

The Louisiana Clinical Data Research Network: Leveraging Regional and National Resources to Improve Clinical Research Efficiency

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ABSTRACT

Background: Mapping of the human genome and technological advancements allowing storage and rapid retrieval of health-care data have heralded a new phase in clinical medicine and have served as a catalyst for the advent of personalized medicine. The use of health information databases provides a unique opportunity to investigate questions of great complexity and real-world application in a way that is most useful in providing high quality, safe, and cost-effective clinical care to patients.

Methods: The Louisiana Clinical Data Research Network (LACDRN) aims to streamline the workflow of multiinstitutional clinical studies and to dramatically expand the clinical research resources available to local investigators. The LACDRN contains health information for more than 1 million patients in Southeast Louisiana and is a rich resource for researchers to conduct retrospective or observational trials and to recruit patients for prospective studies.

Results: The LACDRN is part of a large-scale initiative by the Patient-Centered Outcomes Research Institute to create a national electronic health record network that enables the timely initiation and completion of comparative effectiveness

research in a coordinated effort. For the first time, network research will be guided in part by input from patients and caregivers, increasing their engagement in the research process.

Conclusion: The establishment of the LACDRN is a unique opportunity for clinicians to take part in an innovative national initiative designed to offer new clinical research options for patients and to carry out cutting-edge translational, clinical, and health services research.

INTRODUCTION

The emergence and widespread use of electronic medical records and the ability to acquire, store, and retrieve data in a timely manner are revolutionizing the delivery and quality of healthcare. These developments, combined with advancements in the field of analytics, continue to enhance the capacity for research, allowing researchers to conduct more complex studies. Yet clinical research often falls short of answering the question of greatest interest to individual patients: “Which therapy will work best for me?” This conundrum is not unique to patients; many physicians and healthcare providers are in a similar situation. In a 2014 editorial, National Institutes of Health leadership pointed to the surprising fact that in 2008 almost half of the practice recommendations of the American College of Cardiology and the American Heart Association were based on expert opinion alone, and only 11% of the recommendations were based on evidence from multiple, rigorous clinical trials.¹ In many cases, the evidence needed to allow individual guidance concerning available therapies and achievement of the best clinical outcomes has been too costly and difficult to obtain.

By 2019, an estimated 80% of healthcare data will be recorded electronically.² For the first time, the tools are available to completely transform the clinical research process, reducing costs and inefficiencies

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while increasing value for patients, physicians, and healthcare providers. During the last decade, a number of regional networks have been created that repurpose electronic healthcare and administrative data to answer comparative effectiveness research questions.³ These regional networks have demonstrated the feasibility of initiating projects with large-scale databases and have set the stage for a national effort of this type. The creation of a national, highly representative data network that can streamline the collaborative research efforts of numerous institutions is the goal of the National Patient-Centered Clinical Research Network (PCORnet).⁴

Supported by the Patient-Centered Outcomes Research Institute (PCORI), PCORnet consists of 11 clinical data research networks (CDRNs) and 18 patient-powered research networks (PPRNs). Collectively, these networks will contain health information for more than 100 million patients,¹ allowing for an unprecedented opportunity to launch large interventional and observational trials. This network is envisioned to permit research to be conducted with unprecedented efficiency and accuracy, allowing for timely implementation of novel protocols for the diagnosis and treatment of diseases. Ochsner Health System has joined this landmark national initiative through partnership in the Louisiana Clinical Data Research Network (LACDRN). The LACDRN is a collaborative effort that includes, in addition to the Ochsner Health System, the Louisiana Public Health Institute, Pennington Biomedical Research Center, Tulane University, and the community health clinics that are part of the Greater New Orleans Health Information Exchange (GNOHIE).⁵ The LACDRN aims to provide physicians and investigators access to the longitudinal health data of more than 1 million individuals and to do so with one critically unique factor in place: the promotion of active patient involvement in the research process.

