What Should PCORI Study?

A Call for Topics from Patients and Stakeholders

**Session Reports from a
December 4, 2012 Workshop**

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Background

As a part of its effort to develop and refine a patient-focused research agenda, the Patient-Centered Outcomes Research Institute (PCORI) hosted a workshop entitled, "What Should PCORI Study? A Call for Topics from Patients and Stakeholders," on December 4, 2012 in Alexandria, Va. The event was designed to bring together the broad range of healthcare stakeholders to share and discuss important future topics of patient-centered outcomes research. Materials related to this workshop, including the agenda, a list of participants, information on workshop topics, presentation slides, and archived webcasts are available at www.pcori.org/events .

During the workshop, PCORI staff and attendees discussed the institute's patient-centered approach to research, its plans for engaging stakeholders in the research process, and a method for prioritizing potential research topics. Participants engaged in interactive small-group sessions to solicit their ideas for research in a variety of topic areas, including assessment of screening, diagnosis and treatment options; clinical trials; improving health care systems; addressing disparities; communications and dissemination research; and rare diseases.

The workshop included ten breakout sessions covering four of PCORI's National Priorities and Research Agenda: *Assessment of Diagnosis, Prevention, and Treatment Options*; *Addressing Disparities*; *Improving Health Systems*; and *Communications and Dissemination Research*. The objectives for each breakout session were to (1) recommend research questions relevant to the topic; (2) share best practices on the dissemination of patient-centered outcomes research; and (3) identify best practices for the conduct of patient-centered research. This document captures the key themes and insights from these breakout sessions.

Breakout Sessions: *Assessment of Diagnosis, Prevention, and Treatment Options*

Comparing the effectiveness and safety of alternative prevention, diagnosis, and treatment options to see which ones work best for different people with a particular health problem.

Three sessions on *Assessment of Diagnosis, Prevention, and Treatment Options* were framed in terms of decision-making by patients, since the purpose of patient-centered outcomes research (PCOR) is to generate valid findings that patients can use to make better decisions.

Participants in these sessions believed that it was critical for PCORI to study outcomes measures to ensure patient-centered research would be successful. Specifically, the research process should elicit patient preferences and values to know what outcomes clinicians should be trying to achieve. For example, someone with chronic pain may want to reduce the pain, but they also will likely be concerned

with safety and their ability to function. Engaging patients early in establishing these desired outcomes, and then identifying the choices that should be compared, likely would facilitate dissemination of the eventual research findings.

Outcome measures should also account for the following issues. First, many variants exist within any particular disease – e.g., there is no "cancer," there is only "my cancer" and "your cancer." Thus, in many cases (especially for rare diseases) the population size or the reliance on patient-reported outcomes can render statistically significant findings impossible. Second, the actual process by which many patients receive care is one of "bouncing around" various specialists until they start to see positive outcomes, which makes it difficult to make "apple-to-apple" comparisons of outcomes. Third, many factors, such as co-morbidities, substance abuse, or lack of access to care, can interfere with outcomes that may otherwise have been achieved. Fourth, additional assessments are needed to help identify not just which patients will do well and which will not (which could be related simply to the severity of their condition), but rather who will do well with which treatment.

Related to the topic of outcome measures was the idea of funding studies that looked at those patients who were not served by the treatment highlighted in an earlier study. Rather than funding multiple single studies, this approach could re-engage the same patients to find out what would work for them, given that the treatment in the original study had not. The findings of multiple studies using the same population likely would provide important insights for decision-making by individual patients. Participants also cited a need for new knowledge about patient engagement, including how patient decisions are made, and speculated that the growing field of decision science may provide this information. Key topics to explore could include: How do you create shared decision making? What assistance could be provided to loved ones making important decisions? How can risks be better communicated? How is decision-making shaped by age-related cognitive impairment, even if there is no technical diagnosis of dementia? Participants wanted to know how patients can be activated to move from being a passive recipient of care to becoming an active member of the care team, as well as how caregivers can play a role in that process. Research is needed about the effectiveness of self-management tools that can be used during the 90% of the time that patients are caring for themselves.

