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PCORnet: A Bold Initiative to Advance Comparative Effectiveness Research and Practice-based Learning

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The Patient-Centered Outcomes Research Institute (PCORI) is embarking on a groundbreaking journey to estabish an integrated national research network—PCORnet—for conducting large-scale comparative effectiveness research (CER) studies. In December 2013, PCORI approved $93.5 million in funding over the next 18 months to create 11 Clinical Data Research Networks (CDRNs) that represent consortia of health care systems and 18 Patient-Powered Research Networks (PPRNs) that represent partnerships between patients, advocacy groups, and investigators focused on both common (e.g. chronic obstructive pulmonary disease, arthritis, epilepsy) and rare (e.g. muscular dystrophy, Phelan-McDermid Syndrome) conditions. Both the CDRNs and PPRNs seek to rapdily advance knowledge about the effectiveness of alternative treatments and health care delivery strategies through innovative approaches to improve the efficiency of conducting patient-oriented research and the active engagement of clinicians, patients, and other key stakeholders. Efforts to establish PCORnet as an interactive "network of networks" will be overseen by a coordinating center, led by the Harvard Pilgrim Health Care Institute, the Duke Clinical Research Institute, and 11 different working groups (e.g. health system interactions, ethics, data privacy, patient-reported outcomes) to advance the methods of conducting highly efficient, multi-site clinical and pragmatic trials.

More than 80% of the total PCORnet funding will be directed toward establishing the 11 CDRNs. To be eligible for funding, each CDRNs had to bring together health care systems that in aggregate provide care to more than 1 million patients for whom longitudinal electronic medical record (EMR) data on health care delivery and changes in clinical condition are available.

The CDRNs are extremely diverse. For example, two of the CDRNs bring together the major academic medical centers in Chicago and New York City, while the Great Plains Collaborative brings together 10 major medical centers in the Upper Midwest and Texas.

Collectively, it is estimated that the participating CDRN institutions provide care to nearly 100 million Americans. The CDRNs will be required to demonstrate in short order a number of capabilities that are critical to creating an integrated national research network, including:

1. Data interoperability and data standardization across the participating institutions;
2. The ability to collect patient-reported outcomes and maintain high levels of participation in research;
3. Engagement of large populations with selected conditions;
4. The involvement of health care system leadership in network governance;
5. The capacity to conduct practice-based research without disrupting the business of providing care;
6. The ability to align human subjects oversight and informed consent procedures with the level of risk in proposed studies and to participate in efficient shared institutional review board (IRB) arrangements; and
7. The development of clear policies to maintain data security and patient privacy.

PCORI envisions that PCORnet will provide access to large amounts of diverse, nationally representative data. These data will support a wide range of possible studies that address questions that are highly salient to patients, families, and clinicians. It is further hoped that by supporting core research and informatics infrastructures, PCORnet will dramatically decrease the time and resources need to launch new studies. At a more fundamental level, "PCORnet aims to advance the shift in clinical research from investigator-driven to patient-centered studies."[1]

PCORnet also represents an important vehicle for enabling learning health systems in which… "science, informatics, incentives, and culture are aligned for continuous improvement and innovation, with best practices seamlessly embedded in the delivery process and new knowledge captured as an integral by-product of the delivery experience" (Institute of Medicine, 2006).

The establishment of true learning health systems[2] holds the promise of creating work environments in which the skills and perspectives of general internists will be highly valued. However, it should be noted that PCORnet is on an extremely tight timeline, in large measure because the legislation authorizing PCORI expires in 2019. So, unless PCORI demonstrates the ability to answer questions that can have a significant impact on practice and policy, reauthorizing legislation may be an extremely difficult

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sell if current funding and political environments persist.[3] Given that a large proportion of future PCORI budgets will support studies utilizing PCORnet, a lot is riding on its success or failure.

I believe that three critical areas must be tackled if PCORnet is to meet its lofty expectations. First, the ability to conduct large multi-site lower-cost pragmatic trials will require harnessing the potential power of the big data that exists in EMRs. This, in turn, will require much greater attention to data standardization across different instituitions and different EMR systems and, just as importantly, diligence on the part of clinicians to ensure that EMR information is accurate and up to date. One of the big unknowns is the degree to which EMR data can support generation of the high-quality evidence needed to change clinical practice.

Second, research approval processes must be made proportionate to the risks posed by those participating in a given trial. More specifically, approval processes for conducting low-risk trials that evaluate standard-of-care treatments and obtaining patient consent must be radically streamlined. In addition, IRBs must demonstrate a willingness to participate in shared IRB arrangements, in which a single IRB has primary responsibility for protocol review and other sites defer to the judgment of the primary IRB. These efforts should also seek to eliminate the idiosyncrasies that characterize most IRBs.

While addressing the data and regulatory issues mentioned above will be challenging, I believe that a potentially more difficult third area to address is how to change institutional cultures to enable practice-based research. In most institutions, significant economic disincentives exist to engage in activities that interfere with clinical productivity. While practice-based research must test simple interventions that can be replicated relatively easily, it is important to recognize that recruiting patients for such studies in busy practice settings and implementing interventions—no matter how simple—will invariably interrupt previously established clinical workflows. Practice-based studies will only fluorish if health care leaders, clinicians, and patients value such work and believe at a fundamental level that learning is an essential part of health care delivery.

As a professional organization with a mission to "lead excellence, change, and innovation in clinical care, education, and research in general internal medicine," SGIM should embrace the vision of PCORnet and actively advocate for policies that enable high-functioning practice-based research. More importantly, however, is the role that SGIM members can play within their own institutions to promote cultures that foster learning health systems and enable the ultimate success of the PCORnet national experiment.

References

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