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Leveraging a Statewide Clinical Data Warehouse to Expand Boundaries of the Learning Health System

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Abstract

Learning Health Systems (LHS) require accessible, usable health data and a culture of collaboration—a challenge for any single system, let alone disparate organizations, with macro- and micro-systems. Recently, the National Science Foundation described this important setting as a cyber-social ecosystem. In 2004, in an effort to create a platform for transforming health in South Carolina, Health Sciences South Carolina (HSSC) was established as a research collaboration of the largest health systems, academic medical centers and research intensive universities in South Carolina. With work beginning in 2010, HSSC unveiled an integrated Clinical Data Warehouse (CDW) in 2013 as a crucial anchor to a statewide LHS. This CDW integrates data from independent health systems in near-real time, and harmonizes the data for aggregation and use in research. With records from over 2.7 million unique patients spanning 9 years, this multi-institutional statewide clinical research repository allows integrated individualized patient-level data to be used for multiple population health and biomedical research purposes. In the first 21 months of operation, more than 2,800 de-identified queries occurred through i2b2, with 116 users. HSSC has developed and implemented solutions to complex issues emphasizing anti-competitiveness and participatory governance, and serves as a recognized model to organizations working to improve healthcare quality by extending the traditional borders of learning health systems.

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Leveraging a Statewide Clinical Data Warehouse to Expand Boundaries of the Learning Health System

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ABSTRACT

Learning Health Systems (LHS) require accessible, usable health data and a culture of collaboration—a challenge for any single system, let alone disparate organizations, with macro- and micro-systems. Recently, the National Science Foundation described this important setting as a cyber-social ecosystem. In 2004, in an effort to create a platform for transforming health in South Carolina, Health Sciences South Carolina (HSSC) was established as a research collaboration of the largest health systems, academic medical centers and research intensive universities in South Carolina. With work beginning in 2010, HSSC unveiled an integrated Clinical Data Warehouse (CDW) in 2013 as a crucial anchor to a statewide LHS. This CDW integrates data from independent health systems in near-real time, and harmonizes the data for aggregation and use in research. With records from over 2.7 million unique patients spanning 9 years, this multi-institutional statewide clinical research repository allows integrated individualized patient-level data to be used for multiple population health and biomedical research purposes. In the first 21 months of operation, more than 2,800 de-identified queries occurred through i2b2, with 116 users. HSSC has developed and implemented solutions to complex issues emphasizing anti-competitiveness and participatory governance, and serves as a recognized model to organizations working to improve healthcare quality by extending the traditional borders of learning health systems.

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Introduction

This paper describes steps taken to develop anchoring infrastructure that enables expanding a Learning Healthcare System (LHS) across South Carolina. Health Sciences South Carolina[1] (HSSC) was formed by its members in 2004 as one of the nation's first statewide health care research collaborations with a mission to convene academic and nonacademic health care organizations to accelerate the transformation of clinical research and practice.[2,3] The vision was to accelerate research that would improve the health of South Carolinians through a novel collaborative mode and that would maximize the value of constrained resources for the greatest benefit. Through establishing a governance structure for a multisystem integrated Clinical Data Warehouse (CDW), diverse institutions have overcome competitiveness and have bridged heterogeneous environments to enable use of patient-level data for research, quality improvement, and clinical analytical purposes, establishing a true cyber-social ecosystem[4] for health. HSSC's approach is complementary to national activity establishing research data networks and serves as a recognized[5] model with important lessons to inform national initiatives.

Although the purpose and scope of CDW models vary, every group aggregating data faces common challenges, including governance, data scope, data element standardization, missing data, data accuracy, timeliness of clinical data, and regulatory requirements (e.g., Common Rule, Health Insurance Portability and Accountability Act).[6-10] As organizations are increasingly urged to share data beyond their own borders, a fundamental new challenge is that of managing competitive interests across health systems in geographic proximity. Bringing together academic medical centers, nonacademic health systems, and universities also presents the broader challenge of protecting

and bridging cultures to establish a foundation of collaboration, trust, and respect, and to ensure that research and clinical goals are complementary. HSSC—supported by grant funding from The Duke Endowment, a private regional foundation, to establish its statewide program and tools—has developed important approaches to the challenges of culture, competition, and governance, along with data sharing and security, which complement the technical challenges of working with data across different health systems. Finally, these approaches have established a model of maximizing knowledge sharing in this environment, in an effort to most appropriately use constrained resources.