Workshop participants also stressed the importance of determining how to reach patients in populations that currently are not well-connected to the clinical and research communities. Participants believed that PCORI could learn from social scientists that have made headway in fostering better connections between certain populations and research. Some attendees felt this may require a culture change within the clinical community, as well as changes in training, to ensure that communication channels are available and open between all patients, research and clinicians.

Participants also suggested seeking more information about integrative care, such as support groups, meditation, exercise, sleep, as well as combinations thereof. This research also should take into account the side effects of various complementary and alternative approaches. Participants felt there was a clear need to see the care experience more holistically from the perspective of the patient and his or her overall lifestyle and goals.

Lifestyle itself was suggested as another important topic to explore. Participants suggested PCORI needs to study how to shift to evidence-based methods for preventing and treating obesity, taking into account interventions at school, monitoring at home, and combined approaches. However, some

participants expressed a concern that a focus on lifestyle can create a stigma for some populations. They stated that stigma is already a significant impediment to diagnosis, prevention, and treatment for conditions with specific moral or religious associations, and stigma affects both the patient and the provider. Participants agreed that it will be important to explore lifestyle's role in shaping health outcomes without exacerbating the problem of stigma.

Participants saw care coordination as another promising topic for research. They agreed with the necessity of more information on how to improve continuity of care between primary care and specialists, including ensuring that patients are prepared when they get to the specialist – e.g., checking insurance issues. An area identified to improve information was timely patient-reported outcomes. They believe this is more complicated for patients with multiple chronic conditions, or when care is delivered through emergency rooms, since there is little information available in the ER about what has happened to that patient in the past. Screening related to co-morbid conditions (e.g., depression, incontinence etc.) is an area for research. Research also could address how communication could be improved between primary and specialty care, between outpatient and inpatient settings, and use of interprofessional teams, practicing to the top of their respective licenses.

There was a discussion about a broader view of care coordination from the interprofessional team approach. Transitional care, a subset of care coordination, is a key area for patient-centered focus.

When asked how they identified research questions, participants offered a surprising range of answers. Some organizations "follow the money," looking at what might be funded and developing research proposals that fit those topics. Other organizations generate an initial list of good questions, and then narrow down that list based on the actual funding opportunities. Another organization – an online community – asks members to say when they join what health care questions they want answered, while another organization asks members to vote on questions around which to develop a research agenda. The Gardner Cascade (from HIV/AIDS) was mentioned as a model for identifying research questions by highlighting gaps in care.

Attendees suggested the following promising practices for disseminating research findings:
- Dissemination research coming out of NIH, the work of the IHI Quality Collaboratives, and community advisory boards at HIV centers were all highlighted as worthy of exploration by PCORI.
- Network-based research approaches that can overcome the current challenge of having many different studies using different outcome measures such that there is little statistical power to the results.
- Interactions between clinicians and patients, either through technology (e.g., webinars) or face-to-face, as in the case of a "Night in the Lab" event in which researchers presented their work to visitors from the local patient community. These interactions open a channel of communication that can help in dissemination and in the identification of future research topics.
- Social networks were noted as powerful tools for dissemination. These channels were contrasted with scientific journals, which are important, but are not read by patients.
- One participant suggested a reframing from "research dissemination" to "knowledge translation," noting that the activity itself is different from research and likely requires a different kind of person. Also, in most cases participants thought that the investigator should not be the one determining whether or not the research findings are definitive. Furthermore,

there is not always a one-to-one ratio between studies and important messages, so it may be more useful for a "knowledge translator" to offer a "meta-message" based on multiple studies.

