APPENDIX A

Clinical Data Exchange Efforts in the United States: An Overview

Connecting for Health…a Public-Private Collaborative
Data Standards Working Group
Background Paper

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Executive Summary

As we prepared for the first meeting of Connecting for Health, we had great interest in uncovering early models of community-based projects. While early in their evolution, models that include an infrastructure for clinical data sharing were opportunities to study and understand in greater detail what would be necessary for us to consider as we contemplate a more interconnected health care system.

A bird's-eye view across community clinical data exchange efforts provides both an appreciation for the differing approaches as well as an opportunity to find some common themes. Given that clinical data exchange efforts at the local community level are still rare, we wanted to see if there were any common findings amongst them that might be helpful when considering future models. While we looked at each of these efforts individually, the purpose was to see if there were some common themes that might predict success. As part of this process we conducted interviews with the following community-based initiatives:

- California Information Exchange (CALINX)
- Community Health Information Technology Alliance (Foundation for Health Care Quality)
- Healthbridge
- Indianapolis Network for Patient Care (Regenstrief Institute for Healthcare)
- Massachusetts Health Data Consortium
- Minnesota Center for Healthcare Electronic Commerce and the Minnesota Health Data Institute
- North Carolina Healthcare Information and Communications Alliance
- Patient Safety Institute
- Santa Barbara County Care Data Exchange (CareScience and California Healthcare Foundation)

One of the first observations is that such exchanges are still few and far between, and in all cases; there were many barriers to success. The progress made by those who have been able to lead their communities forward is to be commended; and their efforts have much to teach us.

The overwhelming message we distilled from this overview is that it is not necessarily the technical roadblocks that have most limited opportunities for clinical data exchange – but instead:

- Overcoming the difficulty in bringing diverse stakeholders together towards a common goal, and

- Carefully addressing the need to protect privacy and security; creating the governance models, agreements, policies and practices for building these kinds of exchanges, and
- Building a compelling and sustainable model for devoting ongoing funding, resources and commitment to these projects.

Leadership and vision of a community's hospitals, physicians, health plans, and public health agencies, combined with the leadership of an effective convener, were common traits in all of the clinical exchange efforts reviewed in this report.

It was the breakdown of that organizational commitment and leadership that led to some of the initiatives' inability to move beyond the pilot stage. Additionally, there needs to be a strong and compelling reason for an organization to commit to data exchange, particularly standards-based exchange. If something is "working for [an organization] now", it is harder to convince them to move ahead to standardized ways of sharing information. This is where cooperative, innovative, strong leadership is necessary to pull communities together in order to enable networks like this to be created, which is so necessary for high quality healthcare.

Leadership mattered at all levels. These leaders were not only essential for understanding the importance of exchange, and of data standards for that exchange, but also in getting staff assigned to a project throughout, and committing the funds and resources throughout the lifecycle of the project. Visionaries also helped organizations move beyond competitive concerns to find ways in which they were able to control, yet share, data.

In most cases, the convener was a neutral, non-profit group that the participants could trust. The issue of trust and neutrality seemed to matter a lot in these examples. In some cases its members created the convener in order to bring the community together. That convener also played roles in developing formal governance structures and committees that tackled the day-to-day barriers that came up during the life of the project. In some cases that convener evolved to take on a technical maintenance role, in others it operated more as a project office for modeling of new methodologies and for adding providers, plans and public health agencies to its networks.

Some organizations did a fantastic level of work and demonstration, only to find that big efforts came along, like Y2K and HIPAA that became larger priorities than their effort, draining both staff and funding from the project. Without the staff and funding, they were limited in their ability to build support or move forward. Another organization noted that finding windows of opportunity was important – and that the current need was not just about private sector to private sector exchange, but very much about private to public sector exchange.

September 11, 2001 changed the focus of the nation, and created urgency for finding more efficient and effective ways to enable the public health community to cope with the looming threat of bioterror.

One area of significant variability was the data itself. The organizations differed in terms of the data they chose as their initial, or core, dataset – though some of the more common sets were immunization data, lab and radiology data. A number were also focused on clinical messaging and ways to ensure its security.

From a privacy and security standpoint, communities seemed to feel more comfortable with a networking approach as opposed to the clinical data repository architecture proposed in the CHIN efforts. Though some modeled and successfully tested PKI and other extensive security models, most opted for less intensive ways to get started in exchanging messages and packets of information – and continued to come up with innovative approaches to developing cooperative security standards for healthcare data among otherwise competitive vendors and providers.

In all cases, industry-accepted standards such as HL7 and LOINC were being used where participants were ready to do so, and customized interfaces were being built where they were not.   Many of the groups also focused on bringing participants towards industry standards for data, and continued to identify open issues and new solutions as they moved forward. It was also noted that lab companies were interested in moving to standards if there was a need expressed by their customer base -- and that concept could be extended for technology suppliers and IT organizations in general.