Case Description

HSSC-supported organizations include seven of South Carolina's largest health systems, as well as the state's three research-intensive universities, with three schools of medicine (Figure 1).

In 2010, HSSC's multi-institutional leaders approved the design and implementation of an integrated CDW to serve as a common data resource and central infrastructure upon which to establish a statewide LHS. The resulting CDW became operational in fall 2013 and is housed within HSSC's subsidiary, Health Sciences Health Improvement (HSHI). Currently four major health systems contribute protected health information and other clinical data—and all HSSC organizations participate in governance. The CDW is an integrated clinical data research platform with a system of operation and use based on a comprehensive Data Collaboration Agreement (DCA). The DCA authorizes aggregation of multisystem data and the creation of de-identified data marts for querying for counts. It authorizes the means of operating these systems, and provides a means for governing future use of the normalized data, in coordination with institutional review board (IRB) oversight. The CDW leverages and builds on

Figure 1. HSSC Member Institutions

similar endeavors underway nationally[11-16] and serves as a critical venue for multi-institutional collaboration, answering the call for new partners to work together to solve national health care issues.[17]

HSHI Infrastructure

CDW Infrastructure

The HSHI CDW infrastructure gathers administrative and clinical data from participating health systems. HSSC and site staff work to identify originating feeds or data that correspond to the areas of interest, to capture these, and to then normalize, aggregate, and integrate the data into a structured, searchable format. The data captured include demographics, visit activity, diagnoses, procedures, medications, and laboratory results (Figure 2).

Four health care systems currently contribute "near real-time data" from established sources accepting Health Level Seven (HL7), flat file, and Comma Separated Value (CSV) feeds or files. Near real-time data provisioning includes receipt of data through HL7 feeds on a moment by moment basis, as well as through batched files that are provided from individual enterprise Data Warehouses nightly. These incremental uploads may include enterprise data warehouses, registration and billing systems, and electronic health records, as well as patient-level, historical electronic data. As data are captured, they are mapped and passed through a Master Patient Index (MPI) and probabilistically matched in order to create a *single longitudinal record for each individual, across all health systems*. The near real-time, detailed transaction records are held within the