THE VISION FOR PCORnet

PCORI is a nonprofit, nongovernmental institution established in 2010 by the Patient Protection and Affordable Care Act. The mission of PCORI is to help patients make informed healthcare decisions and to improve healthcare outcomes by assisting in the initiation, execution, and distribution of high-quality, patient-focused research.⁶ PCORI's vision is to promote research that is clinically relevant and provides both patients and providers with information that is most effective for the management of a given medical condition. Examples of this approach may include answering questions such as the following: Of the available strategies, what is the

most effective way to treat and manage childhood obesity or diabetes? Which currently available treatment strategy provides the best outcomes for patients with rare cancers?

PCORnet is an extension of PCORI's vision and is expected to be an active, research-ready network by September 2015. PCORnet will act as a distributed research network, with CDRN partners having the ability to simultaneously initiate multicenter clinical trials with expediency. Research will be guided by governance structures that include researchers and clinicians as well as patients and caregivers. Each CDRN is intended to have specific disease foci, and PPRNs will provide substantial input focused on the improvement of treatments for specific diseases.

The PCORnet project is currently in phase I of its funding, an 18-month infrastructure-building period that began in March 2014. The main goal of phase I is the creation and testing of a common data model (CDM) that will allow bidirectional, secure transmission of clinical data for the purpose of conducting multicenter clinical trials. Data protection and security are paramount, so only the aggregated results of data analysis (rather than identifiable, individual information) will be shared with the PCORnet coordinating center or among CDRNs. All activities will be conducted under the oversight of institutional review boards (IRBs).

Challenges during this period include the establishment of procedures to streamline IRB review processes, the development of strategies for engaging patients in governance and research-related activities, the development and prioritization of research agendas, and the harmonization of various types of electronic health data to a sharable CDM. PCORI has invested more than \$100 million nationwide in the creation of PCORnet with the goal of making this system the industry standard for the completion of clinical research. The vision is for the CDRNs to become primary sites for research that is funded, not just by PCORI, but also by industry and other federal agencies. In September 2015, PCORnet moves into phase II, during which the primary objective is the execution of clinical research trials.

THE LACDRN

The LACDRN is a PCORI-funded partnership coordinated by the Louisiana Public Health Institute that allows patient information from Ochsner's enterprise data warehouse, the Louisiana State University Health System's federated data warehouse (HarmoniQ), and the GNOHIE to be shared for the conduct of multi-institutional research studies. Patient data, stripped of identifiers such as name, address, and Social Security

