

PIPC/AAN Dissemination and Implementation Roundtable Summary and Recommendations to PCORI

On November 21, 2013 the Partnership to Improve Patient Care (PIPC) and the American Academy of Neurology (AAN) jointly hosted a Movement Disorders focused Roundtable on issues specific to the dissemination and implementation agenda of the Patient-Centered Outcomes Research Institute (PCORI). A PCORI representative briefed attending participants (those signing onto this summary and recommendations listed in “Appendix A”) on the Institute’s current thinking and approaches related to its Dissemination and Implementation Action Plan, and participants were offered the opportunity to both comment and ask questions. Subsequently, participants engaged in a wide ranging discussion intended to surface and identify consensus recommendations for both PCORI and the AAN.

Patient-Centered Dissemination of Research Findings

During the initial discussion with PCORI, several consensus observations were made related to patient-centered dissemination of research findings. Among these was recognition that traditionally defined evidence-based medicine (EBM) and evidence-based comparative effectiveness research (CER) are separate from and do not address the need for an understanding of patient-centered outcomes. Therefore, findings and information emerging from PCORI-sponsored studies will need to be integrated into patient care models in novel and creative ways to ensure that they are truly patient-centered and useful for patients and their clinicians. This need has profound implications for dissemination and implementation programs, suggesting that current models may be inadequate or inappropriate for evolving datasets.

PCORI asserted the need for advocacy group engagement to help determine effective mechanisms for disseminating study findings. The legislation provides guidance to tailor dissemination to various audiences in a patient-centered manner, but does not require or describe specific tactics or methods. Therefore, PCORI is seeking guidance from stakeholders. It was noted repeatedly that patients inevitably name their physicians as among the most trusted sources of information, so physicians loom large as targets for the dissemination of results; however, it was additionally and repeatedly noted during the day that there are actually multiple key audiences for dissemination. These audiences not only include the patient and caregiver but a wide range of health care and other professionals, as well as patient advocacy groups, that are in continual contact with and respected by the patient community. The untapped potential of the electronic health record to facilitate the dissemination and sharing of information among these diverse constituencies loomed large in the day’s discussion. It was also emphasized that study participants (including caregivers) need timely dissemination of study results and that advocacy groups can be key allies in designing and vetting multi-modal dissemination approaches that facilitate access across diverse audiences.

The role of peer review, which PCORI is statutorily required to use in assessing its results, received considerable attention. Many of the participants felt that: 1) the current standards may be ineffective because of biases in peer selection; 2) revised standards may be not just necessary, but essential; and 3) perhaps PCORI, as a new organization, has a responsibility to do things a bit differently, to be an “influencer” rather than a protocol follower in the conduct of peer review.

Concern was expressed that patient-reported outcomes, paramount in study design (after significant advocacy for it), might be neglected in study dissemination. An example was offered of a study demonstrating the benefits of exercise in Parkinson’s disease. While this statement might be sufficient for researchers, patients would want much more granularity: what sort of exercise, for how long, using what equipment, at what intensity level, etc. These sorts of issues might not be of critical interest to investigators, but might, in fact, be the key elements of patient-centered outcomes research (PCOR), e.g. outcomes with practical meaning for patients.

There was a corollary discussion about whether PCORI should develop standards and only disseminate what was considered to be “good science.” The point was made that, at least in theory, all PCORI studies should reflect “good science” and that it was important not to conflate “bad science” with negative results. Ideally, there should be broad dissemination of all PCORI studies, even those with negative results, with appropriate explanations for providers, patients and families. PCORI should be an educator (one not overly paternalistic) and not a censor. Ultimately, informed health care decisions should be made between the patient and their provider.

-Afternoon Closed Session-

The afternoon session began with a clear sense of the group that dissemination materials targeted at patients needed to be carefully vetted (if not actually written) by individuals knowledgeable in the specific disease states. This seems self-evident, but has historically been a problem, especially if the goal is to reach previously unengaged patients. This led to the insight (around which there was consensus) that many patients are unaware that movement disorder specialists even exist and that outreach to patients, caregivers and primary care providers is inadequate and represents a major barrier to accessing actionable information. This latter point was emphasized further when the question emerged about whether the goal was simply dissemination of information or behavioral change. PCORI has a mandate to help patients benefit from CER for clinical problems so the answer clearly is “both.” Given that, the need for a supportive infrastructure capable of guiding naïve patients through complex decisions is needed; developing and testing potential infrastructure improvements would be a valuable project element for PCORI’s selected vendor developing a Dissemination and Implementation Action Plan.