Figure 2. Clinical Data Warehouse (CDW) Infrastructure
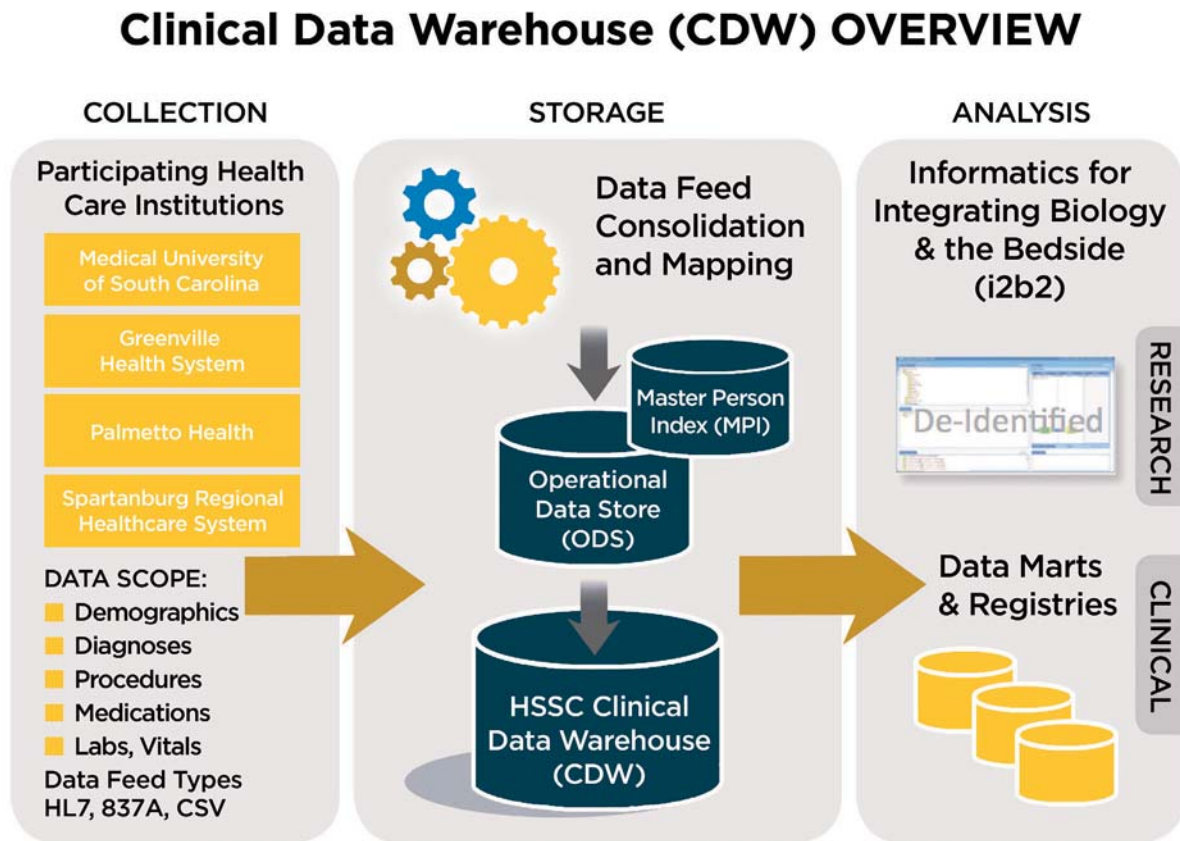
operational data store, and records are extracted on a scheduled basis and added to the CDW in an integrated, normalized structure. Working with site resources, metadata are available, tracing source data back explicitly to each institutional owner, as well as clarifying site specific processes and decisions regarding data.

CDW Security

Data reside within a physically and logically secure facility hosted at Clemson University's Information Technology Center (ITC), where the data management compliance extends to the data and systems they host for HSSC/HSHI. Clemson University has nearly three decades of securely handling large-scale data in compliance with Federal Information Security Modernization Act (FISMA) and Health Insurance Portability and Accountability Act (HIPAA) regulations for federal and state agencies. Data are stored behind secure firewalls with proper network segmentation to allow only internal development and honest broker (HB) access. The HBs are specially trained statisticians, database specialists, and research coordinators, who work closely with the development team to serve as a resource for data quality testing, to train statewide investigators, to analyze the CDW for reporting, and to consult with investigators for development of research questions that can be answered based on available data and governance structure.

The HSSC security and privacy officer (based at Clemson University) leads audits at least annually to ensure security of the CDW environment; recommended changes are implemented through Governance and Operations. Audits are also performed with the addition of new applications, systems, or data types. Data are transmitted between participating institutions using the South Carolina LightRail—a private broadband, 10 gigabit high-speed optical network that directly links South Carolina universities and health care systems. Although the HSHI CDW is a private network, individual institutional-level access is secured with site-to-site Virtual Private Network connections between specific resources and HSSC resources inside the ITC.