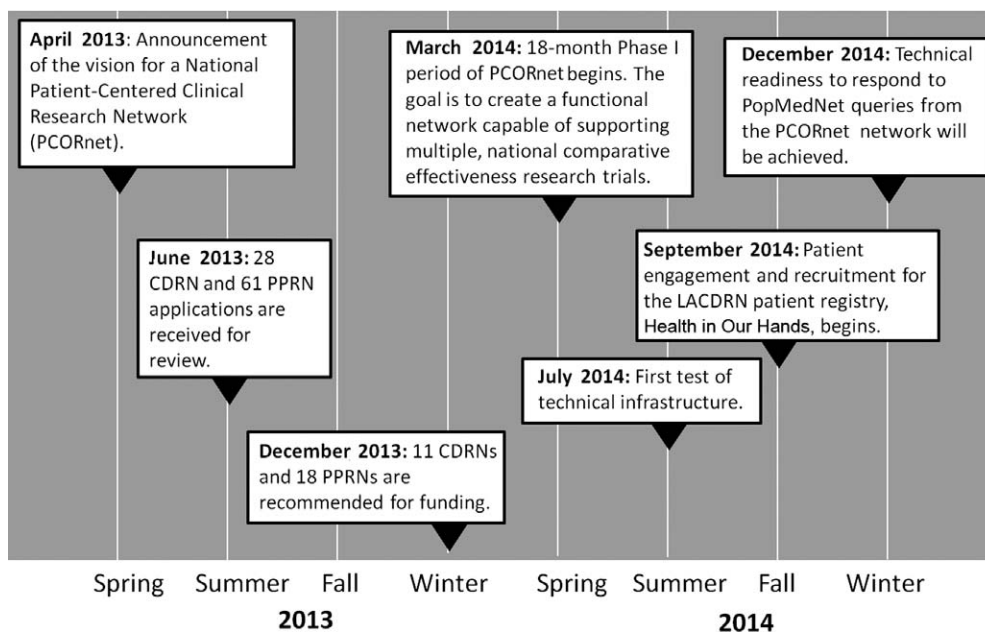


Figure 1. National Patient-Centered Clinical Research Network (PCORnet) and Louisiana Clinical Data Research Network (LACDRN) timeline. CDRN, clinical data research network; PPRN, patient-powered research network.

number, are masked by linkage to a pseudoidentifier and shared with a central LACDRN repository in compliance with parameters outlined in the PCORnet CDM. The CDM consists of demographic information and health information such as encounters, diagnoses, and procedures. The LACDRN seeks to build cohorts of patients with health conditions such as diabetes, weight management challenges (obesity), sickle cell anemia, and 10 rare cancers. Diabetes and obesity are highly prevalent diseases statewide and nationwide with serious deleterious public health impacts. Additionally, sickle cell disease is particularly relevant to Louisiana and the New Orleans area because of its prevalence in the African American population. Ultimately, the partnership's vision is for the LACDRN to support research in a variety of areas of interest to physicians and patients.

A major goal of the LACDRN is the active engagement of patients. Research agendas are often driven by incentives and grant awards that are not necessarily in line with the most urgent needs of patients, caregivers, and providers. Conversely, the sophistication, knowledge, and interest level of patients actively participating in their own health-care have never been higher. The LACDRN strives for patient involvement through the determination of research agendas, through research participation via submission of patient-reported outcomes surveys and patient-generated data, and through the dissemination of research findings to the broader community.

New technologies such as social media, web-based patient forums, wearable monitoring devices, and smartphone applications (apps) have created unique opportunities for individuals to collect and share health information. While levels of enthusiasm and comfort vary among individual patients, recent surveys suggest that the majority of people (>90%) would be willing to share personal health information if it is used for public health research and privacy is assured.⁷ The LACDRN will engage the community via a voluntary patient registry (Health in Our Hands) that allows the dissemination and collection of surveys and research results. The goal is that the collection of patient-reported outcomes and concerns will be linked back to the clinic to create a learning healthcare environment in which outcomes and performance are continually improved.

BENEFITS OF THE LACDRN

The LACDRN benefits patients and clinicians alike by streamlining the work processes involved in conducting effective and expeditious clinical research. Typically, the rate of recruitment and overall speed of clinical trials have been areas of difficulty and frustration. The efforts of the LACDRN and PCORnet outline a process to more efficiently identify and recruit eligible patients for interventional studies and reduce barriers for initiating multi-institutional trials by aligning IRB requirements and information-gathering procedures. The LACDRN creates a regional incentive for the construction of a