The discussion then moved to information access, especially the challenges for many patients who, because of inadequate resources, insufficient technical skills, or multifactorial health

literacy challenges, lack access to sophisticated technology. This challenge falls comfortably under PCORI's Health Disparities agenda and Communications and Dissemination Research agenda, and also warrants focus under the contract for development of a Dissemination and Implementation Action Plan. Among the solutions proposed was that PCORI collaborate with electronic health record (EHR) vendors to incorporate critical patient-centered information, including considerations for patient subpopulations and the strengths and limitations of the study results, into the EHR. Presumably this could be designed for providers, patients and caregivers, and continuously updated with information approved for dissemination after vetting by PCORI's peer review process. It was also noted that the EHR, as a repository of information, could serve a research function; perhaps PCORI could support research into the feasibility and development of EHR-reported quality measures for patient-reported outcomes and participate in advocacy for patient-reported outcomes to be included in general quality reporting efforts?

Another potential use of the EHR surfaced in connection with providing decision support tools to help create a national information infrastructure; included in these support algorithms would be information on when basic care stops working and referral is necessary. One of the key benefits of such a database will be the ability to "push" critical information about less common disorders. The example that surfaced repeatedly in our conversation involved the critical need for Parkinson's patients to maintain access to and continue their medications as directed when hospitalized. From PCORI's perspective, decision support infrastructure should be engaged to disseminate the results of key (once again, peer reviewed) PCOR outcomes data to assure it was timely and appropriately integrated into patient care. This infrastructure could be used to alert patients about PCOR projects with potential "game changing" impact. PCORI could communicate directly to stakeholders with targeted messages about the potential of projects so that they would know about them, advocate for them, and connect with the researchers to reinforce the value of their patient-centered work. This process could create a self-perpetuating mechanism for the dissemination of outcomes in real time.

When the group heard from a patient, the first point made was the personal price paid due to the missed opportunity to receive education about her disease upon diagnosis: "if I'd only known then what I know now..." Elements mentioned as important included a packet of information including a list of new words that she was likely to hear in her disease; "bradykinesia" for example. Patients are entering a world of frightening symptoms, new medicines with strange side effects, and an unfamiliar provider network. Both they, and potentially their clinicians, need support in managing multiple aspects of their new illnesses, including when (and how) to identify and access expert subspecialty consultation. This insight corroborated a point made earlier, that patients need improved training about managing chronic and progressive illness. (*Of significance, this observation transcends this movement disorders roundtable, in fact, similar observations have been made at other roundtables; this recommendation is, therefore, genuinely cross-cutting*). A patient-focused training course for self-management of disease (which the group agreed should be a reimbursable service for new patient education) deliverable at the time

of diagnosis could include periodic, peer-reviewed updates, summarizing the importance of findings from CER; once again, as with the enhanced EHR, PCORI could play a central role in both pushing information into this module and pulling and analyzing feedback about the effectiveness of their own, and potentially others' dissemination and implementation efforts.

A very specific (and presumably remediable) problem surfaced around the dissemination of information to the Groups about ongoing studies to which they've referred patients or families for participation. Evidently the feedback loop is often faulty, and groups don't receive timely information about study status and results. Research subjects, their families and caregivers, make a profound commitment when they participate in a clinical trial and timely communication of results is the least they should expect. This is a clearly definable and remediable goal for PCORI dissemination efforts; relevant advocacy groups should be looped into PCORI studies and proper feedback should be part of protocol design.

The participants then discussed the role, and potential, of social media and the internet in dissemination and implementation. Overall, participants considered the potential value significant. In fact, the point was made that the overwhelming majority of patient information is now pulled from the internet and those who are not tech-savvy tend to get information from those who are. The internet, then, is a 'tool' rather than a source, and it's a tool that augments the very limited time that patients have with their physicians and additionally allows information access at the convenience of the user, e.g. when the user has time and is emotionally ready. In addition, the internet allows evaluation of how patients are searching for information and potentially how they are acting upon it; this bidirectional potential could be exploited by PCORI to evaluate dissemination strategies. Information could be pushed through internet sites and evaluations conducted about which sites have the most effective uptake and even which generated the desired follow-up actions. Finally, the potential for social media and internet applications to disseminate information to geographically sequestered patients, caregivers, and families surfaced in the context of collaborating with advocacy groups. These groups, who know the communities best, could be vital in the design and evaluation of these communications initiatives and would, quite probably, not only be anxious to work with PCORI but willing to co-brand their initiatives.

An array of both cautionary and aspirational suggestions emerged as the conversation moved towards closure. Concern was expressed that the statute's requirement for study dissemination within 90 days might lead to rushed summaries of diminished quality, especially since this is a new mandate requiring, presumably, new and untested processes. Given the speed and reach of electronic media, there is significant potential for errors to spread quickly, causing considerable damage and requiring significant resources to repair. This is a risk best avoided. A possible solution emerged in the suggestion that PCORI partner with analysts (a Google-like approach was suggested) to evaluate the scientific reliability of various internet sites. This reflected the

attendees' belief that PCORI, in its dissemination efforts, needs to “play” cautiously in new arenas, taking requisite care to avoid patient and family harm.

