Toward a True Rapid Learning Health Care System: How Can We Build Both the Will and the Skill?

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KEY POINTS . . .

PCORnet aims at uniting researchers, patients and clinicians to enable rapid, large-scale, patient-centered clinical research in real-world delivery systems and communities.

PCORnet is the world's first network infrastructure to be based on EHR data rather than claims data.

PCORnet supports both large observational studies and embedded randomized clinical trials.

The Virtuous Cycle of a Learning Health Care System: Real-World, Real-Time Engagement

In a Learning Health Care System, research influences practice and practice influences research. Creating a Learning Health Care System takes both will and skill, as well as real-world, real-time engagement. The effort to integrate research into health care systems and translate knowledge into action is complex, which means we have a steep hill to climb.

The steps to developing a Learning Health Care System begin with a design based on evidence generated from multiple sources that leads to the implementation of a pilot study, complete with control settings. Collected data must be analyzed to understand what works and what does not. The evidence gained through data should influence continual improvement, and results should be shared widely to improve care. The value of research is important to people, but often out of sync with the pace, needs, and demands of the health care system. The interests of researchers and what health care system leaders focus on is not always in step.

Building the Will

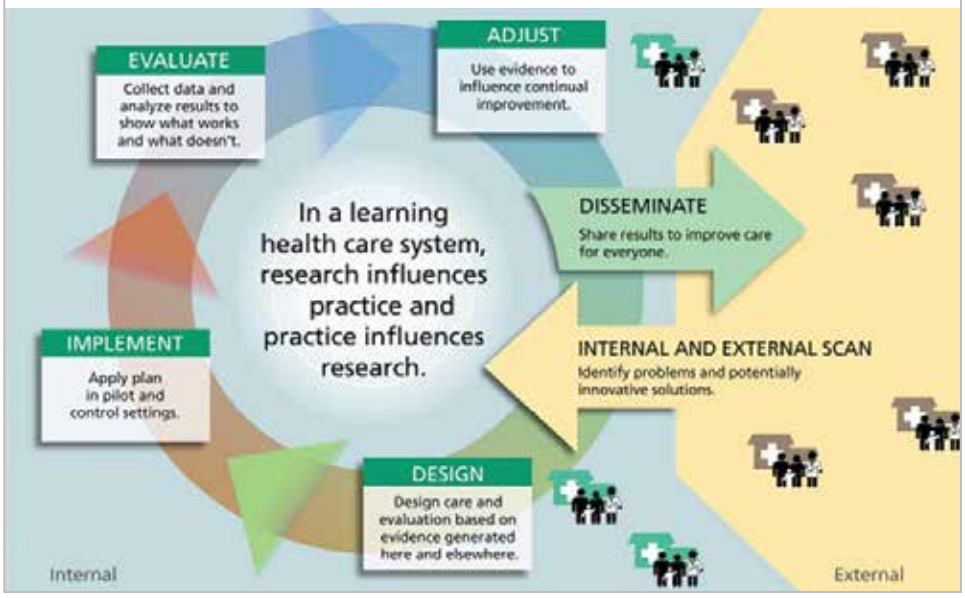
Research can offer a "value proposition" that is relevant to both patients and clinicians, even if they have differing perspectives on research. We want OUTCOMES research to have value by providing a bridge to learning. However, there are many unanswered questions. For example, will clinical decision makers actually put research into practice? There may be financial trade-offs? Some may ask "What do I get as a return on my investment?" Will patients want to be part of a Learning Health Care System? Or would they rather be part of a system that "knows?"

In an effort to develop real-time engagement, the Patient-Centered Outcomes Research Institute (PCORI) has developed PCORnet, a national learning health care network designed to help build a Learning Health Care System. For the last 15 months, PCORI has been creating and developing both the will and skill to make it work for multiple stakeholders.

Building the Skill

As a national, learning health care network, PCORnet will enable rapid, large-scale, patient-centered clinical research in

Figure 1. Virtuous Cycle of a Learning Health Care System: Real-World, Real-Time Engagement [1].



real-world care delivery systems and communities. PCORnet unites researchers, patients, clinicians and system perspectives to enable rapid, large-scale, patient-centered clinical research in real-world care delivery systems and communities.

To help ensure success, the architecture of PCORnet mirrors the components of a Learning Health Care System. The components of PCORnet include data and analytics; people and partnerships; patient and family engagement; ethics and oversight; evaluation and methodology; funding; organization; prioritization; and deliverables.

In other words, the attributes of a Learning Health Care System and PCORnet align and complement each other. Both require the involvement of patients, clinicians, and other stakeholders. Both leverage data sources and embed clinical trials into routine clinical care using pragmatic and realistic trial designs, and both ensure continuous learning based on accumulating evidence.

We want research to add value to the health care system. However, we know that the value proposition is relative, and that we need to consider what changes and trade-offs are needed to be able to more seamlessly integrate research and practice and consider what those investing in such a system will get in return.

How can we build the will and the skill for PCORnet to serve as a national platform for comparative effectiveness research that leverages real-world EHR data based on patients' daily care experiences? First, we must ensure that research must offer a viable value proposition and a pathway to long-term improvement and sustainability. We must also specify what is important to patients, clinicians and health care systems. The challenge is to create conditions in which findings are integrated into clinical workflow and have naturally occurring "best care." This entails a paradigm shift, where researchers, clinicians, and patients partner together to address "what matters," rather than "what's the matter?"