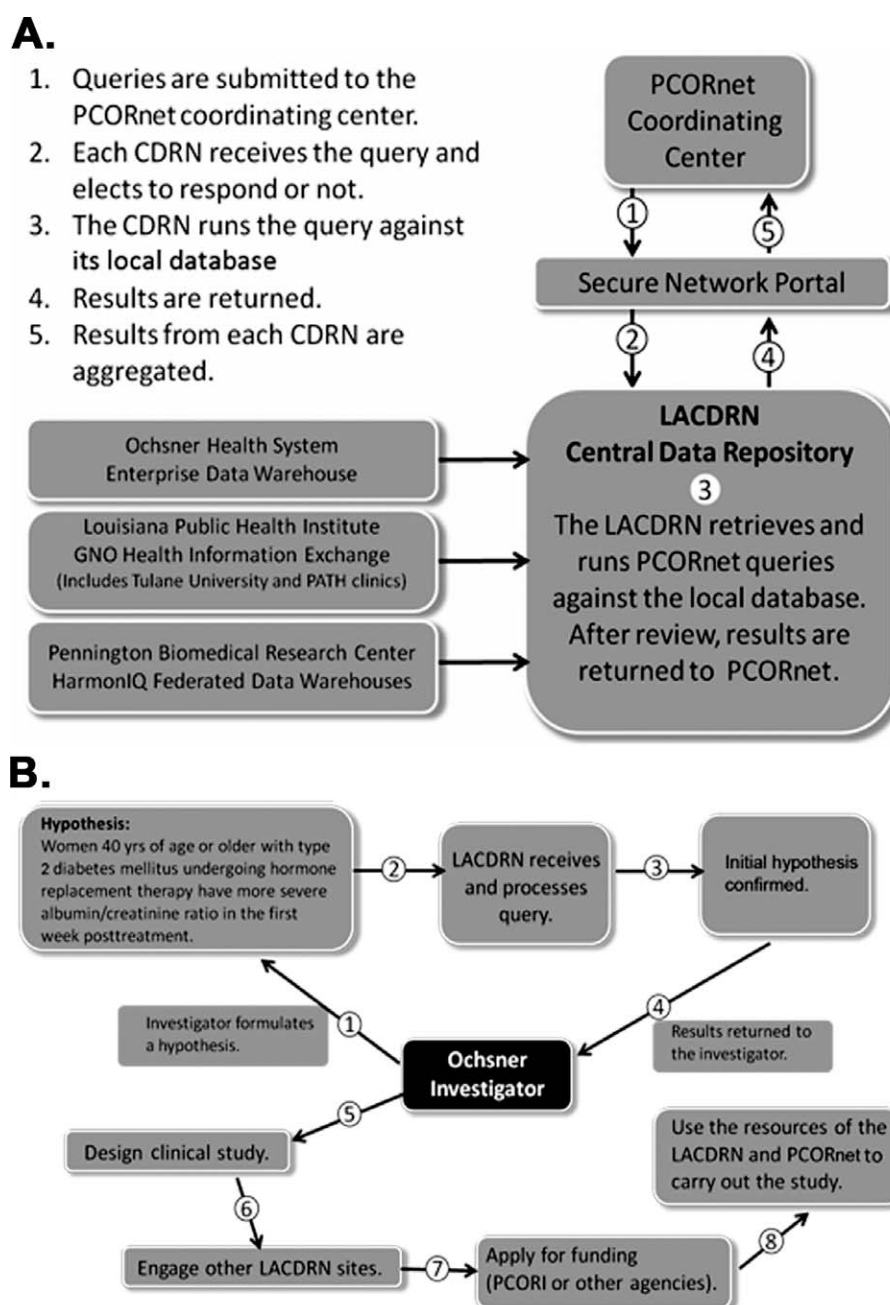


Figure 2. A: National Patient-Centered Clinical Research Network (PCORnet) query process. B: The process by which an individual Ochsner investigator may use the resources of the Louisiana Clinical Data Research Network (LACDRN). CDRN, clinical data research network; GNO, Greater New Orleans; PATH, Partnership for Access to Healthcare, PCORI, Patient-Centered Outcomes Research Institute.

robust research network that is integrated into the clinical workflow. The network is a powerful resource for conducting retrospective chart reviews and observational studies.

Comparative effectiveness trials conducted via the LACDRN allow providers to offer patients the chance to participate in innovative research, and the network empowers patients to actively partake in

public health activities related to their condition. The resources available through the LACDRN and PCORnet also represent a unique opportunity to improve the competitiveness of partnering institutions in obtaining external funding. This opportunity benefits potential investigators and positively impacts the delivery of cutting-edge innovative clinical care to our patients.