- Mobile phones are a promising channel for dissemination, since more than 80% of people access health information from mobile devices, and rates are higher for minorities than for Caucasians. "*Promotoras*," community health workers, have seen a great response from the use of texting to spread health information.
- Policy drives a lot of activity (e.g., structures and processes of care employed) in health care that ideally improves outcomes, yet participants thought policymakers were a neglected audience for research dissemination. While there was some concern that this dissemination might be viewed as "lobbying," some participants noted that congressional staffers are very receptive to health-related education, and appreciate having someone to turn to with their questions.

Another challenge is that researchers typically do not want to publish in consumer-focused magazines since they are rewarded for publishing in academic journals, which consumers do not read. Also, many of these journals are not publicly accessible, although the NIH is now requiring that a certain percentage of research be publicly accessible.

Breakout Sessions: *Addressing Disparities*

Identifying potential differences in prevention, diagnosis or treatment effectiveness, or preferred clinical outcomes across patient populations and the healthcare required to achieve best outcomes in each population.

Two sessions discussed *Addressing Disparities*, which was highlighted as a major opportunity for PCORI. Participants highlighted several different factors that give rise to health disparities: ethnic and cultural differences; physical and intellectual disabilities; health literacy; mental health issues, including the associated stigma; and geography, including both distance from care and distance from *high-quality* care.

Ethnic and cultural differences correlate with significant health disparities, which will become an ever more pressing issue as U.S. demographics continue to shift in the years to come. Providing linguistically and culturally appropriate care is an important area to explore, particularly since most providers continue to rely on family members or other community-based caregivers to translate for their patients.

Research is also required to close the gap in access to primary care for people with physical and intellectual disabilities. At the same time, participants believed we need to find approaches (e.g., school-based health) to close the gap in the lives of people with disabilities who are able to live independently, e.g., as measured in terms of their ability to be included in activities within their communities. Another appropriate topic for research would be how outcomes for people with disabilities change based on how their care is paid for – e.g., by the VA, private insurance, Medicare, Medicaid, or the Department of Defense. Also, many American adults with intellectual disabilities

continue to see the providers they saw during childhood. Research on the cascading of these patients' conditions from childhood throughout the life course would provide insights on how to improve care.

Many in the sessions were interested in research on how to integrate mental health into other health care services. For example, there is a strong relationship between cancer and depression, but the focus of research has been the cancer itself. Identifying effective mental health interventions (in schools or the community) for children living in poverty generated significant enthusiasm among participants. Given that very few disorders have a concrete ideology for diagnoses and that trauma and socioeconomic status can cause a spectrum of symptoms that could be diagnosed as a condition such as ADHD, it is appropriate to research how the ideology of the disorder in question shapes treatment outcomes.

Geography offers another source of disparities. One participant shared that for cancer, there seems to be a 75-mile rule – if a patient lives more than 75 miles from care, then his or her chances for survival drop significantly. Others shared that the rule holds for many other diseases, though not all. Geography also comes into play based on disparities in the quality of care that is available in different parts of the country. About 50% of people still prefer to go to the doctor or hospital that is closest to home. Thus, if a local hospital is underperforming, patients' treatment outcomes are likely to be worse than if he or she lived near a better hospital. This is of particular concern for safety-net clinics, since readmission penalties can increase disparities by redirecting money providers participating with payers that employ readmission penalties.

Learning how the health care system could better understand and measure these disparities is important enough to suggest additional research topics. For example, participants wanted to understand how to achieve a more multicultural coordination of care that integrates community health workers (e.g., *promotoras*) from faith-based and community-based organizations as part of the team. To reduce disparities associated with access, participants suggested learning how to communicate with diverse populations about differences in health plans

Addressing disparities within the health care system will require a better understanding of issues related to trust and communication. For specific conditions (e.g., stroke), it will be essential to understand what the best mechanisms are for educating underserved populations (e.g., minorities) about symptoms so that they can get care in a timely manner. This understanding can come from questions such as: what role does primary care and prevention play, what are the best messages, who should deliver them, and how should they be tailored for different audiences? What are the venues where the information should be communicated – e.g., corner grocery stories, barber shops, drug stores? With respect to those communities with high disparities, researchers and clinicians should resist the temptation to dismiss those communities as "hard-to-reach." Rather, they should figure out what they need to do to reach them and the best mix of interprofessional team members yield the best outcomes for a specific at-risk population.

