



CHANGING THE CONVERSATION ABOUT HEALTH RESEARCH

Gaylord National Resort & Convention Center | National Harbor, MD

DRAFT AGENDA

Thursday, November 17, 2016

- 9:00 a.m. - 2:00 p.m. Pre-Conference Session for Trainee Scholarship Recipients (by invitation only)
- 9:00 a.m. - 2:00 p.m. Pre-Conference Session for Patient/Caregiver Scholarship Recipients and Ambassadors (by invitation only)
- 2:30 p.m. - 3:30 p.m. Onsite Registration Opens
- 3:30 p.m. - 5:00 p.m. **Opening Plenary Session: How Can We Make Patient Needs and Values Central To Health Research and Decision Making?**
Our opening plenary session will put the voices of patients, caregivers, and their advocates front and center in a discussion of why their needs and values matter in health research and decision making. Our keynote speaker and plenary panel will talk about what has and still needs to change in health research and delivery to be sure studies and outcomes that matter to patients become the rule rather than the exception. And they will look at the opportunities patient-centered outcomes research and comparative clinical effectiveness research present to help patients and those who care for them make better-informed healthcare decisions.
- 5:30 p.m. - 7:00 p.m. Welcome Networking Reception

Friday, November 18, 2016

- 7:00 a.m. - 8:30 a.m. Registration
- 7:30 a.m. - 8:30 a.m. Morning Networking Breakfast
- 8:30 a.m. - 10:00 a.m. **Plenary: Taking Stock: How Is Patient-Centered Outcomes Research Advancing Patient-Centered Care?**
There has been a surge in recent years in efforts to make healthcare research and delivery more patient-centered. This includes the 2010 creation of PCORI as the Nation's main funder of comparative clinical effectiveness research that focuses on outcomes important to patients. During the session, we will look at the evolving changes in the healthcare landscape in recent years and how patient-centered outcomes research has led or can lead to care that is more effective and useful to patients, their families, and clinicians. This session will focus on the potential drivers of change in health care at the individual, community, institutional, health system, and public health levels. Finally, there will be a discussion of what research directions need greater emphasis and how patient-centered outcomes research can contribute going forward.

10:00 a.m. - 10:30 a.m.

Break

10:30 a.m. - 12:00 p.m.

Morning Breakout Sessions

Golden Years and Easing Fears: Complex Medical Decision Making Among Older Adults

The older adult population is the fastest growing portion of the population worldwide. Older adults make up the majority of patients for certain health conditions including cancer, cardiovascular disease, arthritis, and Parkinson's disease. Typically, clinical trials conducted in adult populations include patients between the ages of 18 and 64 years. Improving communication about age-related concerns that could affect health outcomes is needed for individuals age 65 years and older. This session will highlight three research studies focused on improving complex medical decision making among older adults as it relates to cancer treatment decisions, advanced care planning, and health plan selection for Medicare Part D enrollees. This session will highlight the projects individually, the work done to date, outcomes, and how to engage patients and stakeholders. The session will also include a panel discussion focusing on the challenges and successes panelists have had applying patient-centered outcomes research concepts in this field.

The Goldilocks Dilemma—PCOR and How It May Help to Ensure That Care Interventions Are “Just Right”

Maximizing the use of effective high-value care across the care continuum is a priority for all stakeholders within the health care system. One of the barriers slowing progress toward the optimal use of health care is the lack of rigorous comparative effectiveness research that evaluates patient-centered outcomes including benefits and harms at the individual level. Multi-stakeholder-led research has the potential to capture the most relevant aspects of the decisional dilemmas encountered when considering the appropriate use of more versus less care. This interactive session will highlight several PCORI-funded studies that intend to address the gap in evidence necessary to support informed decision making when considering alternatives to immediate or continuous treatment. Discussion will explore the barriers and facilitators to attaining appropriately tailored care, how cultural readiness influences the capacity to generate robust evidence, and how stakeholder partnerships can contribute to the rigor of studies considering the effectiveness of alternative management strategies.

Patient and Stakeholder Engagement in Research: Identifying Challenges and Developing Solutions

This session will be an opportunity to share emerging and promising practices in engagement of patients and other stakeholders in patient-centered comparative effectiveness research. PCORI staff will present recent data about engagement collected from PCORI awardees and their partners to provide an overview of how patients and other stakeholders are involved in PCORI-funded projects. The presentation will address challenges that awardees and their partners have faced and their strategies for resolving those challenges. Breakout groups, led by current funded investigators and partners, will provide an opportunity for attendees to discuss reactions to the presentation, share promising practices from their own experiences, and identify other challenges and solutions.