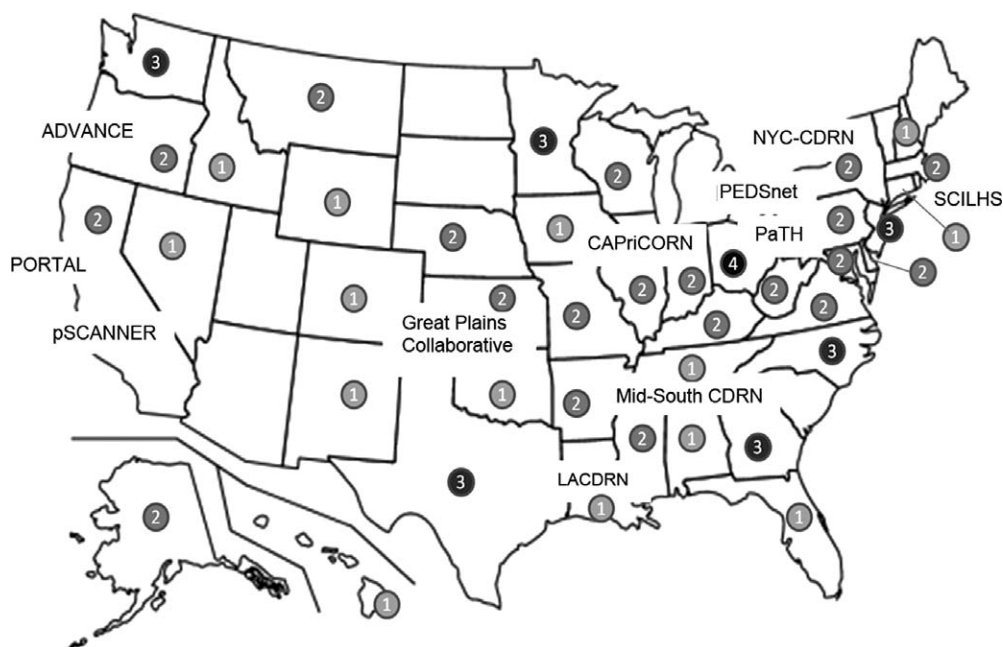


Figure 3. National Patient-Centered Clinical Data Research Network (CDRN) map. Each CDRN consists of partnerships between multiple institutions in various geographic locations. Numbers represent the number of CDRNs with partners operating in the state. ADVANCE, Accelerating Data Value Across a National Community Health Center Network; CAPriCORN, Chicago Area Patient-Centered Outcomes Research Network; Mid-South CDRN, Mid-South Clinical Data Research Network; LACDRN, Louisiana Clinical Data Research Network; NYC-CDRN, New York City Clinical Data Research Network; PaTH, Toward a Learning Health System in the Mid-Atlantic Region; PEDSnet, National Pediatric Learning Health System; PORTAL, Kaiser Permanente & Strategic Partners Patient Outcomes Research to Advance Learning Network; pSCANNER, Patient-Oriented SCALable National Network for Effectiveness Research; SCILHS, Scalable Collaborative Infrastructure for a Learning Healthcare System.

CONCLUSION

The current healthcare environment demands that we continually adapt and create new models to increase the value of clinical research. PCORnet represents a shift from the old way of conducting clinical research that included small numbers of participants, big budgets, exclusively researcher-derived questions, and labor-intensive collection of study data that ultimately have provided little benefit to the patient or to the burden of chronic diseases on the nation. This new, more innovative way of conducting research involves multiinstitutional networks, large participant pools, streamlined budgets, patient-oriented questions, and the use of patient-reported data from multiple digital data sources. The ultimate goals are to ask relevant questions, to involve multiple partners to conduct cost-effective research in the most expeditious manner, and to publish outcomes in a timely fashion. The substantial investments that have been made in the last decade in large network-based systems and comparative effectiveness research are illustrative of a shift in purpose that is occurring within the research community. This shift by no means suggests that basic science questions

and investigator-sponsored hypotheses are not important parts of the scientific endeavor. However, the technological capabilities of today combined with the existence of large, highly descriptive healthcare data repositories have created new opportunities for seeking innovative and practical solutions to existing challenges in the delivery of quality healthcare. The LACDRN provides an exciting opportunity for a geographical region with many public health concerns and disparities in the delivery of clinical care to be involved in what is the new frontier in clinical research.

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