



OPEN ACCESS

Open Access
Scan to access more
free content

For numbered affiliations see
end of article.

Correspondence to

Dr Anjum Khurshid, Louisiana
Public Health Institute, Suite
1200, 1515 Poydras St,
New Orleans, LA 70112, USA;
akhurshid@phi.org

Received 21 February 2014
Accepted 10 March 2014
Published Online First
12 May 2014



- ▶ <http://dx.doi.org/10.1136/amiajnl-2014-002864>
- ▶ <http://dx.doi.org/10.1136/amiajnl-2014-002747>
- ▶ <http://dx.doi.org/10.1136/amiajnl-2014-002758>
- ▶ <http://dx.doi.org/10.1136/amiajnl-2014-002764>
- ▶ <http://dx.doi.org/10.1136/amiajnl-2014-002744>
- ▶ <http://dx.doi.org/10.1136/amiajnl-2014-002746>
- ▶ <http://dx.doi.org/10.1136/amiajnl-2014-002743>
- ▶ <http://dx.doi.org/10.1136/amiajnl-2014-002827>
- ▶ <http://dx.doi.org/10.1136/amiajnl-2014-002727>
- ▶ <http://dx.doi.org/10.1136/amiajnl-2014-002751>
- ▶ <http://dx.doi.org/10.1136/amiajnl-2014-002745>
- ▶ <http://dx.doi.org/10.1136/amiajnl-2014-002759>
- ▶ <http://dx.doi.org/10.1136/amiajnl-2014-002756>



CrossMark

To cite: Khurshid A,
Nauman E, Carton T, et al.
J Am Med Inform Assoc
2014;**21**:612–614.

Louisiana Clinical Data Research Network: establishing an infrastructure for efficient conduct of clinical research

Anjum Khurshid,¹ Elizabeth Nauman,² Tom Carton,² Ron Horswell³

ABSTRACT

The state of Louisiana, like the nation as a whole, is facing the salient challenge of improving population health and efficiency of healthcare delivery. Research to inform innovations in healthcare will best enhance this effort if it is timely, efficient, and patient-centered. The Louisiana Clinical Data Research Network (LACDRN) will increase the capacity to conduct robust comparative effectiveness research by building a health information technology infrastructure that provides access to comprehensive clinical data for more than 1 million patients statewide. To ensure that network-based research best serves its end-users, the project will actively engage patients and providers as key informants and decision-makers in the implementation of LACDRN. The network's patient-centered research agenda will prioritize patients' and clinicians' needs and aim to support evidence-based decisions on the healthcare they receive and provide, to optimize patient outcomes and quality of life.

population in Louisiana. Representing a state and region that has unique health challenges related to disparities, natural disasters, high prevalence of chronic diseases, and some rare conditions,⁴ LACDRN is an important resource for clinical and health system research that will advance evidence-based diagnosis, treatment, disease management, and healthcare delivery. LACDRN brings the healthcare community and patients together with researchers to be actively engaged in the generation of patient-centered research questions, the design and implementation of comparative effectiveness research, and the translation of results into more effective healthcare. By engaging patients, providers, and health systems leadership, LACDRN aims to transform Louisiana healthcare into a learning health system that will continuously inform innovations in healthcare and health systems.⁵

Participating organizations

LACDRN's partners represent a unique cooperation between the public health discipline, the academic research community, a biomedical research center, large integrated health systems, and small community-based health centers.

LPHI has implemented and supported many community-based health programs which bring together clinical and public health stakeholders, local government, and members of the community in united efforts to solve some of the challenges of improving the health of our population. As convener of the Office of the National Coordinator for Health Information Technology (ONC)-funded Crescent City Beacon Community, LPHI worked with local community-based healthcare organizations to improve population health outcomes using HIT, including establishing the Greater New Orleans Health Information Exchange (GNOHIE).⁶

Pennington Biomedical Research Center, a subsidiary organization with the Louisiana State University (LSU) System, brings to LACDRN extensive research experience in both prevalent and rare chronic diseases, including obesity, diabetes, and rare cancers. The Pennington Biomedical researchers have been actively engaged in synthesizing and analyzing data from large clinical systems and in merging data from disparate sources. Pennington Biomedical has initiated joint efforts between several of the LSU academic health science and healthcare delivery institutions to improve the care of patients in Louisiana through large-scale collaborative projects such as LSU's Improving Clinical Outcomes Network (LSU ICON).⁷