At an individual level, participants asked how clinicians can communicate better with different groups, and be flexible in their language depending on the audience. Furthermore, participants stated PCORI should study   the barriers and facilitators for increased trust between providers, patients, family members, and neighbors. For example, identify what specifically is off-putting about patients' experience in facilities that they do not want to use? In terms of the actual information communicated,

providers need to understand that many patient information materials are at a reading level beyond that of the intended recipient of the information. Some warned, though, that a problem with emphasizing reading level is that many marketing writers tend to assume that simplifying the language means dumbing down the concepts, citing it as a pervasive problem in medical pamphlets and something health writers ought to avoid.

Participants identified the potential of technology to help support communications with these populations. Mobile health (e.g., smart phone-enabled applications), electronic personal health records, and telehealth are great strategies to break down barriers and reach those we could not reach before. Yet the formal health care system is lagging behind other sectors in using such technologies. To help realize the full potential of these technologies, PCORI could bring a disparities focus to the mobile health movement. For example, PCORI could identify the areas where the standard quality improvement approach works for everybody, and where it must be tweaked to address disparities in specific populations.

When asked how they would use PCORI research findings, participants offered several answers. Some would use studies to teach students communication skills, empathy, teamwork skills, and evidence-based information on anything that reduces disparities and improves outcomes. Others would use the findings to reorient residency programs and other interprofessional education toward patients and families, which should be central in their training. Others would share it with policymakers, or to raise the bar of evidence-based practice among health care providers.

Breakout Sessions: Improving Healthcare Systems

Comparing health system-level approaches to improving access, supporting patient self-care, innovative use of health information technology, coordinating care for complex conditions, and deploying workforce effectively.

Three sessions addressed the larger issue of how health systems could be improved. The key question from participants was how care coordination across systems can be improved. They suggested defining the "health care system" in the broadest possible terms, including hospitals, health homes, physicians, nurses, and other clinicians; public health departments, pharmacies, caregivers, patient navigators, as well as community supports, social services, alternative medicine, and telehealth.

At the most general level, participants were interested in how social determinants of health can be integrated into the health system, and what evidence base can be developed. Some were especially interested in how public health could be coordinated with the health care system. Others wanted to know how prevention could be better integrated into primary care, particularly since many doctors either do not have time to do it, or do not view it as a priority. Also, participants wanted to know how communication between all primary care providers and family and other community-based caregivers can be enhanced, as well as how patient navigators' roles could be most effective.

Participants stated that the actual location of care delivery systems can prove important. For example, how does the range of options available at a certain institution affect where people go to get care, and

what their outcomes are? How does the quality of care and outcomes differ between primary care providers that are co-located with mental and behavioral health providers and those that are not? Similarly, what is the effect of scheduling issues – e.g., needing to be seen in a week but having to wait three weeks for an appointment with a specialist –on patient outcomes?

Patients need better tools for decision making so they have increased power for self-management in a system with an evolving culture (i.e., evolving from provider-centric to patient centric). These tools should address the risks and benefits of various options, and should help patients decide which side-effects or potential harms they can accept or wish to avoid and choices that support their goals, particularly when care options are complex. More generally, patients need more education – not just for selecting a health care provider, but also for knowing health care systems and how they work. This education should extend to insurance options, so that providers are not left with the burden of analyzing the costs of various options. Participants felt that patients themselves must be involved in the development of these tools and education materials.