CDW Governance

A comprehensive governance system was developed to account for the needs, perspectives, and requirements of HSSC-supported organizations, including the CDW data contributing institutions, as well as regulatory bodies. Central to the CDW governance was the creation of a DCA that provides an overarching framework for governance policies and operations, enables the aggregation of multisystem data with the creation of de-identified and limited data sets, and includes provisions for data security, as well as compliance with federal and state laws. Each health system had to overcome concerns about sharing data with other regional health systems with whom it may compete for patients. Data types shared include those in Figure 2, and include demographics, diagnoses, procedures, medications, and laboratory results. Core to this was the provisioning of data to HSSC as a neutral and noncompetitive trusted entity, to serve as the convening technical body. Each system that contributes clinical data remains the owner of this data, and through the DCA framework, grants participatory stewardship of the data to HSSC/HSHI,

along with data oversight. Each site participates in an HSHI-managed program of active review, participating monthly in a multisite Data Request and Review Committee (DRRC), which provides a crucial element of direct oversight and engagement in data use. This means that uses of data beyond the de-identified data marts are explicitly governed by the contributing system, and that no data can be provided without specific approval by the contributing system. HSSC/HSHI oversee that process, assuring it is timely and effectively managed and, once approved, that the data provided are consistent with both the DRRC and IRB approvals and requirements. Project-specific IRB approvals are required prior to provisioning of any data set, and are provided by the IRB of record for the site in which research is being performed, most often the IRB of the requesting principal investigator. Together, through this governance model, researchers and health systems are enabled both to use de-identified data and to establish a system to request and engage data and collaborators beyond one's own system.

Governance is seen as an active process, not an end in and of itself. The governance system engages key leaders from each HSSC organization and is informed by operational and policy advisory groups. The policy advisory groups provide expert advice regarding data quality, stewardship, IRB requirements and interactions, data use, privacy, and security. Operations are provided by a DRRC, HBs, IRBs, Information Security, Privacy, and Compliance Officers.

Anticompetitive, User Access, and Data Use Standards

The DCA establishes boundaries for de-identified data marts containing multi-institutional data. Through the participatory governance process, specific guidance regarding types of data and

data exposure has been developed and tested over time. Core goals are not to unmask patients or contributing institutions. Five data marts are created from the CDW; each data mart contains de-identified data with dates of clinical service that are date shifted to further maintain privacy. One of these data marts contains all patients from all participating systems; the other four data marts contain data that are institution specific. Within these data marts, rules have been established, which include those noted in Table 1. The focus of these rules is on maximizing data availability while protecting systems from discovery by regional competitors. Important drivers of these decisions have been the ongoing expansion and evolution of the data that are added to the CDW and data marts used with Integrating Informatics from Bench to Bedside (i2b2)[18], when such elements are added in an asynchronous manner. Due to the rapid progression of electronic health records and the volume and complexity of clinical data, review of these rules is ongoing and is anticipated to require regular, planned attention.

Institutions desiring access to the CDW and its attendant data marts must have agreed through the DCA to participate either as a data contributor or a research user. This agreement is reciprocal, and these organizations must be accepted by current participants. All individuals accessing these systems must be associated with one of the systems that is joined to the DCA. Organizations not yet joined to the DCA and contributing data are those that either are undergoing significant changes to IT infrastructure—precluding additional activity in working with the HSSC technical team at present, or that may be an organization that is developing research teams and infrastructure, and is not yet ready to participate.

Individuals from across HSSC organizations are authorized by their home IRB to access the CDW, and their sign in is verified through Shibboleth—a secure, federated, open-source, single sign-on authentication system. All users may access the all-system data mart and that of their own home institution. Each user must consent to a master Data Use Agreement (DUA), established by the DCA. While the DCA specifies the institutional boundaries and requirements, the DUA is the individual user agreement. It specifies to individual users the limitations of their use of the data for research purposes and the agreements they must adhere to, including not using the tool to try to identify patients or systems. This DUA also specifies that the tool is not to be used for competitive purposes, and that the use of the data system is completely auditable. Appropriate human-subjects training is verified by the user's sponsoring institution. Users access the CDW for de-identified queries preparatory to research or project development through i2b2, a web client query tool. No individual identifiable patient-level data are accessed. The i2b2 tool is applied to the five de-identified data marts. The establishment of this data mart approach with i2b2 has been approved by the Medical University of South Carolina (MUSC) IRB and has been accepted through a cooperative IRB review across all member institutions with data in the CDW.