INTRODUCTION

The Louisiana Clinical Data Research Network (LACDRN) will encompass a health information technology infrastructure to enable the efficient conduct of comparative effectiveness research. It is one of 11 CDRNs participating in the National Patient-Centered Outcomes Research Network (PCORnet) with the goal of facilitating large-scale clinical outcome research.¹ Two significant shifts in the fields of clinical practice and research underscore the opportunity to adopt innovative research approaches such as LACDRN. First, the widespread adoption of electronic medical records (EMRs), incentivized through the 2009 Health Information Technology for Economic and Clinical Health Act, will allow unprecedented electronic data aggregation, which can facilitate more efficient clinical research than ever before.² Second, a social change in the field of clinical research has recognized the need for active engagement of patients and providers throughout the research process, so that research better serves its end-users.³ On the basis of these trends, LACDRN is poised to drive considerable improvement in research capacity that is more technically efficient and increasingly driven by clinician and patient stakeholders.

The LACDRN project is a collaboration between the Louisiana Public Health Institute (LPHI), Pennington Biomedical Research Center, Tulane University, and Ochsner Health System. The network includes several sizeable clinical data warehouses that provide broad coverage of the

LACDRN co-investigators from Tulane University Schools of Medicine and Public Health bring clinical and population health research expertise in various fields including diabetes, obesity, sickle cell disease, and community engagement in addressing the prevention and treatment of highly prevalent chronic conditions.

Ochsner Health System is southeast Louisiana's largest non-profit, academic, multi-specialty, healthcare system with eight hospitals and over 38 health centers. It has demonstrated success in integrating clinical research with outstanding patient care and translating research results into evidence-based, innovative medical care. Participation in LACDRN is in line with Ochsner's purpose to serve as an innovative resource for investigators in regional academic and non-academic institutions to conduct clinical studies.⁸

LACDRN STRATEGY

The LACDRN project involves the following main components:

1. Building the technical infrastructure for efficient research using comprehensive clinical data sourced from the network's component health systems via a common data model.
2. Engaging patients and providers throughout the research process to foster the capacity to embed studies in clinical settings without disrupting the provision of quality healthcare.
3. Developing a patient-centered research agenda that prioritizes addressing patients' needs and measuring and improving health outcomes.
4. Establishing a governance structure that engages patients, providers, researchers, and health system leaders equitably in development and oversight of the network's policies and operations.

The subsequent sections describe LACDRN's approaches to establishing the technical infrastructure for conducting comparative effectiveness research in Louisiana, as part of PCORnet.

LACDRN's component data sources

Initially, LACDRN will consist of three data nodes: GNOHIE's clinical data repository (CDR), LSU Health System's HarmonIQ data warehouses, and Ochsner Health System's Enterprise Data Warehouse (EDW). During phase I of the project, which has an 18-month timeline, LACDRN will expand to include additional partner organizations, such as the Louisiana Tumor Registry, whose participation is pending final contract at the time of writing. The network composition is depicted in figure 1. The 18-month objective is for the network to include longitudinal clinical records on more than 1 million unique active patients.

GNOHIE, established in January 2012, is a community-shared HIT infrastructure designed to facilitate care coordination and chronic disease management by enhancing information and process linkages across health systems. Currently, it uses an open-source platform (Mirth) to enable exchange of electronic clinical records among 11 community health clinics and two hospitals in a Health Insurance Portability and Accountability Act (HIPAA)-compliant, secure manner. While the system provides real-time patient information at the point of care, it also maintains a centralized CDR that stores all information passing through the health information exchange. Currently, different EMR systems interface through nationally certified data standards, and the data are normalized before storage in the centralized CDR in a star schema database structure. This centralized CDR of GNOHIE is a core component of LACDRN.

