



Summary of The Partnership to Improve Patient Care's 2012 Roundtable Series on Incorporating Clinical Expertise into Patient Centered CER

Background

Creation of the Patient-Centered Outcomes Research Institute (PCORI) under the Affordable Care Act (ACA) marked a new phase in comparative effectiveness research (CER); one that presented the opportunity for research to be done differently by centering on the needs of patients. The Partnership to Improve Patient Care (PIPC) strongly supported these provisions of the ACA during the health care reform debate, and since enactment has continued working to support PCORI's mission of patient-centered, high-quality comparative clinical effectiveness research.

Since the creation of PCORI, it has been clear to PIPC that it would be crucial for patients and physicians to work together in support of an agenda that is responsive to our shared needs at the point of treatment decision-making. To that end, PIPC supported a series of roundtables with leading physician and patient organizations beginning in early 2012 to identify, discuss, and define potential next steps in key areas of PCORI's work. Leading medical societies that serve on PIPC's Steering Committee – such as the American College of Cardiology and American Association of Neurological Surgeons – were instrumental in helping organize several of these roundtables.

The roundtables proved very successful in identifying priority issues of common interest to leaders in the provider and patient communities. Issues identified and discussed during these roundtables included research priority setting, research infrastructure, physician and patient engagement strategies, and results communication.

One important, cross-cutting theme conveyed through all the roundtables was the willingness of physicians to partner with patients and patient organizations in support of PCORI's mission of achieving patient-centered CER. Physicians want to see the development and use of tools and supports in delivering individualized, evidence-based care to each patient, and understand the potentially valuable role PCORI can play in this area.

The roundtables that PIPC hosted provided valuable input and perspectives, and PIPC committed to continuing these roundtables in 2013 to continue developing patient-centered solutions to some of the key challenges that have been identified.

The Structure of the Roundtables

PIPC began more robust engagement of provider organizations in 2012 by hosting a series of four roundtables focused on getting physician perspectives on PCORI's research process. These forums facilitated discussion between a myriad of practicing physicians, physician specialty societies, patient organizations, and other clinical experts. Each roundtable was co-hosted by a different PIPC Steering Committee member organization. These invite only, roundtable discussions focused primarily on ensuring that the expertise of physicians and clinicians is given a prominent role in PCORI processes, strategic research agenda, individual research project decisions, and communication of research results. Soon after the first roundtable event, PCORI staff responsible for stakeholder engagement reached out to PIPC to request that PCORI be able to participate in subsequent roundtables. At the request of PCORI, the three subsequent roundtables featured a presentation from PCORI staff and a follow-up memo from roundtable participants highlighting consensus recommendations.

Through the roundtables, PIPC quickly discovered that physicians were both willing and eager to partner with patient organizations in advising PCORI on the development of research priorities for comparative clinical effectiveness research. Roundtable participants also requested that PIPC facilitate further roundtables to collaboratively advise PCORI on how to best create a patient-centered CER program. Therefore, PIPC's final roundtable for 2012 brought together both patient organizations and practicing physicians in an effort to facilitate consensus recommendations for how to bring together patients and their providers in the development of PCORI's research agenda.

Key Themes from Roundtable Discussions

Although the format and structure of the four roundtable discussions evolved over the course of the series, important themes emerged from the four roundtables. Each of these is described in detail below:

Roundtable participants were willing to commit to working together to identify current research gaps in clinical practice and developing consensus research agenda designed to identify, clarify, frame and meaningfully answer current patient-centered questions in specific clinical areas. Participants expressed that PCORI is well positioned to address the key challenge of developing and maintaining effective collaborations between content experts—i.e., patients with specific diseases and the experts researching and treating them, alongside the relevant health services researchers and methodologists. Once these collaborations are established, the patients and content experts would be able to effectively inform PCORI's research process to ensure that PCORI is pursuing the most pressing clinical research questions in a particular area. The participants in the roundtable discussion co-hosted by the American Association of

Neurological Surgeons stressed that Medical Society practicing members have unique and important perspectives on patient-centered outcomes. Medical societies also have valuable resources, such as datasets, that PCORI could access to design creative approaches to define, measure, and ultimately improve patient outcomes.