PCORnet PHASE I

PCORnet networks are coming together as new partnerships with relatively little collaboration before being funded through PCORnet. Through the networks, PCORI is simultaneously building infrastructure and culture.

Figure 2. Component Parts of a Learning Health Care System [2].

Component	Definition
Data and Analytics	Infrastructure, resources, processes, and mechanisms needed to leverage informatics for learning.
People and Partnerships	Personnel and relationships involved in establishing and maintaining learning activities within and external to the organization.
Patient and Family Engagement	Centrality of patients and their families as partners in the processes of learning, whether the immediate goal of a given process is to provide high value care to a given patient or is to elucidate the factors that advance or impede this goal.
Ethics and Oversight	Rethinking the traditional and strictly separate frameworks for clinical patient care and research, and developing both a conceptual and a practical framework more suited to the needs and aspirations of an LHCS.
Evaluation and Methodology	Activities and methodological approaches needed to identify, implement, measure, and disseminate learning initiatives.
Funding	Mechanisms to fund the operational effort needed to enhance learning capability, as well as strategies for sustained funding of learning efforts.
Organization	Organizational and managerial activities and resources needed to operationalize a systemwide LHCS.
Prioritization	Process in which learning activities and opportunities are aligned with strategic goals across different levels of the organization.
Deliverables	Products or outcomes of learning activities across various levels of the system, and which draw attention to the need to embed learning across the system.

Up and running since October 2015, Phase I of PCORnet includes 29 networks. Eleven of these networks are Clinical Data Research Networks (CDRNs) that are based in integrated delivery systems, academic medical centers, and federally qualified health centers. Eighteen are Patient-Powered Research Networks (PPRNs) where patients with certain conditions in common have formed networks, often in collaboration with academic researchers. Among the 18, nine are focusing on rare diseases, and nine on common conditions. To help oversee the networks, a Coordinating Center is being co-led by an ambitious and talented team from Harvard and Duke Universities that lends technical and logistical support, especially for data-related activities and initial demonstration projects.

The guiding principle of PCORnet infrastructure is to make research easier … and to integrate simple, pragmatic studies into routine care.

Infrastructure, Demonstration, and Learning

The networks, funded through PCORnet, are simultaneously building infrastructure and a culture of collaboration that will help align the attributes of a Learning Health Care System and PCORnet. This alignment means that patients, clinicians and other stakeholders will be involved in identifying relevant research and study topics. Attribute alignment also means that systems and data sources are being leveraged to enable efficiencies in study operations; this means "hard wiring" the ability to embed clinical trials into routine clinical care and using pragmatic and realistic trial designs that can close the gap between the pace of research and its relevance to care delivery decision makers. Our goal is to ensure continuous learning based on accumulating evidence.

As Phase I of PCORnet comes to a close, we are on a rapid trajectory and a culture of collaboration is taking hold. PCORI recently funded the first demonstration project, "ADAPTABLE." ADAPTABLE is a pragmatic clinical trial to investigate daily aspirin dosing of 81 mg versus 325 mg. It is employing novel methods, such as leveraging EHR data and bringing together a large group of pioneering networks that includes patients as co-creators of the

Figure 3. Ideal: LHCS & PCORnet Attributes Align.

- Involvement of patients, clinicians, and other stakeholders in identifying relevant research study topics
- Leveraging data systems and data sources to enable efficiencies in study operations
- Hardwire the ability to embed clinical trial operations into routine clinical care
- Use pragmatic and realistic trial designs that close gap between pace of research and relevance to care delivery decision makers
- Ensure continuous learning based on accumulating evidence

research protocol. ADAPTABLE itself needs to be "adaptable" as it could evolve along the way. Our hope for ADAPTABLE is that it will demonstrate that at this scale we can develop a clinical trial and also create a usable infrastructure for subsequent trials and observational research.

the identification, recruitment, consent and follow-up of participants.

We have established links to other databases and registries and we are ready to apply the will and skill we have built in Phase I to help make rapid learning and translation possible.

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PCORnet PHASE II

PCORnet Phase II, which begun October, 2015, will rely on the operational and sociocultural building blocks created in Phase I as a springboard for Phase II. By creating a collaborative culture that shares freely, we are aiming to leverage and harvest the knowledge we already have so as to lead to clinical trials that are conducted affordably through improved contracting, IRB coordination, engagement of clinicians and sites as well as

References

[1] Greene SM, Reid RJ, Larson EB. Implementing the learning health system: from concept to action. Ann Intern Med 2012;157:207-10. [2] Psek WA, Stametz RA, Bailey-Davis LD, et al. Operationalizing the learning health care system in an integrated delivery system. EGEMS (Wash DC) 2015;3:1122. ■

Additional information:
The preceding article was based on an address given at the First Plenary Session, "Taking Stock of the Learning Health Care System: What Have We Achieved and Why Does it Matter," at the ISPOR 20th Annual International Meeting 16-20 May, 2015, Philadelphia, PA, USA.

Patient-Centered Outcomes Research Institute http://www.pcori.org/

PCORnet: An Update on Our Blueprint for Transforming Health Research http://www.pcori.org/blog/pcornet-update-our-blueprint-transforming-health-research

To view Ms. Greene's presentation, go to: http://www.ispor.org/Event/ReleasedPresentations/2015Philadelphia