HarmonIQ is a unified and integrated data structure that supports research and analytics across the LSU System. HarmonIQ data warehouses draw data from two EMR systems—LSU's

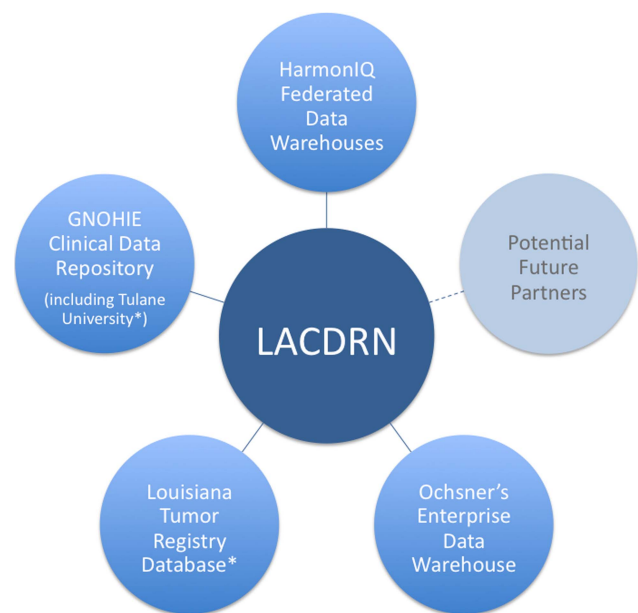


Figure 1 Louisiana Clinical Data Research Network (LACDRN) component data sources

home-grown 'CLIQ' (Clinical InQuery) system and an EPIC program currently being phased into the LSU System. Data enter HarmonIQ via ETL (extract, transform, load) routines unique to each EMR format and are then reconciled into a common structure. HarmonIQ's data model encompasses partitioned warehouses, and extracts are governed by each data-contributing entity. The data sources for HarmonIQ's component warehouses are Siemens DSS, Epic Clarity, and CLIQ Clinical Data Repository. HarmonIQ itself is a Microsoft SQL star-type relational database. HarmonIQ data include: (1) all types of encounters—outpatient, emergency department, inpatient, ambulatory, tele-medicine, etc; (2) diagnosis codes for all encounters; (3) charge information for all encounters; (4) all coded procedures; (4) payment information; (5) demographics; (6) vital signs for all patients seen in clinics; (7) outpatient prescription information; (8) pharmacy fill data for on-site pharmacies; (9) laboratory values; (10) pathology reports; (11) echocardiogram reports; (12) patient-reported tobacco use; (13) death dates from the state death registry; and (14) patient-perception data routinely gathered from Medical Home clinic surveys.

Ochsner's EDW contains data from over 23 different sources, including clinical data for Ochsner's entire statewide health system. The subject areas include accessibility, financial transactions, diagnoses, procedures, encounters, laboratory reports, appointments, orders, phone statistics, medications, and quality measures. The backend database is Oracle, and it contains over 500 tables and 3 billion rows. Ochsner's EDW uses an Informatica ETL process to import data and Oracle's Business Intelligence Enterprise Edition as the presentation tool.

Network infrastructure

The data infrastructure envisioned for LACDRN will enable the assembly of data from the network's component data nodes centrally for specific research projects while preserving autonomy of data ownership by partner health systems. The network comprises independent data warehouses for each data-contributing organization, with data being sent in response to specific

requests for centralized assembly in a common format that is yet to be determined based on collaboration with network partners and consultation with PCORnet. Data will be masked with unique identifiers before being exported to the centralized database from the network's component data sources. The assignment of unique identifiers using a common algorithm will enable linkage and deduplication of patient records from different sources centrally. Detailed masking and deidentification procedures are to be determined, based on HIPAA guidelines and data requirements for specific research objectives. To reidentify records for patient recruitment, the central data center will return subject IDs to the network data sources, where identifying information can be retrieved.

Currently, the network's data nodes do not share a common structure. To operationalize the network initially, data-contributing organizations will perform data abstracts and write to a common database format following standardized abstraction criteria to ensure comparability of data from the disparate sources. The establishment of federated data warehouses at each node is envisioned as a potential longer-term solution to achieve interoperability across the network. The common format of these federated warehouses would allow extraction codes to be written centrally for specific research projects and then run by each data-owning organization to retrieve the requested data from their warehouse. This would increase the efficiency with which standardized and comparable data extractions can be conducted and assembled centrally. Recognizing that it may not be feasible to establish a federated warehouse at all data nodes, the network may perpetually rely on the capabilities of some current and future partners to fulfill data requests in the common data format.