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Contact and Follow-up Information

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Background

Since 1994, a community wide electronic medical record system has operated in Indianapolis, Indiana called the Indianapolis Network for Patient Care (INPC). The Regenstrief Institute has served as the administrative home. Much of the initial startup cost was funded by the National Library of Medicine.

Description of the Group's Work

The INPC is an electronic medical record system, which contains clinical data shared between participating institutions. Clinical data from eleven hospitals in five competing health systems, the county department of health, a large primary care network and a homeless care network are stored with consistent structure and codes. The initiative built on the Regenstrief Medical Record System and developed solutions to data structure and coding inconsistency, patient matching, security and confidentiality as well as inter-organizational cooperation. The INPC currently includes 11 different hospital facilities (out of 14 in the city) and more than 100 geographically distributed clinics and day surgery facilities. Collectively, the participating hospitals admit 180,000 patients, and serve almost 400,000 emergency room visits and more than 4 million clinic visits annually.

Functionality

The system is a medical record system and provides cross-institutional access for Emergency Department and other care.

Functions include:
- Results retrieval
- Clinical messaging / document delivery
- Data Entry
- Reporting
- Clinical Decision Support
- Public health:
    - Case detection (electronic lab reporting)
    - Cancer research (supported by NCI)
    - Showing outcome results
    - Prompting physicians to screen
    - Immunization registry
    - Syndromic surveillance using ED chief complaint

INPC also provides access to literature searching, various medical information sources and other services.

The functional flow for ED data is as follows: a patient checks into emergency room and a message is sent to INPC from the registration system. A paper summary of key ER data is printed in the appropriate emergency room. MDs in that ER can access that online patient data for 24 hrs.

Data Being Exchanged

All institutions are currently exchanging the following data:
- All ED and outpatient visits: 400,000 ER visits / year
- All inpatient lab results: 50 million lab results added / year
- All hospitalization discharge summaries (diagnosis/ procedures for 180,000 discharges / year)
- Radiology reports
- Tumor Registry Data
- Anatomic pathology reports
- Immunizations

Additionally, some institutions are exchanging:
- Ambulatory notes
- Vital signs
- Visit reasons and diagnoses
- Medication profile
- Cardiac testing (echos, caths, etc.)
- Radiology images
- Gastroenterology reports

Organizations Involved

- 5 major Indianapolis med/ surg hospitals (95% of non-office care)
    - Community Hospitals Indianapolis, St. Vincent Hospitals and Health Services, St. Francis Hospital and Health Centers, Clarian Health Partners, and Wishard Health Services.
- Homeless care system
- County and state public health departments
- A large primary care network

Organizational and Political Roadblocks and Solutions

Fortunately, the senior management of the health care systems involved understood the vision and the potential value to improve care. While there is support for participating in the INPC at the senior management level, there are obviously competing interests within all of the participant organizations. It was, and at times continues to be, difficult to get focused attention from the right

resources within the participants' organizations at times. This is one of the situations in which they turn to the INPC champion inside the organization. Regenstrief was fortunate to have a champion inside of each participant — someone we could go to when progress stalled. The person varied in each participant, some being more administrative and others more clinical. They "unstuck" things that became bogged down in the organizational bureaucracy or when someone at a departmental level became uncertain whether they should do a specific thing.

A related issue is that it is important to develop relationships with the management within the participant organizations at a level close enough to influence the day-to-day operational issues that need to be monitored and sometimes improved. The relationship should also be high enough up to understand the organizational commitment and to be comfortable making decisions. Even with this support, some problems have proved to be recurring. At one participant for example, one of the printers in one of the emergency departments frequently runs out of paper and it may be hours and require a phone call from the INPC operations staff before the supply is replenished. The nursing personnel who have to replenish the supply are not the consumers of the information and are very busy triaging patients so they don't see this task as a priority. Their management will improve the situation for a while, but then the process starts to fail again in a few months. They are sometimes able to solve these types of challenges by tying the INPC processes to other processes to which they do tend. By printing INPC materials on a printer that is used to print the patient's "face sheet" for example, several of the participants almost never have "out-of-paper" conditions. Another problem, which has proven difficult to solve permanently, is getting the printed reports attached to the rest of the patient's paperwork in the ED. In the participants that have workflows that support it, the INPC reports print with the face sheet and are always on the patient's ED "chart". At others, where the registration process happens asynchronously from the patient triage process, we have difficulty ensuring the INPC reports get to the physician. Again, the initiative has tried to solve this problem by tying the INPC processes more closely into their workflow. When the triage nurse enters the triage data into the ED tracking system, the tracking system sends an HL7 message to the INPC and we print the report on a printer adjacent to the triage nurse. This is a very fast process and the printer is located on a counter where the nurse stands to "call the patient back." All they have to do is reach down and pick up the patient's report from the tray. They still don't do it 100% of the time. The reason — the INPC report is not viewed by the triage nurse as important to patient care.