Establishing PCORI research priorities at a more granular level would enable significantly more meaningful input and participation in PCORI's research agenda by clinicians and their organizations. PCORI's current research priorities are currently too broad, creating uncertainty about PCORI's specific research focus. This ambiguity could potentially discourage clinical organizations from responding to PCORI's requests for proposals; given the lack of clarity about what types of research topic proposals will be competitive. In addition to pursuing how PCORI could best capture the expertise of physicians, several of the roundtable discussions spent considerable time deliberating PCORI's research priorities and process for funding research. For example, participants felt that PCORI's broad priorities especially discouraged proposals from smaller organizations with less access to resources, as they would be unable to risk the potential loss of time and dollars pursuing grants that might ultimately not be "on point."

Physician societies and organizations have established research resources that can help inform and advance PCORI's work. Medical Society practicing members have unique and important perspectives on patient-centered outcomes in addition to potentially valuable underutilized research resources. PCORI should work closely with professional societies, voluntary health organizations, and other organizations that have established robust research infrastructure, such as clinical databases and patient registries, in order to leverage them where possible. There is an opportunity for PCORI to work with societies to design creative approaches to access and utilize these data to define, measure, improve, and inform patient centered CER. There is potential in creating and communicating longitudinal registries among different specialties treating similar disorders. PCORI should consider support for developing these registries, making them operational, and helping societies incorporate randomized designs and analyses.

Conducting research to meaningfully address health disparities is a significant opportunity for PCORI. PCORI should consider incorporating research that addresses health disparities in ways that are "cross cutting" across all five broad priority areas, including health care delivery systems. PCORI also should consider tapping into existing advisory bodies and other organizations focused on health disparities to ensure the Institute's research agenda appropriately addresses the goal of reducing disparities.

Roundtable participants viewed effective, practical communication of research results to providers and patients as important a priority as the conduct of the research itself. When asked to prioritize among the draft elements of PCORI's research agenda, an unexpected trend

emerged; although participants' views varied widely on the importance of new clinical effectiveness research in their field of expertise, almost all participants stressed the importance of research translation and communication. A key challenge identified was not the lack of scientific evidence, but rather an inability to translate and present existing research in an understandable and appropriate format to guide physician and patient decisions. This sentiment was expressed as the consequence of the lack of standards for how to effectively communicate research results, and a lack of proper tools to assist patients and physicians in applying research information to a specific set of unique patient circumstances.

The engagement of physicians, clinicians, and patients should continue in a longitudinal fashion throughout PCORI's research process, and this plan for engagement should be clearly articulated by PCORI. Facilitating meaningful clinician and patient input into PCORI's work will help foster these organizations' willingness to ultimately communicate the research PCORI produces. PCORI's sustained plan for engagement should include specific steps such as: creation of expert advisory panels with the majority of participants representing practicing physicians, clinical experts, caregivers, and patients; and training patients and clinicians to be full participants in priority-setting and other PCORI activities.

Conclusion

In conclusion, PIPC and its roundtable participants were able to provide PCORI with tangible and actionable recommendations from their activities in 2012. Although not all recommendations have been fully incorporated into PCORI's practice, PCORI appears to be working toward a process that is unique and results in truly patient-centered outcomes research, through its new initiatives to develop specific topics for research. Although PCORI continues to define its national priorities for research broadly instead of at the granular level recommended by our roundtable participants, the institute has created processes to develop specific topics for research through advisory panels. A remaining concern is the expertise of those panels to advise on specific topics due to the broad scope of the panel representatives. Whether content experts—including both patients and clinicians—are meaningfully engaged to drive those choices will likely be determined in the process of evaluating these evolving new processes at PCORI.

One of the challenges PCORI will face in creation of advisory panels is ensuring they fulfill their purpose of eliciting the input of clinical experts and practicing physicians with knowledge and expertise in various diseases and medical specialties. This will be particularly important in ranking of research priorities for comparative clinical effectiveness research related to disease prevention, diagnosis, and treatment. It will also be valuable for research related to care management, organization and delivery. PCORI may need to consider either creating standing advisory panels representing particular medical specialties (e.g., oncology or cardiology) or



creating high-level advisory panels that are structured to draw on the input of leading experts in different disease areas.