LACDRN's technical infrastructure will also enable the integration of new types of data, such as patient-reported outcomes, with clinical data obtained from network partners. Patient-reported outcomes collected for specific research purposes can be stored centrally with coded unique identifiers to enable merging with masked clinical data so that data privacy is maintained at the point of assembly. A near real-time consent management database will also constitute part of the core data infrastructure. This centralized system will maintain up-to-date consent status for all patients participating in network-based research, including consent for participation in specific studies and consent to be contacted for future research.

The LACDRN infrastructure will be extended to the national level by establishment of the capability to share data with other networks via the PCORnet common data model, which will be determined in cooperation with PCORnet partners. Data standardization procedures will be conducted across LACDRN data nodes and to conform with national parameters to enhance integration within LACDRN and with PCORnet.

Network-based research

LACDRN will advance the capacity to conduct efficient clinical research on two highly prevalent health conditions—obesity and diabetes—and on rare diseases, including sickle cell disease and rare cancers, by conducting ongoing patient recruitment across partner health systems to build cohorts of patients with these specific conditions. The data infrastructure described above provides the capacity to efficiently identify and recruit patients with defined clinical characteristics. Point-of-care recruitment will be

used initially, facilitated by recruitment support personnel. Recognizing that direct patient recruitment by clinicians will improve efficiency, the network will use a practice-based research network model across the LACDRN participating health systems with the subset of providers that are willing to actively engage in network-based research.⁹ This will enhance the network's capacity to embed research activity within functioning health systems without disrupting the provision of quality healthcare. Patients and providers will be actively engaged as key informants and decision-makers in the implementation of LACDRN to empower them as active participants in the research process and ensure that the network best serves the healthcare community and patient population by facilitating research that informs critical improvements in the quality, efficiency, and effectiveness of healthcare.

CONCLUSION

LACDRN provides a unique opportunity for the Gulf South region to benefit from a patient-centered research infrastructure that is focused on improving health outcomes. Clinical researchers, providers, and patients will come together to achieve these goals in Louisiana and to partner other CDRNs through PCORnet to help achieve these goals nationally.

Author affiliations

¹Louisiana Public Health Institute, New Orleans, Louisiana, USA

²Research & Evaluation Division, Louisiana Public Health Institute, New Orleans, Louisiana, USA

³Pennington Biomedical Research Center, Baton Rouge, Louisiana, USA

Contributors AK and RH contributed substantially to the conception of the LACDRN project. EN and TC contributed substantially to the project planning and strategy development. All authors are actively involved in project implementation. All authors contributed to the manuscript content. Substantial portions of the manuscript were drafted and revised by AK and EN. Contributions to the content were provided by TC and RH.

Funding LACDRN is funded by the Patient Centered Outcomes Research Institute.

Competing interests None.

Provenance and peer review Commissioned; internally peer reviewed.

Open Access This is an Open Access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 3.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited and the use is non-commercial. See: <http://creativecommons.org/licenses/by-nc/3.0/>

REFERENCES

- 1 The National Patient-Centered Clinical Research Network. <http://pcornet.org> (accessed Mar 2014).
- 2 Hsiao CJ, Jha AK, King J, *et al.* Office-based physicians are responding to incentives and assistance by adopting and using electronic health records. *Health Aff (Millwood)* 2013;32:1470–7.
- 3 White MA, Verhoef MJ. Toward a patient-centered approach: incorporating principles of participatory action research into clinical studies. *Integr Cancer Ther* 2005;4:21–4.
- 4 United Health Foundation. *American's Health Rankings 2013 Annual Report, State Rankings, Louisiana*. <http://www.americashealthrankings.org/la> (accessed Mar 2014).
- 5 National Research Council. *Best care at lower cost: the path to continuously learning health care in America*. Washington, DC: The National Academies Press, 2013.
- 6 Louisiana Public Health Institute. *Crescent City Beacon Community 3rd Annual Report*. New Orleans, LA: Louisiana Public Health Institute, Dec 2012. <http://www.crescentcitybeacon.org> (accessed Mar 2014).
- 7 LSU's Improving Clinical Outcomes Network. <http://lsuicon.org> (accessed Mar 2014).
- 8 Ochsner Research. <http://academics.ochsner.org/research.aspx> (accessed Mar 2014).
- 9 Westfall JM, Dolor RJ, Mold JW, *et al.* PBRNs engaging the community to integrate primary care and public health. *Ann Fam Med* 2013;11:284–5.