Know Before You Go: Planning Upstream for Successful Recruitment in Clinical Trials

Data from systematic reviews have shown that there are promising strategies for increasing recruitment to trials, yet recruiting participants into clinical trials remains one of the biggest challenges in the research field today. This session will feature discussions of public awareness of clinical trials, including how American knowledge and perceptions of public health research impact the research field. Presentations by three PCORI-funded PIs and their partners will also cover (1) strategies to assess trial feasibility and site selection, (2) effective modes of delivery and partnerships, and (3) recruitment communication planning. The focus

by PCORI awardees will be on the upstream planning necessary for successful recruitment launch and trial success, specifically on data-driven approaches to selecting appropriate sites and patient/stakeholder engagement required to design outreach/communication efforts. Participants will engage in a session designed to provide insight and tools to inform the development of stronger studies and successful recruitment efforts.

Patient-Centered Outcomes Research (PCOR): Filling the Evidence Gap in Obesity Treatment Options

While obesity trends have plateaued in recent years, prevalence remains unacceptably high, affecting over one-third of adults and around 20 percent of children and adolescents. Working with limited knowledge of personal preferences, and against cultural and community obstacles, healthcare providers often have little success in influencing their patients to make necessary behavioral changes. This panel highlights select obesity research funded by the Patient-Centered Outcomes Research Institute to fill specific evidence gaps in the treatment and management of obesity. Patient-centered outcomes research involves stakeholders in helping to identify relevant research questions and in collaborating on the design and implementation of studies that will improve their ability to make informed choices among treatment options. The presentations evaluate a range of interventions, with a common theme – the design and implementation of each one has been guided by patients and other stakeholders to provide critical information on how to best treat obesity. Presenters will focus on the evidence gap their project is aiming to fill and how the findings will likely impact practice.

Conducting Patient-Centered Outcomes Research in Rare Diseases: Success and Challenges

This session will explore the challenges and successful opportunities associated with conducting patient-centered outcomes research (PCOR) related to the treatment and management of rare diseases. It will describe ongoing PCOR studies of management approaches for two different rare conditions as well as a prospective registry designed to support clinical research on pediatric rheumatic diseases. Presentations will provide an overview of current progress, discuss the challenges associated with conducting research and building registries, explore strategies for overcoming those challenges, and consider how lessons learned can help inform future research activities. A representative of PCORI's Advisory Panel on Rare Disease will moderate the session. Panelists will include three PCORI awardees currently engaged in rare disease research activities and their patient partners; their projects fall under PCORI's broad funding initiatives and PCORnet (National Patient-Centered Clinical Research Network).

Novel Delivery of Evidence-Based Behavioral Interventions for Anxiety and Depressive Disorders

Anxiety and depressive illnesses are some of the most common mental health disorders in the country, with a lifetime prevalence of 28.8 and 16.6 percent of the population, respectively. They are associated with a significant public health burden due to medical costs, missed days from work and school, and decreased productivity. However, less than half of Americans with mental health disorders receive treatment annually. Although many patients prefer behavioral interventions to pharmacological treatments, and some behavioral interventions are highly effective for depression and anxiety, many Americans are unwilling or unable to access these treatments in their current forms—including those who cannot afford treatment, those who do not seek treatment due to stigma, and many who have a dearth of trained professionals in their area. Interest in novel methods of delivering evidence-based interventions has emerged in response to these barriers to evidence-based care. Investigators will discuss PCORI-funded projects featuring novel delivery methods for evidence-based interventions, including peer-led support groups, telehealth, and co-location of mental health clinicians in primary care settings.

Both investigators and patient partners will discuss their experiences and challenges conducting these trials, all of which are at various stages of completion.

12:00 p.m. - 12:30 p.m.

Break

12:30 p.m. - 2:30 p.m.

Lunch Plenary: How Can PCOR/CER Improve Care for People With Multiple Chronic Conditions?

An estimated one in four Americans lives with more than one chronic condition. This is a major challenge for individuals, their families, and the US healthcare system as a whole given the need for substantial levels of care and, in many cases, poor health outcomes. Managing chronic conditions is often uncoordinated, focusing on addressing individual diseases or conditions rather than focusing on the whole person and their challenges. During this session, we will discuss ways in which evidence from patient-centered outcomes research and comparative clinical effectiveness research can improve the health outcomes of people with chronic conditions, with a particular focus on children and older adults.

2:30 p.m. - 3:00 p.m.

Break

3:00 p.m. - 4:30 p.m.