As PCORI increases emphasis on the communication of its research results, the engagement of organizations like those participating in the roundtables should continue, ultimately using their communications capabilities to disseminate research results, encourage incorporation into practice, and facilitate long-term patient engagement and registry development. In response to this increased focus, PIPC is planning to convene a follow-up series of roundtable discussions exclusively focused on the topic of communicating research results in ways that are consistent with the conduct of patient-centered CER.

Appendix I: Overview of 4 Roundtable Participants and Discussion

Roundtable One

The roundtable series began on January 10, 2012, with the first roundtable being co-hosted by the **American Gastroenterological Association**. Although PCORI's Board of Governors was chosen in September, 2010, PCORI was still looking forward to making public its first set of national priorities for research at the time of this first roundtable. While this first roundtable set the stage for future roundtables, it did not result in direct recommendations to PCORI. Participants in the roundtable discussion had a strong focus on how information is communicated and disseminated, recognizing the need to better capture patient preferences and better empowering patients in their medical treatment by providing them with understandable information. Several participants highlighted their Societies' existing capabilities related to CER infrastructure and dissemination, including robust patient registries that could be leveraged by PCORI. Participants generally placed a high priority on research that identifies approaches and tools to effectively communicate CER results and close gaps between what is known and what is done in practice. Participants had a wide range of views on how PCORI should allocate funding among the broad research areas that the Institute has proposed as priorities, but discussion focused more generally on the role that medical societies should play in a patient-centered research model.

Roundtable Two

The **American College of Cardiology** co-hosted the second roundtable discussion on May 17, 2012 to discuss the research priorities and funding processes announced by PCORI. A conclusion of the roundtable discussion was that PCORI need not, and should not attempt to recreate the agendas or duplicate the processes of either the Agency for Healthcare Research and Quality (AHRQ) or the National Institutes of Health (NIH), a concern that emanated from PCORI's broad national priorities for research. PCORI was created to have a unique mission to focus on patient-centered outcomes with projects developed with genuine patient input. This roundtable did result in tangible recommendations that were later submitted to PCORI.

Roundtable Three

On June 1, 2012, PIPC and the **American Association of Neurological Surgeons** co-hosted a roundtable to assess the progress and publicly disseminated strategies of PCORI. The conversation focused on how PCORI could capture the expertise of physicians, and took a critical look at PCORI's process for funding research. For example, the group felt that PCORI's

broad priorities especially discouraged proposals from smaller organizations with less access to resources, as they would be unable to risk the potential loss of time and dollars pursuing grants that might ultimately not be “on point.”

Roundtable Four

The fourth roundtable in the series was convened on December 14, 2012 and was co-hosted by the **Epilepsy Foundation** with a focus on Epilepsy and Parkinson’s disease. Collectively, the views of patients, providers, advocates, and investigators were represented. The group concluded that research methodology should serve the needs of patients and providers to identify and subsequently address meaningful questions. Also, research methodologists should help these groups frame and analyze questions that matter to them, e.g. help them “count” variables that are clinically important rather than, in the interests of “methodological purity”, craft protocols assuring the accurate and statistically pristine assessment of variables that may not be the most meaningful for patients.

Appendix II: List of Participating Organizations

American Academy of Neurology
American Epilepsy Society
American Academy of Neurology
American Academy of Orthopedic Surgeons
American Academy of Pain Medicine
American Academy of Physical Medicine and Rehabilitation
American Association of Clinical Endocrinologists
American Association of Neurological Surgeons
American College of Cardiology
American College of Radiology
American College of Rheumatology
American College of Rheumatology
American Gastroenterological Association
American Geriatrics Society
American Heart Association
American Osteopathic Association
American Psychiatric Institute for Research and Education
Practicing Physician, Baystate Medical Center
Citizens United for Research in Epilepsy
Practicing Physician, Doctors Hospital
Epilepsy Foundation
Finding a Cure for Epilepsy and Seizures
Heart Failure Society of America
Heart Rhythm Society
International League Against Epilepsy
Practicing Physician, Mayo Clinic
North American Spine Society
NYU Langone Medical Center
Predictive Health, LLC
Society of Thoracic Surgeons
Spectrum Health System
The Endocrine Society
Practicing Physician, Washington Hospital Center