Participants believed that health information technology creates another research topic with the potential to improve health systems. For example, how do conventional delivery models compare to telehealth, or to models that include telehealth as a component? How can social media create new connections among the various stakeholders of the health care system, including patients, caregivers, providers, administrators, and researchers? Participants also recommended exploring what constitutes the effective use of biometrics and genetic information.

Other questions focused on improving access to timely and high-quality care. For example, participants noted a need to know more about how to utilize providers to the full extent of their abilities to reduce gaps in the continuum of care, particularly in transitions of care. Other suggestions were to look at how staffing, interprofessional mix, and certifications (e.g., palliative care) on teams affects re-admission rates and how to get patients into the right institution with the right providers from the beginning. Patients are often ill- equipped to know where to go, and may avoid good health care systems due to misconceptions, or inaccurate information.

Some of the discussion focused not on how to improve health systems but rather on how to radically transform them. For example, participants suggested that rather than comparing System A with System B, a better approach might be to introduce innovations in both systems and measure their effects. More may be learned from the different ways the systems respond to innovation than from a direct comparison of two different systems. Through such efforts that take a new approach to research, participants suggested PCORI could create a learning community aligned with the Institute of Medicine's "learning health system" to drive major changes within the health care system.

Participants also said that "best practices" for health systems may need validation. For example, holding "huddles" at the beginning or the end of the day can be very effective, but is this true in all systems? Group visits have been shown to be effective, but yet they are not a routine part of care.   Disease education programs will be needed for medical homes, and patients may want to be around other people who are experiencing the same things, i.e., support groups.

Communications and Dissemination Research

Comparing approaches to providing comparative effectiveness research information, empowering people to ask for and use the information, and supporting shared decision-making between patients and their providers.

Two sessions on *Communications and Dissemination Research* brought many new questions and suggestions to PCORI. Participants felt that the top research questions for PCORI could be: What do patients value in terms of health? In particular, this question should be elicited from those in older age groups, different cultures and geographical areas, as well as from people with different conditions and care needs (e.g., those with multiple chronic conditions as compared to those with less complex care needs). Knowing these answers will help make dissemination truly patient centered. Participants agreed that clinicians and patients are overloaded with information and messages. A key question is how information is shared among them, as well as how decisions are made.

Specifically, they stated a need to know which research study results create immediate, intermediate and lengthy change in decisions and behavior when they are disseminated. Which media best speed uptake with different decision makers? PCORI could study what decision support tools work for different demographics, settings and members of health care teams. What differences does a seminal study make compared with a series of studies when it comes to affecting change? Can we identify the fast information seeking methods that can provide clinicians in their offices and patients in their homes what they need just in time?

Participants felt that the key will be information that helps both clinicians and patients assess risk as they make decisions, but acknowledged that we do not know how best to communicate probabilities. They also noted the challenges presented by rare diseases, particularly around identification of symptoms and developing more accurate diagnoses. Additionally, it was noted that research around information clearinghouses, such as an inventory of techniques and a guidebook for evaluation or risk information, likely would be helpful.

Another way to frame dissemination is by using the community as the focal point for dissemination research. Learning who is trusted within a community, can lead to learning what common or unique characteristics of trusted intermediaries may affect dissemination rates. This information could help PCORI and its partners find community translators, including e-Patients, whose reach may extend farthest and who can disseminate findings fastest. The speed of information dissemination may also be furthered through integration of PCORI's dissemination methods with electronic medical records. Another question is whether or not there are new and different models of decision making in the online world. Naturally, patient registries and patient reported data would play an important role. Participants also wanted to know where communication fits in and what roles payers play in dissemination. They wanted to know how to enlist clinician team members as disseminators in the community.

These discussions led to offers by participating organizations to partner with PCORI. Some suggested that PCORI could help establish communication standards that assured open access while state medical societies—medical, osteopathic and nursing, for example—established professional standards to advance dissemination. Other suggestions were to reach a broad audience by conveying findings in

simple language while maintaining the rigor of research. Other participants suggested empowering community partners to be the communicators and also to teach students across health professions to engage patients and disseminate research.