Afternoon Breakout Sessions

The Transitional Care Evidence to Action Network: Approach, Accomplishments, and Exemplars

Transferring from one healthcare setting to another, or even to home, can be a vulnerable time for patients and those who care for them, prompting researchers and policy makers to identify and validate strategies that improve transitions of care. For this reason, PCORI has invested more than \$68 million in 20 transitional care research projects. The studies in the Transitional Care Evidence to Action Network (TC-E2AN) represent five PCORI science programs and multiple funding mechanisms. These studies are designed to reduce readmissions, enhance patient experience, and improve outcomes by evaluating transitional care interventions in diverse populations. TC-E2AN connects PCORI-funded research teams working in transitional care to facilitate collaborative learning and leverage promising practices. This session (1) describes the TC-E2AN's approach to engaging researchers and stakeholders, noting accomplishments from the first 18 months and highlighting upcoming activities, and (2) showcases two studies utilizing robust evidence and strategies for translating evidence into action.

PCORnet Functionality: Achievements in Data, Research, and Engagement

PCORnet (National Patient-Centered Clinical Research Network) is in the second phase of infrastructure development to make clinical research faster, easier, and less costly. In August 2015, the PCORnet Governance Policies were approved, establishing three key content committees to drive forward PCORnet development. The Data, Engagement, and Research Committees enhance the distributed leadership of PCORnet by harnessing the power of the Clinical Data Research Networks (CDRNs) and Patient-Powered Research Networks (PPRNs). This session, led by the Data, Engagement, and Research Committee Chairs, will emphasize advancements in increasing the focus on enhancing public trust, models of engagement for participants and clinicians, research resources within PCORnet, current research underway utilizing the network, and advancements in the data infrastructure. This breakout session will showcase the progress in the areas, led by the Data, Engagement, and Research Committees, in strengthening PCORnet's ability to conduct more robust patient/participant-centered research.

Meet the Journal Editors

As PCORI-funded studies near their end dates, PCORI wants its awardees to get advice on how to succeed with top-tier journals. This 90-minute breakout session is an opportunity to engage in conversation with journal editors who are interested in attracting manuscripts that describe patient-centered comparative effectiveness studies. Each editor will speak for about 10 minutes. A brief moderated panel discussion will follow. A question-and-answer period will conclude the session.

Interventions to Reduce Disparities in the Home, Hospital, Clinic, and School

Previous research has identified pervasive disparities in access to high-quality health care and worse health outcomes for specific populations across multiple conditions and multiple settings, outcomes that are based on race/ethnicity, gender, geographic location, socioeconomic status, disability, and other factors. This panel highlights research funded by the Patient-Centered Outcomes Research Institute aimed to improve outcomes for populations at risk for disparities. The panel will discuss interventions set in the home, schools, hospitals, and clinics for a range of health conditions and topics. Presenters will focus on preliminary findings from their research as well as lessons learned related to implementing comparative effectiveness research in diverse populations.

Comparative Effectiveness Research on Nonpharmacologic Approaches for Chronic Pain

Chronic pain exerts a significant burden on the general population, with approximately 35 million Americans suffering from chronic pain and costs of \$635 billion dollars per year to the U.S. healthcare system. Although opioid analgesics are commonly used to treat chronic non-cancer pain, little is known about the safety and effectiveness of long-term opioid therapy. At the same time, mounting evidence suggests that opioids are associated with increased risk of significant harms including misuse, dependence, and overdose. Subsequently, interest in nonpharmacological strategies has increased. The current symposium will discuss several projects, including two funded by PCORI, that address alternative approaches for chronic pain, and methodological challenges and potential strategies for conducting comparative effectiveness in this area.

Smarter, More Appropriate Use of Antibiotics

This session will focus on comparing appropriate management of infections with antibiotic treatment strategies for a range of conditions.

5:30 p.m. - 7:00 p.m. **Closing Networking Reception**

Saturday, November 19, 2016

7:00 a.m. - 8:30 a.m. **Registration**

7:30 a.m. - 8:30 a.m. **Morning Networking Breakfast**

8:30 a.m. - 10:00 a.m. **Closing Plenary: A New Vision for Health Research: Finding Common Ground Among Stakeholders**

Steady progress is being made in meaningfully engaging stakeholders in health research. Bringing diverse stakeholders to the table offers unprecedented opportunities to design and conduct research that serves patients more effectively than ever before. But it also poses challenges, such as how to truly find common ground when patients, professionals, and other healthcare stakeholders bring different needs and perceptions to the discussion. In this session, we will talk about how we can refine a health research and healthcare agenda and culture that focus on improving patient outcomes while ensuring that all stakeholders—

patients, clinicians, insurers, employers, industry, policymakers and others—have a real voice in the process while ultimately acknowledging that the patient is at the center.