Changes within participants and stresses can represent significant challenges. One pharmacy chain that initially agreed to participate was acquired by another chain and, before they could really establish a relationship with that company's

leadership, another chain acquired them. The INPC was able to maintain the interest, albeit at a lower level than we initially experienced, but not without a good deal of anxiety and work. As another example, a physician practice group who had initially planned to work with us ran into financial problems and they soon abandoned participation, leading to some wasted work.

Ongoing improvements in the participants' information systems' infrastructure is another source of change. The INPC relies on knowing the IP address of workstations that will be used to access the data as an additional security layer and of printers to deliver reports. As emergency rooms are remodeled, these devices are replaced and moved, usually without any notice. In addition, most organizations transitioned from fixed to dynamic (DHCP) IP address assignment strategies since the INPC was started, and so the project had to accommodate ranges of IP addresses based on the DHCP server that the devices will check to receive their IP address. The initiative created a management structure that consists of the INPC Management Committee that includes two representatives from each initial INPC participant. Most participants have designated the CIO and someone representing the emergency department. The Management Committee meets quarterly to provide oversight. Members of the committee also serve as conduit for information back to the participants' senior management and ED staff and providers.

Governance
Day to day operations and decision-making are carried out by individuals in the EDs, medical records or health information and information services departments.

After establishing the organizations' interest in the project, they created a participants' agreement that each participant signed. This agreement established roles and responsibilities as well as financial obligations. They invited each of the initial participants to help define the participants' agreement. Each participant's management and legal staff reviewed a draft agreement and eventually the committee created a mutually satisfactory agreement. The main features of the agreement are:

- Consistent informed consent from patients
- What data would be shared under what circumstances
- A small, but not insignificant, penalty for withdrawal
- Cross enforcement of confidentiality agreements
- Ownership of the data

Technical Roadblocks and Solutions

Infrastructure

The INPC project constructed a database of databases. Each participant's data is stored in their own "vault" — a database that is completely independent from the other participants' databases. All of these databases use a common term dictionary, a "global patient registry" that tied together registration data from each participant to link patient data between participants and a "global doctor registry."   The application is browser-based.

Data Exchange
They rely heavily on a locally developed "interface engine" to reformat and translate the data. Participants send nearly all data as HL7 messages and they convert all data that is sent in another form to HL7 messages. The INPC message pre-processor standardizes the HL7 messages – restructuring them to conform fully to the HL7 standard. They list (Table 4) some of the common ways that messages fail to comply with the standard, the consequences of that failure to comply, and how they resolved the problem. The pre-processor also moves various elements of information such as normal ranges and units to the proper segments and fields in the message. The HL7 message processor then maps the identifier combinations (OBX-3, OBR-5 and sometimes result) to the common dictionary code using data stored in an "external codes" table. They always retain the original codes and names from the HL7 message for troubleshooting and clarification. Next, the software converts the results to standard units (usually this is a factor of 10 to convert mg/dl to kg/L or mg/ml versus mg/dl for example). Finally, these data are stored in the participants' individual data repository described below.

They did not anticipate the magnitude of the task of mapping the laboratory codes at each participant to a standard set of codes. The magnitude of the task was larger than anticipated partly because they decided to map all the laboratory results rather than just the subset of laboratory parameters that they originally planned but also due to some inherent challenges in mapping. First, the lists of laboratory tests and their codes, the lab masters, do not contain much of the data needed for mapping. Second, the laboratories often have difficulty providing details of methods and, sometimes, which specimens are used for specific results (serum vs. whole blood, for example). Third, there are many ambiguities that they didn't previously appreciate, such as the quantitative test, which is reported as "negative" if the result is under specific threshold, but is reported as an integer if the result is over the threshold. Fourth, the LOINC standard was not mature and they had to considerably expand the codes it contained. The approach they now use is to collect several months result messages that they then summarize to provide the basis for mapping. This approach shows the range and type of results, the units and even, the frequency of the OR result, all of which are needed in order to properly map them. They then use a publicly available tool called the Regenstrief LOINC Mapping Assistant (ReLMA) to match the laboratories codes to the common codes. The INPC

project discovered a few principles through the mapping experience. First, "You should never guess." If the project participants couldn't be absolutely certain about mapping, they asked the laboratory. Asking the laboratory can require a lot of time and follow-up to obtain the information needed to avoid guessing. Second, they represent the result at the appropriate level of granularity — that is, the project retained the specifics of method, sample and other details. Splitting clinically similar results into several categories will make retrieval and result review more difficult but the project believed they could overcome this difficulty by merging these data at display time.