CDW users, including investigators and clinicians, may make self-service de-identified queries through i2b2; results of these queries consist of counts of patients meeting query criteria, along with a limited demographic profile (age by decade of life, race, religion, gender, or vital status.) Users may request data beyond these counts through the DRRC and institution-specific IRB. The DRRC reviews data set requests from the perspectives of

Table 1. Guidance for Constructing Anticompetitive De-identified Data Marts in i2b2

DATA MART TYPE	RULE	PROTECTION/GOAL	BENEFIT	EXAMPLE
All-system data mart	Data available for only 2 systems will only be exposed in the all-system data mart	Onboarding new data elements can occur asynchronously while preventing inadvertent disclosure (through deduction) of another systems' specific results	De-identified data is available to maximal individuals for non-site-specific research or project development	Hemoglobin A1C brought into CDW in a staggered manner are available for non-system-specific aggregation and analysis
All-system data mart	If only a single system provides a data type, it will be available only at that individual system level	Onboarding new data elements can occur asynchronously; enabling most rapid access to new data types	Site-level work in data provisioning can have immediate value or use by that site	Hemoglobin A1C brought into CDW by one organization allows de-identified use for local analysis of diabetic population
Each individual-system data mart and the all-system data mart	Date shifting will occur up to 365 days from Date of Service (no provision of future dates)	Enhances de-identification for smaller cohort sizes as programs may be initiated by new systems	Allows analysis while removing ability to include temporal factors that may be publicly known that would indicate site-specific outcomes	System starting a new cardiac surgery program cannot readily evaluate outcomes of another specific system through deduction
Each individual-system data mart and the all-system data mart	Cohort size<20 not provided	Enhances protection of persons with rare disease or uncommon characteristics	Further safeguard reinforcing multisystem IRB approval and preventing inadvertent exposure of a system's results	A system with 5 patients with a genetic disease cannot determine through deduction another system's outcomes for 10 patients with the same disease

the clinical systems, and the IRBs review requests from the perspective of research systems; this ensures that research regulations, ethical concerns, and competitive business issues are systematically addressed for each request.

CDW Data Totals and Data Use Activity

The HSHI CDW contains clinical data for over 2.7 million unique patients from 2007 to the present. The MPI has identified 138,817 individuals moving between systems, for whom there now exists an individual longitudinal record. There are data for 33 million encounters, which include inpatient, outpatient, and emergency department activity (Table 2).

A series of HSSC-led activities have promoted CDW use.[19] In the first 21 months of use, there have been 2,896 self-service i2b2 queries made by over 116 users, with 15 data set requests. The ability to look at aggregate multisystem data with new clinical elements has created an opportunity for clinical researchers and clinicians, partnering together, to look in new ways at important health conditions or procedures such as diabetes and surgery. There have been 34 grant applications and 14 funded projects, with awards ranging from $10,000 to $15.3 million, with various federal and private foundation sources. Data requests cover the entire patient lifespan and show a distribution across multiple disease and health condition domains.

Discussion

The HSSC LHS model shifts the concept of "system borders" in order to expand the number of collaborators, enabling the start of the health care "learning" process with partners beyond the usual definitions of systems. Convening unique and disparate organizations requires a broad engagement platform, such as that provided by this multi-institutional, integrated CDW platform. HSSC's success to date has required critical investments of time and innovative approaches from participating organizations and stakeholders. Crucial additional factors are the participatory governance model with a focus on anticompetitive standards and the creation of a shared culture. As these factors have developed over time and through active engagement, a successful cyber-social ecosystem[4] has been established. The full test of the ability of HSSC and the CDW to enable learning will come through the use of the system as funded projects and clinical uses move into action.