10:00 a.m. - 10:30 a.m.

Break

10:30 a.m.

Workshops

10:30 a.m.

PCORI Dissemination and Implementation Workshop

Initiatives to disseminate and support the implementation of PCORI's research findings are critical to ensuring that these findings contribute to improving health services, and ultimately, health outcomes. This workshop will offer participants the opportunity to learn more about PCORI's initial activities in dissemination and implementation, and to discuss more broadly the challenges and opportunities in bringing research into practice. Following an overview of PCORI's plans and activities in dissemination and implementation, this workshop will describe PCORI's initial processes, now underway, to ensure the scientific integrity of findings from its funded research and to release these results in comprehensible, accessible formats. A second session will highlight PCORI-funded Engagement Awards that are designed to lay the groundwork and build capacity for successful dissemination of findings to specific audiences — employers, patients, and clinicians working in different clinical settings. The second half of the workshop will begin with a discussion of challenges encountered by those who have worked to implement research findings in a variety of settings. A final session will highlight successful implementation efforts that have been funded by the Agency for Healthcare Research and Quality, which has been the locus of extensive work in dissemination and implementation of research evidence and is tasked broadly with disseminating and implementing PCOR findings including the results of PCORI-funded research. The workshop will close with a description of current PCORI funding opportunities related to dissemination and implementation of research findings.

10:30 a.m.

Getting to Know PCORI: From Application to Closeout

This interactive workshop is open to all meeting attendees and is designed to provide you with the tools and strategies to develop a responsive PCORI application. This workshop will offer an overview of PCORI and the work that we do, including National Priorities for Research, Funding Announcements, Application Process, Methodology Standards, Merit Review Process, and Post-Award Administrative Requirements. The workshop will provide opportunities to meet PCORI staff, ask questions, obtain resources, and network with other participants.

10:30 a.m.

Management of Human Subjects Protections in Conducting Pragmatic Clinical Studies

The purpose of the morning session is to lay out the distinct challenges that apply to human subjects protections in pragmatic clinical trials and other prospective clinical studies studying standard of care interventions, with issues that include determining whether the trial meets the definition of minimal risk, obtaining informed consent, and implementing centralized Institutional Review Board (IRB) approaches. The focus will be on current thinking in addressing the ethical and regulatory challenges in ways that balance the need for high-quality protection of trial participants with the goal of efficiently implementing these trials and generating evidence that can be used to improve clinical care for patients. The open session will have three podium presentations of 15 minutes each to allow time for audience questions and discussion.

10:30 a.m.

PCORnet in Action: The Journey Toward People-Driven Research Transformation

The development of PCORnet has supported PCORI's strategic priorities of developing patient-centered data networks and expanding researcher and patient capacity to participate in PCOR. The PCORnet Workshop will present the current and future capabilities of PCORnet to investigators (potential users) and funders for studies utilizing PCORnet. The workshop will

begin by highlighting current research that is underway. The preliminary panel presentation will present an in-depth look at a few examples of studies, highlighting the range of potential capabilities of PCORnet. Following the opening session, an interactive poster session will allow attendees to explore all current research underway and to interact with the investigators. The afternoon session will focus on innovative tools and resources available within PCORnet to external investigators. After brief introductions, this session will take place as smaller table discussions to allow for a higher level of interaction with the attendees.

10:30 a.m.

Pre-Engagement in PCOR: Incorporating Lessons From the Field

The purpose of this interactive workshop is to identify and promote emerging promising practices and principles in the early phase of patient-centered outcomes research (PCOR), known as "pre-engagement," when trustworthy, bi-directional relationships are formed. The "pre-engagement" phase of PCOR has been acknowledged as "one of the most important (but often overlooked) phases of patient engagement in research, especially when working with underrepresented populations" (University of Maryland 2012 - Patient Engagement Best Practices Resource Document). The workshop will convene select teams across various and diverse PCORI-funded projects (Pipeline to Proposals, PCORnet, Eugene Washington PCORI Engagement Awards and the comparative clinical effectiveness research portfolio) as well as other strategically selected individuals or organizations that have demonstrated exemplar "pre-engagement" practices and will work collectively to identify, distill, categorize, and prioritize key factors, promising practices, and principles in the "pre-engagement" phase of research.

10:30 a.m.

Research in Real-World Settings: PCORI's Model of Rigorous Comparative Effectiveness Research (CER)

During this session, we will review PCORI's model of CER and how to frame research questions using this model. We will address issues of study design and how to evaluate the trade-offs among alternative designs. We also will introduce PCORI's Methodology Standards and show how they can be used to improve the quality of clinical research.