Security
Because they wanted to reduce barriers to participation as much as possible and because security and confidentiality were high on the list of concerns, they chose to construct a network of networks to create a secure extranet — linking each of the participant's internal networks using dedicated T1 lines or other dedicated circuits. The extranet created was "outside" the participants' firewalls and the INPC servers are located behind Wishard Health Service's firewall. The participants had to treat the INPC extranet as a "trusted" network in order to provide seamless access from workstations on their own network to the INPC servers and from the INPC servers to printers on their network. Most of the participants have implemented private networks, which has required considerable configuration to the network address translation, or NAT, tables in order to allow access to the INPC. In order to eliminate the dedicated data circuits and thereby decrease costs and increase scalability, the INPC project has been working to move the data exchange to the Internet by using Virtual Private Networks (VPNs). This approach will improve the scalability and reduce the expense of maintaining the INPC network infrastructure and will actually increase security.

ED providers use a browser-based interface to access data in the INPC database with secure socket layer or SSL protocols. In addition to the physical network access security, they have configured the INPC web server to accept connections only from "known" IP addresses. They chose the computers that have access, in part, based on their location being physically secure. In addition, they require a user ID and password. An independent computer security specialist performed a security audit in order to testify/document/demonstrate that appropriate security measures are in place to protect the INPC servers.

The group also chose less sensitive data to at the start of the project, and progressed with more sensitive data, as organizations were more comfortable with security procedures.

Some of the recent technical difficulties have been in de-identifying data for public health. Challenges exist in the following areas:

- in pinning down the definition of 'de-identified',
- scrubbing data of identifiers is difficult,
- in translating identifiers into unique keys, and
- in linking de-identified data via these keys.

Another challenge has been user authentication. The initiative is currently looking at smart cards that would enable all providers in the area to have access to the EMR at low cost, as well as an unmatched database for clinical research and options for clinical decision support.

Project Status

Being added to all institutions are:
- Operative notes
- Inpatient medications
- Admissions summaries
- Citywide prescribing (possibly)

Future Plans

The initiative also plans to extend physician access through smart cards. They plan to install 3,000 smart card readers in city and issue 4,000 smart cards. The system would have full encryption capability so there would be no chance of snooping, as compared to other mechanisms. This would allow them to add 4 major cardiology groups (90% of cardiology for city) and eventually bring all Indianapolis practitioners into the network.

Patient Safety Institute (PSI)

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Background
PSI was founded in December 2001, as a national, non-profit membership organization governed by leading consumer, physician and hospital advocates who are working together to improve healthcare quality and lower costs. PSI was formed to provide the healthcare industry with a commonly owned, utility-like organization that could inexpensively develop a shared communications and operating infrastructure. This infrastructure enables real time access to critical clinical information at the point of care.

Description of the Group's Work
PSI is deploying a VISA-like communication network based on existing technology that provides real-time, secure, patient-centric clinical information in the five key areas that physicians collectively agree are critical for the delivery of quality care. These five key data elements are: Problem Lists/Diagnoses, Laboratory Results, Medications, Allergies and Immunizations. The network backbone is based on a community-driven, patient-centric model. To facilitate expansion of PSI nationwide, PSI will offer access to the system through publicly available, open-standard technology. PSI is platform and software independent, making access to its inexpensive and trusted network service open to all communities that join the network and agree to abide by PSI's principles. The principles are as follows:

- Participation must be equitably open to all individuals and organizations that materially affect patient health and safety.
- Deliberations must be conducted, and decisions made, by bodies and methods that reasonably represent all such parties, controlled or dominated by none.
- Individually identified data must remain the property of that individual and must not be disclosed or disseminated to others without that individual's consent.
- All participation shall be voluntary with the right to withdraw.
- Any data accessed for the development of improved health or patient safety must be de-identified and remain under the control of PSI.
- PSI operations shall be funded from benefits produced for participants.

- PSI will be designed and will function to enable and enhance community-based collaboration for improved health and patient safety.

Functionality

PSI is built on an opt-in model. To participate, a patient, physician, and hospital must first elect to be part of the PSI system. For a patient, the opt-in process includes identification of physicians who are approved to view their PSI clinical data. A participating physician, using the tool of his or her choice, (e.g. printed report, clinical workstation, or handheld computer) will request specific patient-centric clinical information. The request will then be authenticated and the information provided in real-time via an encrypted transmission of the PSI clinical data for the patient. Clinical data is updated locally through existing clinical systems every time a patient visits a physician at a participating clinic or hospital. The physician is then able to obtain the patient's up-to-date clinical information from any location. Additionally, patients will be able to view their PSI clinical information and provide comments for their providers.

Data Being Exchanged

The core dataset includes the following data elements (referred to as Basic Safety Data):
- Problem Lists / Diagnoses
- Laboratory Results
- Medications
- Allergies
- Immunizations

To promote the effective use of clinical information, PSI will make its collaborative communications network available to communities that choose to exchange additional permitted data within the bounds defined by PSI's principles. To the extent that communities organize and choose collaboration beyond the PSI Basic Safety Data set, PSI is able and willing to provide efficient and inexpensive connectivity.

