</sup>, as well as the quality measures developed by the National Quality Forum related to long-term services and supports. These were viewed by roundtable participants as largely reflecting the quality of life metrics that should be part of research looking at health care outcomes, except that the prerequisite of “continuation of life” should also be added.

### **Study Designs and Methods:**

In a conversation related to rigorous study designs and methodologies, Dr. Hasnain-Wynia referenced work in mental health services regarding minority communities that utilized a qualitative methodology.<sup>5</sup> She noted that PCORI could support a research project utilizing a qualitative methodology that has been published, vetted and shows a good track record, especially to address a question for which there is not an established database. Dr. Boulton reiterated that PCORI’s Methodology standards, as approved, include qualitative methods.<sup>6</sup> Dr. Hasnain-Wynia also clarified that PCORI is interested in implementation research, including comparative studies that look at implementation particularly in the area of disparities.

Dr. Hasnain-Wynia also clarified that PCORI is interested in studying multiple outcomes, therefore proposals do not have to focus on one topic only. Moreover, there was recognition that PCORI is not authorized to do work on cost-effectiveness, and therefore proposals put forth to PCORI should not be articulated in that context.

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3 Devaluing People with Disabilities: Medical Procedures that Violate Civil Rights, [http://www.ndrn.org/images/Documents/Resources/Publications/Reports/Devaluing\\_People\\_with\\_Disabilities.pdf](http://www.ndrn.org/images/Documents/Resources/Publications/Reports/Devaluing_People_with_Disabilities.pdf)

4 [http://www.mathematica-mpr.com/publications/pdfs/health/comparative\\_care\\_rschrbrief.pdf](http://www.mathematica-mpr.com/publications/pdfs/health/comparative_care_rschrbrief.pdf) page 3

5 <http://www.multiculturalmentalhealth.org/cered.asp>

6 <http://www.pcori.org/assets/PCORI-Methodology-Standards.pdf>. In the section labeled AT4, PCORI states, “In simple adaptive trials, qualitative verification of the capabilities of the proposed trial infrastructure may be adequate.” The section labeled RQ6 states, “Measure Outcomes that People Representing the Population of Interest Notice and Care About.”

## **Data and Infrastructure:**

PIPC Chairman Tony Coelho noted the persistent challenge of data for people with disabilities. Dr. Hasnain-Wynia responded that the meaningful use regulations should be helping to generate more information on people with disabilities, although it may not yet be a reliable source of information. In the context of data development, Dr. Hasnain-Wynia described a potential project that PCORI could consider to define the population of people with disabilities as part of a comparative effectiveness project, so the collection of information leads to better outcomes. Dr. Boulton responded to the issue of data as potentially being related to PCORI's work on methodology and infrastructure led by PCORI's staff person, Rachel Florence.

Dr. Hasnain-Wynia described the Clinical Research Data Networks (CDRN's) and Patient-Powered Research Networks (PPRN's) for which PCORI recently announced funding. CDRN's were described as large data networks driven by large health care systems using electronic health records as platforms, but including data that is patient-centered and reflects more quality-of-life questions so that patient-centered outcomes are embedded within these data networks. The PPRN's are data networks driven by patient and stakeholder communities around specific conditions, with the goal to connect them with CDRN's and use PPRN's to disseminate findings.

It was noted that PCORI had the capability to accelerate the work of an organization such as the National Quality Forum in its efforts related to quality measures for long-term services and supports. Dr. Hasnain-Wynia used the example of taking the NQF-developed quality measures and integrating them into CDRN's and PPRN's. The letters of intent for CDRN's and PPRN's were due on June 19, 2013, and therefore efforts to take this next step would rely on partnerships with existing applicants, which represent large consortiums, as this is a one-time funding opportunity. Nevertheless, the projects funded could be amended in the future to incorporate new data needs. We can expect a future announcement from PCORI seeking a large study using partnered CDRN's and PPRN's as a platform.

## **Process:**

In conclusion, PCORI described two tracks to potential funding for a comparative research project related to people with disabilities:

1. Targeted Funding Announcements: The PIPC/AAPD Roundtable of people with disabilities could submit to PCORI a list of research areas, which would trigger PCORI to conduct the appropriate landscape review to identify research gaps in those research areas. Based on that landscape review, those research areas could then be submitted to the appropriate

advisory panels. If the appropriate advisory panel endorses the topic, it would then go to the full Board for approval. Once approved, it would then be translated into a targeted funding announcement and contracted for research in a competitive process.