When participants discussed how stakeholder organizations use CER, the opportunities for PCORI were especially compelling. For example, the specialty societies can play a key role because they use CER in licensing and board certification, and they believe there is an appetite for using CER for policy making. Findings from health systems also could affect benefit designs. We could work on clinician interpretation of CER with patient representatives joining to learn how dissemination can improve. This might be particularly helpful in learning how systematic reviews are communicated effectively to consumers. The learning could then extend through "mom blogs" using social communities as dissemination channels.

Participants thought that PCORI had an opportunity both to build on the current uses of CER and partner to develop an infrastructure for disseminating outcomes research. The medical and nursing specialty societies can use their journals for dissemination and can partner to create an infrastructure that quickly builds outreach in a variety of ways, such as -data registries, query networks and clinical assessment programs. Participants also suggested the Avoid Readmissions through Collaboration (ARC) project may offer channels for patients who may not be well-connected to the health system. The National Institutes of Health's Clinical and Translational Science Award (CTSA) program has a community engagement core that can bring questions to research partners. PCORI may even be able to collect questions from Google. There was strong interest among participants in partnering to build a new dissemination infrastructure.

The discussion of best practices provided both general guidance and very specific models from which PCORI may learn. The general advice was to use peer-to-peer learning using technology run by trusted partners. Other suggestions were to identify the communication practices that work within systems, as well as between systems, and learn from community-wide pilot projects to determine the best vehicles that work for dissemination. Participants asked for research on the amount of up-to-date information that is used outside communities with high levels of health literacy. They suggested that searching for decision aids that could spur the conversations providers need to have about research with their patients. Other thoughts were to look at financial incentives used to promote uptake of effective care coordination models.

Many specific organizations offered best practices for PCORI to learn from, such as the following:
- The Veterans Administration model with an ROI for every level and an EMR in every setting to address:
    - Obesity using the "Move Program"
    - MRSA reduction using the Positive Deviance method
    - Magnet hospitals.
- The Diamond Initiative for evaluating care in depression,
- Kaiser Permanente with the "Guinness Book of World Records for PAP smears,"
- Dr. Peter Pronovost's method of team-building for safety,
- Physician Consortium for Performance Improvement (PCPI), which convenes physicians to develop practice guidelines that are based around outcomes, rather than process measures,

- Payers and plans, such as Kaiser Permanente, using "Partner Portals" to develop patient defined outcomes,
- Independent Health in New York,
- Partnership for Patient's Hospital Engagement Network and CMS (see Action Network Registry hosted by the National Priorities Partnership)
- Partnership for Patients Readmission Action Team (http://www.qualityforum.org/Setting_Priorities/NPP/NPP_Action_Teams.aspx)
- Faster Cures for dissemination,
- Critical Path Institute and the FDA,
- PatientsLikeMe for graphics,
- Wikipedia for real time updating,
- Group Health Puget Sound for data mining,
- Genetic Alliance for dissemination and community development around rare diseases,
- NQF Critical Paths: Care Coordination Technical Expert Panel report (http://www.qualityforum.org/HIT/Critical_Paths/Care_Coordination.aspx)
- Office of the National Coordinator Standards Wiki Workgroup - Longitudinal Care of Coordination (http://wiki.siframework.org/Longitudinal+Coordination+of+Care+(LCC))
- Institute of Medicine – Educating for Practice: Learning how to improve health from interprofessional models across the continuum of education to practice (http://iom.edu/Activities/Global/InnovationHealthProfEducation/2012-NOV-29.aspx)
- American Nurses Association and the American Academy of Nursing Care Coordination Papers - http://www.nursingworld.org/care-coordination.
- IOM – The Learning Health Care System in America report (http://www.iom.edu/Activities/Quality/LearningHealthCare.aspx)