Organizations Involved

Initial financing has been provided by a group of Core Founding and Supporting Partners: Avaya, Cingular, Dictaphone, First Consulting Group, Hewlett-Packard Company, Medicity, Netegrity, SeeBeyond, TeleTech and WilTel Communications. The Board consists of equal representation from the patient, physician and hospital communities, and may be expanded to include representation from the insurers, pharmacies and lab constituencies in the future:

Physician Community
- Jack C. Lewin, MD, CEO, California Medical Association
- William F. Jessee, MD, CMPE, President & CEO, Medical Group Management Association
- Richard F. Corlin, MD, past President, American Medical Association

Hospital Community
- Don C. Black, President, Child Health Corporation of America
- Daniel H. Winship, MD, Vice Chancellor of Health Affairs and CEO, University of Missouri Health System, and member, Executive Committee of the University Healthsystem Consortium
- Karin Dufault, SP, PhD, RN, Chairperson, Providence Health System and Trustee, Catholic Health Association

Patient Community
- Twila Brase, RN, PHN, President, Citizens' Council on Health Care
- Jane L. Delgado, Ph.D., President & CEO, National Alliance for Hispanic Health
- Linda F. Golodner, President & CEO, National Consumers League

Ex-Officio
- Johnny Walker, CEO/Executive Director, Patient Safety Institute

Demonstration Project

PSI recently completed its Demonstration Project, which involved three hospitals in the Seattle area. The PSI solution received tremendous reviews from the physicians that participated in the Demonstration, with the vast majority of them reporting that access to the PSI system resulted in significant tangible benefits for their clinical practice, often within the first few hours of having access to the system. Physicians reported that the technology interface was intuitive, easy to use and required little or no training. The hospitals that were part of the Demonstration Project have elected to continue using the system, choosing to leverage the PSI technology in ways that promise significant technology cost savings, and have committed to being PSI's national technology showcase.

Organizational and Political Roadblocks and Solutions

PSI plans to address the limitations of other information exchange initiatives that have preceded it through the following strategies:
- PSI is a non-profit organization that unites respected and trusted national leaders from the consumer, physician and hospital constituencies in a committed and collaborative governance board,
- Patients are the core focus; they control access to their Basic Safety Data and there is no cost to them to be part of the system,
- Governance is collaborative among the constituencies and employs a community-driven model that allows flexibility in prioritization and customization to individual communities in concert with PSI Principles,

- PSI is singularly focused on providing a secure, technologically open and accessible healthcare communication network, allowing PSI to play a supportive role and enhance local technology solutions, rather than competing with the myriad of healthcare value-added vendors.
- PSI has been designed to be a national, rather than regional, model that provides the missing connectivity piece that will enable local providers to come together in a collaborative manner for the good of patients

The greatest roadblock faced by similar initiatives has not been the technology; it has been bringing the leaders of the various constituencies involved in providing healthcare together in a collaborative manner to address the shortcomings of the current system. The lack of a trusted entity that includes the nations top consumer advocates in its bid to safeguard patient privacy has left a void in which the proprietary and competitive interests of the various constituencies prevail.   PSI's approach to tackling this issue has been to bring together the most visionary leaders in each of the three primary constituency groups in a collaborative model, creating an organization that is both equipped and positioned to play the role of patient privacy trustee. This inclusive, private sector, national governance body is entrusted with the operation of the nationwide network.

The influence of Dee Hock (CEO Emeritus and Founder of VISA), who guided the creation of the banking and retail consortium called VISA 30 years ago, has been immensely valuable as advisor to the Board. Mr. Hock's global experience and knowledge are invaluable to the success PSI has enjoyed to date. PSI's healthcare model incorporates many of the lessons learned by VISA in building a national collaborative network and will continue to capitalize on that body of knowledge.

Technical Roadblocks and Solutions
A great number of healthcare provider communities do not employ a common data standard. Where standards exist, PSI has incorporated them; where they do not, PSI will accept and communicate automated clinical data as it is currently available. This process has been developed to encourage and accelerate the adoption and development of meaningful standards. Where there has been little collaboration across enterprise boundaries, the need for and value of such standards has not been a priority. The process of communities joining and using PSI will spotlight the role of standards, particularly for clinical data.

Additionally, the quality of the data provided through traditional interface approaches may vary. For example, laboratory systems may output multiple versions of the same lab results. Logic must be provided to discern a single, autonomous lab result from this string of repetitive data. PSI addresses these

complexities through reliance on ANSI's Health Level 7 (HL7) messaging standard, which provides a standards-based framework that enables examining, manipulating, mapping and transmitting data in a health care setting.