The success of this approach required board-level engagement by the presidents from each organization. Recognizing the broad and long-term scope of commitment, along with establishment of support and ongoing participation at this level, has allowed successful development of sensitive infrastructure across competitive organizations. This

Table 2. Patient Totals and Encounter Activity in the Health Sciences Health Improvement (HSHI) Clinical Data Warehouse (CDW) 2007–March 2015

	TOTAL
Unique Patients with Clinical Data	2,737,123
Patients with Encounters in Multiple Systems	138,817
Total Encounters	33,806,965
Total Procedures	11,815,995
Total Diagnoses	99,425,444

vision, commitment to innovation, and ongoing work to establish culture has allowed the organization to thrive despite turnover of each board member during the past decade.

Also critical was the creation and implementation of a governance, training, and engagement model. Governance of multi-institutional clinical data systems present unique challenges; our approach has been to address these challenges through a fully participatory, transparent process. The DCA creates context to manage competition; moving to operational governance was carefully informed by studies of data holder requirements,[16] including complete control of use and access to data regarding patients, strong security and privacy features, limited impact on the respective processes and internal systems of those providing data, auditable processes, standardization of administrative and regulatory processes, transparent governance, and ease of use. This governance model is transferrable to other multisystem data use, as the overarching tenents are strong: establishing a participatory and structured data request and review process was essential in gaining the "buy-in" by nonacademic organizations regarding data use for research purposes. Transparency of this data-request review process allowed groups to see the potential value to their patients and to develop knowledge and collegiality between and among organizations. As the CDW and data requests matured, this governance and data request review has matured as well, and an iterative engagement approach and a "micro learning system" has been established.

Once the overarching DCA was established, the resources to create the data network—along with the technical expertise to capture data from disparate systems and to normalize it for multisystem interpretation and use—required significant investment. Technical resources have been needed both centrally and at each participating system;

however, the on-site resources at each system have been less impacted because of the centralization of the project technical team within HSSC, creating economies of scale. Each system has been required to provide knowledge regarding its data sources and feeds—in order to assure the appropriate mapping—and accurate data definitions. All systems have significant information technology staff, and both large and small health systems are able to participate in our model, with the most significant limitation being the available time of their staff. As the HSSC onboarding experience has grown, HSSC has been able to minimize the impact on health systems once key site-based resources are identified. The goal is for centralized HSSC staff to efficiently engage knowledge sources regarding data capture processes on the front line of the health system, as well as decision-making regarding data within business or clinical units. HSSC has been fortunate to receive major regional private-foundation support, as well as federal grant support to enable development of different aspects of the organization and team. Each participating organization has made important in-kind contributions of their technical team to engage with HSSC's team.

Important challenges continue, with time constraints and limited resources in health information technology and informatics being among the leading ongoing limitations. Establishing key controls and multisite, ongoing engagement are important time-consuming steps, which continue to require attention. As health care continues to transform and data needs evolve, engagement of key site-specific resources that are needed for new data mapping and normalization are challenging to identify and requires repeated leadership engagement. Health systems are often in a tightly competitive position within regions regarding patients, and sharing identified patient data remains a concern, although one that is lessened by the complete transparency

of the data governance process. Each system retains full control of the approvals of their own identified data uses. Providing an auditable trail—along with neutral stewards of data—have been essential elements in building the system and the trust. All health systems continue to modify their IT systems, which creates ongoing rework for the HSSC technical team. Finally, ongoing support of this key infrastructure through diverse funding sources is needed, and this will require continuous vigilance, as with all infrastructure.

Conclusion

Through the CDW project and other initiatives,[20-22] HSSC has shown that a neutral convening organization with shared governance and bidirectional engagement can be vital to creating an expanded view of an LHS. As a convening organization, HSSC has implemented solutions to complex issues in the creation of a statewide, multisystem South Carolina LHS, with an integrated data system at its foundation. These solutions serve as a framework for addressing the national imperative to improve health care quality through building learning health systems. The collaborative HSSC model can inform other similar national efforts, as well as programs focused on quality improvement or patient-centered priorities.

Acknowledgements

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