2. Broad Funding Announcements: PCORI solicits broad funding announcements related to its priority areas every quarter. As discussed above, a collaboration of people with disabilities could engage in the Pipeline to Proposals, through which they would connect to the appropriate researchers to work on the development of a funding application on topic(s).

### **Dissemination:**

Roundtable participants expressed that dissemination of PCORI-generated research findings should be distinguishable from traditional dissemination practices at other federal agencies. In particular, patient engagement should not stop at the research stage, but continue through the dissemination of research findings. As such, roundtable participants concluded that there should be protocols for dissemination embraced by PCORI. For example, roundtable participants described the literature on changing clinical practice that supports peer-to-peer communications. In addition, PCORI also must ensure that physical facilities in which research is conducted are accessible and that print research findings are disseminated in accessible formats and posted on accessible web sites.

### **Final Recommendations to PCORI:**

As a result of this roundtable conversation, the participants concluded that they want to continue working with PCORI in several ways:

Targeted Funding Announcements: The participants in the roundtable of people with disabilities hereby endorse and submit to PCORI the following topics for consideration through its targeted funding process:

- *Integrated care coordination*: What are the outcomes of care coordination for people with disabilities? This would include the provision of community-based long-term services and supports.
- *Barriers to Access to Care*: What health system changes would eliminate existing barriers to access to care, including lack of accessible medical and diagnostic equipment, failure to modify policies and procedures in order to accommodate people with disabilities, and disability stereotypes that affect care and treatment decisions including life-sustaining care, for people with disabilities? Examples of needed system changes could include



health care provider education, including education to raise cultural competency and related testing for professional licensing and certification, and implementation/enforcement of the ADA, as well as procedural and substantive civil rights protections in the context of health care decision-making.

*Technology-Enabled Supports:* What is the impact of technology-enabled supports on health care outcomes, including quality of life outcomes, for people with disabilities? For example, technology-enabled supports could include complex rehabilitation technologies such as high-end wheelchairs, devices including hearing aids and augmentative communication systems, respiratory support technologies, health information technology, durable medical equipment, prosthetics and orthotics, lifting systems, and other supportive technologies to monitor health status.

Broad Funding Announcements: The participants in the roundtable of people with disabilities intend to collaborate in the future in order to participate in the Pipeline to Proposals. PCORI recently released a Request for Quotes seeking intermediate funders (IFs) to manage up to 10 engagement contracts each. The RFQ states, “IFs will be asked to provide input on the selection of the Tier I awardees, though PCORI will have the final authority in making the award selections.” Nevertheless, the roundtable of people with disabilities seeks the following clarifications:

- How will PCORI assure that the selected IFs have the appropriate experience on issues related to people with disabilities and how will such experience be defined?
- Could an IF be a patient advocacy organization? If so, will the funding provided to IFs support the necessary personnel and administrative costs to manage engagement contracts?

Data and Infrastructure Development: The roundtable participants conveyed to PCORI the significant challenges surrounding the development of data related to people with disabilities, and want to work with PCORI to address those needs. Therefore, the roundtable participants seek the following:

- Please clarify the process for partnering in the future with the newly funded PPRN’s and CDRN’s to incorporate data collection related to the quality measures for long-term services and supports.
- Please describe any future data and infrastructure projects at PCORI that may be relevant for the collection of data related to people with disabilities.
- We hereby request a meeting with Rachel Fleurence at PCORI to discuss the issue of data and infrastructure related to people with disabilities to explore future opportunities.

Dissemination: The roundtable recommends that PCORI develop protocols for the dissemination of research findings in consultation with organizations and individuals representing people with disabilities to ensure that they meet certain criteria for accessibility, while representing policies that are proven to enhance clinical practices.

**Signed by:**

**Alliance for Aging Research**

**American Association of People with Disabilities**

**American Association on Health and Disability**

**Consortium for Citizens with Disabilities Health Task Force**

**Disability Rights Education and Defense Fund**

**Easter Seals**

**Epilepsy Foundation**

**National Association of Councils on Development Disabilities**

**National Alliance on Mental Illness**

**National Council on Independent Living**

**Not Dead Yet**

**Partnership to Improve Patient Care**

**The Arc of the United States**

**United Cerebral Palsy**