There was also a note of caution about paying excessive attention to “averages” and neglecting the reality that, to patients, the important research is what impacts them personally, not the statistical means. Implicit in this warning is that research studies must include diverse populations, happily already a goal of PCORI and a statutory requirement. The precision of this recommendation was subsequently enhanced: Parkinson’s symptoms, it was noted, are sufficiently individual that consideration of how best to disseminate results to the specific subpopulations that are potentially impacted by a study is sufficiently important to justify incorporating a focused dissemination plan into any approvable funding request.

Summary and Recommendations

- EBM and CER are defined independently of patient-centered outcomes research. PCOR findings need to be recognized as important and actionable evidence and that failure to include considerations from evidence for improved patient-centered outcomes constitutes failure to practice evidence-based medicine. Historical approaches to and targets of dissemination and implementation efforts may need to be reconsidered by PCORI in development of a Dissemination and Implementation Action Plan.
- There are multiple audiences for PCORI-generated datasets, and these audiences have varying needs and levels of sophistication. An effective dissemination and implementation plan needs the flexibility to provide meaningful feedback to these various entities. PCORI should engage advocacy groups as key allies in designing, implementing and vetting these plans.
- Peer review of study results prior to dissemination, while acknowledged to be important, needs to be expanded beyond its traditional definition. While assuring scientific rigor is necessary, it is insufficient to ensure the patient-centered requirement of PCORI. In order to assure that dissemination and implementation plans are informed by patient needs, the reviewers need to have a broader perspective. Advocacy groups, many of which have scientific advisory boards, can assist in defining and implementing a new model. For PCORI to be an “influencer” of an evolving peer review process, advocacy groups should be engaged to provide guidance and insight.
- It is critically important that dissemination and implementation materials be vetted, if not actually written, by individuals with knowledge of patients with the relevant disorders. This is especially vital if the goal is to reach and encourage behavioral change, especially among previously unengaged patients.

- The electronic health record was proposed as a mechanism to push information to patients, especially disenfranchised patients without internet access, and pull information back into the system, including information about the real time efficacy of new diagnostic and therapeutic interventions. The idea of PCORI collaborating with major EHR vendors surfaced as both a research project and as a component of the development of a dissemination and implementation action plan.
- Other proposed uses of the EHR included “pushing” algorithms addressing the proper timing of referral, the pending availability of important new information from completing clinical trials, or other critical but often ignored needs, e.g. the need to assure patients with Parkinson’s the ability to retain access to medications when admitted to hospitals or other settings.
- Patients made the point very clearly that they and their caregivers need better education about how to manage a chronic disease. Issues raised included why self-care is essential, learning a new vocabulary, learning about new medicines and their side effects, navigating the health care system (especially knowing when subspecialty referral is needed), managing disability, and re-learning how to be a maximally functioning member of society. (*Of note, this issue surfaced at other roundtables so can accurately be considered ‘cross-cutting’ and relevant to multiple chronic conditions.*) The idea of a reimbursable training course, informed by PCORI-generated PCOR, was raised as a potential dissemination pilot project.
- The feedback loop by which patients and families who participate in studies are apprised of the results needs to be improved. Although this observation and critique was not specific to PCORI, it should be addressed for PCORI sponsored investigations.
- As anticipated, the role of the Internet in delivering information loomed large in the discussion. Even those who are “technologically-challenged” access information from the internet, albeit indirectly through others. Roundtable participants recommended that PCORI explore the value of the Internet as a tool to access appropriate, evidence-based information, and then use its bidirectional potential to assess whether (and if so how) the delivered information impacted patient behavior. Finally, use of the Internet to deliver information to geographically diverse patients was recommended as an important adjunct to serving the disenfranchised and ameliorating disparities.
- There is a quality control problem with internet sites; PCORI should consider a collaboration with a major new media or technology player (Google was mentioned) to consider how patients might be properly guided to higher quality sites, such as through a PCORI/advocacy group co-branded site.
- Patients differ profoundly, and so must dissemination and implementation plans for various audiences. It is important that a plan for distinguishing study results as they apply to defined,



relevant subpopulations be built into study proposals from the onset. A proposal without such a plan is not suitable for funding.

Appendix A

Participating Organizations Signing the Summary and Recommendations:

American Academy of Neurology
American Parkinson's Disease Association (APDA)
CurePSP Foundation
Davis Phinney Foundation
Dystonia Medical Research Foundation
International Essential Tremor Foundation (IETF)
Huntington's Disease Society of America (HDSA)
Michael J. Fox Foundation
National Parkinson Foundation (NPF)
Parkinson's Action Network (PAN)
Parkinson's Alliance
Parkinson's Disease Foundation (PDF)
Partnership to Improve Patient Care (PIPC)