Providing end-to-end security, user access and authentication across a federation of digital networks is a perceived technical roadblock. PSI provides rigorous end-to-end security through the use of various, nested encryption algorithms. PSI also uses a combination of Virtual Private Network technologies at the "wire" level. User access, rights and authentication are provided via the use of sophisticated directory management and access control tools. This approach allows the establishment of various levels of access and service authentication within the PSI network.

The primary focus of this sophisticated combination of security technology is to exceed the baseline of healthcare security outlined in the Health Insurance Portability and Accountability Act of 1996 (HIPAA). PSI has established its consent, authorization and clinical information collaboration methods under a thorough legal review, to comply with HIPAA and other relevant federal and state regulations.

National Network
PSI is beginning its national rollout of the PSI system, beginning with work on the first statewide network beginning in Jun 2003. A number of other states and local communities have expressed strong interest in participating in PSI, and a number of significant announcements are expected shortly.

North Carolina Healthcare Information and Communications Alliance (NCHICA)

Contact and Follow-up Information
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Background
NCHICA was begun in 1994. In 1997, a project called PAiRS (Provider Access to Immunization Registry Securely) was initiated to prove that secure access to an aggregated data set could be done using the Internet. Childhood immunizations were selected because there was a recognized need for providing access to the records, the records were relatively harmless should any breaches of security take place, and the State immunization registry staff were anxious to provide access and to begin the process of developing a statewide system with full input and retrieval capabilities. A number of public and private forces came together to build the demonstration capability.

In 1999, a group of Emergency Physicians from the NC Medical Society approached NCHICA with a request to form a group to bring together vendors and providers to standardize the way data was being collected in Emergency Departments, and collect the information electronically and transmit the information securely to a central, protected repository.

Physicians wanted to form this group within NCHICA so that they could develop best practices in emergency medicine and do community assessments. The group was approved by the NCHICA Board of Directors and established as STEER (Standardization and Transmission of Electronic Emergency Records). When CDC became interested in funding the project in October of 1999, the NCEDD (North Carolina Emergency Department Database) was begun shortly after STEER. The group recognized from the beginning that the information would be particularly useful in the early detection of public health events, but it took 9/11 to bring that aspect to the forefront.

Description of Group's Work
Through the PAiRS initiative, immunization status (record of immunization, provider of immunizations, immunization dates, child's name, birth date, home address, SSN, Medicaid no and mother's maiden name) is gathered and stored in a centralized database.

Through NCEDD, the group is exchanging emergency department data in standardized ways according to CDC recommended format (DEEDS). The project

is encouraging 3-6 EDs in busy North Carolina hospitals to adopt selected DEEDS data elements. They aim to show that ED data can be collected electronically for use by public health, and demonstrate secure data exchange of ED data to a central repository can work. They also wish to investigate link between NCEDD and other state data repositories and assess potential for real-time electronic reporting of ED data to NCEDD.

Functionality

NCEDD

The primary feature of NCEDD is to collect ED data in an open and straightforward approach with minimal impact upon participating hospitals. It implements this by:
- Capturing existing data in a hospital's information systems, with no additional data entry required,
- Using transparent, scaleable, and distributed technical architecture,
- Using 128-bit encryption and Secure Sockets Layer for transmission security,
- Providing hospitals and public health officials near real-time access to reports on their own data, and aggregate data from other hospitals, via a secure web portal,
- Being cost-effective since NCEDD uses off-the-shelf, non-proprietary tools,
- Establishing an automated daily batch process of data from hospitals,
- Requiring minimal effort by hospital staff once the system is established.

PAiRS

Provider Access to Immunization Registry Securely (PAiRS) offers a secure Internet solution for sharing immunization records between the State Immunization Branch and immunization providers. The information in PAiRS is updated every other month, ensuring that the providers have access to timely information to use in clinical decision-making. Access to PAiRS can prevent overimmunization of children, and ensure providers administer the correct, needed immunizations to children at all visits. In many cases, using PAiRS eliminates the need to make phone calls and wait for faxes and return calls from other NC healthcare providers. PAiRS is being marketed by the North Carolina Division of Public Health (DPH) as an interim tool that providers can use as they await a new statewide immunization registry. Using PAiRS is a key strategy to ready provider sites for the new web-based registry.

Data Being Exchanged

NCEDD

The NCEDD data repository contains data captured electronically from participant emergency departments (EDs) for patients who are either treated in the ED or patients seen in the ED and then admitted to the hospital. NCEDD will accept the data in the format easiest for a hospital to produce and then translate the data elements to the CDC's Data Elements for Emergency Department Systems (DEEDS) standard. Once standardized, the data are then aggregated with data from other participating hospitals.

In contrast to many data systems that rely on billing data, NCEDD collects data that includes clinical information and information specific to EDs (e.g. chief complaints, admitting diagnoses). An abbreviated list of the data elements NCEDD collects appears below.

NCEDD Data Elements (Abbreviated List)
Patient Identification Data
NCEDD Patient ID, demographics, address….
Facility and Practitioner Identification Data
ED Facility ID, ED Practitioner Type….
ED Payment Data
Groups of Insurance Coverage, Private, Medicaid….
ED Arrival and First Assessment Data
Chief Complaint, Triage Acuity, Mode of Arrival, Vitals….
ED History and Physical Examination Data
Coded Cause of Injury ICD-9 E-Codes
ED Procedure and Result Data
ED Procedure, ED Procedure Result….
ED Disposition and Diagnosis Data
ED Disposition, ICD-9-CM Coded Diagnoses….

PAiRS

On a bimonthly basis, a fresh extract of data is taken from the existing state immunization registry, and from Blue Cross Blue Shield of North Carolina, and that data is put into PAiRS. This data includes demographic information on children 0-18, and their associated immunization records (date vaccine administered, name of vaccine, name of provider who gave vaccine). Healthcare providers then use PAiRS to "look up" that data and utilize it as needed in providing care to those children.

Organizations Involved
PAiRS involves nearly 200 health care providers, health plans, professional associations, government agencies, health research, vendors and pharmaceutical companies. The lead in this project is the Immunization Registry Section of Women's and Children's Health in the North Carolina Department of Health and Human Services with support from NCHICA, Blue Cross Blue Shield of North Carolina, Madison Information Technologies, Peak 10 Data Services, Quintiles Transnational, and EDS.

NCEDD currently involves 3-6 EDs in North Carolina, NCHICA, NC Dept of Public Health, CDC, National Center for Injury Prevention and OnSphere.

Organizational and Political Roadblocks and Solutions
In the NCEDD effort, the project team has, to date, identified the following organizational roadblocks that they've surmounted during the NCEDD effort:
- Security and legal concerns have been more problematic than technology, and HIPAA has been a struggle.
- Voluntary participation makes participation less likely.
- Different stakeholders have different ideas and expectations for the project.
- It is important to identify an ED clinician (preferably an MD) to serve as a "champion" for the project in the local hospital setting.
- NCEDD recommends that a hospital IT analyst should be assigned to work exclusively with an NCEDD staff member on site for a specified amount of time during the critical initial phase.
- Managing the budget for this project takes far more time than it should due to federal, state and university bureaucracies.
- Real-time, web-based availability of ED data is a benefit for participating hospitals and an enticement for participation.
- In future system releases from HIS vendors, public health and clinical needs should be address. Most HIS requirements were defined for business end uses and not necessary for clinical utility and public health needs. Systems should be designed to meet the needs and share data for all healthcare stakeholders.

Technical Roadblocks and Solutions
NCHICA found, through the PAiRS effort:
Security and privacy were the main focus. User name and password were used to access the system, and the challenge of having multiple users per individual PC were addressed. When a user was authenticated, keys were exchanged between user's web browser and the database Web Server – allowing connection using 128-bit SSL technology. It was ensured usernames and passwords were not shared. Several team members were trained as registration agents to allow them to issue certificates on behalf of the authority.

Because multiple staff members often use the same PCs, the project team issued key fob identifier devices made by Dallas Semiconductor Corp to users, and inexpensive reader devices on PCs. They worked with UNC-Charlotte School of IT to create a custom JavaScript application to allow keys to be used to authenticate individual users over the Web. Certificates were issued real-time to ensure they were up-to-date.

They also needed to create an effective search mechanism to deliver useful results despite millions of records. They used 'patient record disambiguation' to address this problem. This system provides the ability to differentiate between similar immunization records and identify and display multiple instances of records for the same person, giving users the most complete view possible of a patient's immunization history.

On the NCEDD project, NCHICA found that:
- Off-the-shelf software is preferable to customized systems in terms of cost and implementation time.
- Lack of reliance on UB92 hospital billing/administrative data confuses many people.
- Lack of ability to collect patient identifiers in NCEDD limits both the ability to clean and update the data and the utility of the data for many purposes (e.g. linkage, surveillance, research, benchmarking).
- Ability of local hospitals to provide accurate data dictionary for translation purposes is questionable.
- Because local hospitals often have not worked with and used their ED data, they often cannot identify problems/issues with their data and troubleshoot them.
- Because central NCEDD staff do not know local hospital information systems or local EDs or local ED data, it is difficult for them to immediately recognize problems or to even ask the right questions to identify and correct problems in source data.
- Integration models for real-time application level interfaces that are complex and expensive to implement are not practical. A data level integration model that accomplishes near-real time data transmission is less expensive and

invasive to hospital systems and is more practical to implement, and the probability of a successful integration is much higher.

They addressed these issues by using non-proprietary architecture using off-the-shelf software. Hospitals identify data sources, create a source file and provide a data dictionary. Quality checks are made, and then data are translated to DEEDS format. A copy of the translated data is placed on a hospital server, and also loaded into the aggregate database.

Secure SSL-enabled FTP transmissions and SSL for secure web data transmissions for web-based reports are more appropriate for this type of project than PKI user certificates/tokens. Hospital firewall technical issues and policies hamper real-time data collection and create barriers that must be addressed for timely and secure data transmission.

Data cleaning processes were important to acquiring usable data and may require additional work for the site hospitals. Once the data are rolling in, the project requires a data manager/administrator to maintain the database and respond to inquiries. The initial period that the NCEDD staff worked with the hospital staff, to develop a data dictionary and source file, was also key to successful implementation.

Project Status
PAiRS--Currently there are over 200 sites accessing a combined public-private database with records of 16 million vaccinations for over 1.6 million children. Also, underway is the full-capacity immunization registry with initial sites to begin coming on line perhaps as early as later this year. PAiRS received a "Corporate Cooperation" award from Every Child by Two Foundation in 1999 and received another award in DC from the National Partnership for Immunization in 2002.

NCEDD--NCHICA is in the process of implementing NCEDD, and are currently transferring data from 3 hospitals. Specifically:
- NCEDD currently has three hospitals providing data on a monthly basis for translation to DEEDS and loading into the aggregate database.
- Data from October 2001 – March 2002 are available from these 3 hospitals, including data on over 55,000 ED visits.
- Current data collection does not include any patient identifying data elements.
- Efforts are currently underway to implement secure FTP of the data and to implement an automatic scheduling process.
- Standard web-based reports have been and are being developed. These reports provide secure and restricted access to the data for authorized users.
- Data quality and cleaning efforts are underway.

- The project was designated a HIPAA Exemplar Project of NCHICA for the development of policies and procedures related to HIPAA privacy and confidentiality requirements.
- NCEDD has become a key player in North Carolina's efforts to address the development of public health infrastructure and the identification and response to bioterrorism, with the recognition that NCEDD has the potential to provide ED visit data to the state's public health and bioterrorism surveillance efforts. With this increased profile for NCEDD in the state's Division of Public Health have come calls and efforts to move North Carolina towards mandating the collection of ED data for public health surveillance efforts. These involve NCHICA and DHHS, as well as discussions with the North Carolina Hospital Association.

Future Plans

PAiRS—In December 2001, the state Department of Health and Human Services was approved to receive 90% match funding from the federal Centers for Medicare & Medicaid Services (formerly known as the Health Care Financing Administration) to implement a new statewide immunization registry. The new registry will be based on a system currently in operation in Wisconsin and will allow providers to enter as well as view immunization information.

The PAiRS project has attracted considerable attention throughout the state and nationwide. The unique experience of the PAiRS team has provided a valuable understanding of the issues surrounding the consolidation and distribution of large quantities of health care data. By helping to solve a health data problem that affects many health care professionals on a daily basis, the PAiRS team has provided a very tangible benefit for health care providers in North Carolina and also helped to build confidence throughout the state in the concept of sharing health care information securely over the Internet.

NCEDD—As a result of the events of September 11, 2001, the NCEDD project has become an integral part of the state's adverse event response strategy. Current plans call for the inclusion of up to 20 of the state's most heavily utilized EDs.   This will be accomplished through new funding of a proposal for the rapid expansion of NCEDD into up to 20 priority hospitals across the state. These plans include rapid expansion not only to include more hospitals but also to move to daily transfer, translation and loading of local hospital ED data. Such a rapid expansion will require additional staff and hardware/software but the basic technical architecture for the project will remain the same. The plan is also for NCEDD to eventually feed NEDSS. NCEDD has plans to increase the disaster management utility for emergency preparedness at a state, local and hospital level. Also, NCEDD plans to aid clinical data users in decision support and reducing medical errors and healthcare cost.

Minnesota Center for Healthcare Electronic Commerce (MCHEC) and the Minnesota Health Data Institute (MHDI)

Contact and Follow-up Information
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Background
MHDI was established in 1993 by the Minnesota Legislature with the stated mission of "supporting the information needs of consumers, purchasers, providers, plans and other stakeholders in measuring and improving the quality and efficiency of health care services in Minnesota." Initially, this was brought about by the move towards the use of the public Internet to exchange healthcare information for business and clinical purposes, along with new national privacy regulations.

In 1994, the Minnesota Health Data Institute created the Minnesota Center for Healthcare Electronic Commerce, which became the first independent education resource center dedicated exclusively to promoting the use of electronic commerce within the healthcare industry. Early in the process, the MCHEC board and its Security Task Force decided to focus on interoperability standards.

The Minnesota HealthKey effort built off of a 1997-98 effort by three states Mednet became operational in 1995. MHDI and has a PKI effort being funded under the Robert Wood Johnson five-state HealthKey project.

Description of the Group's Work
MCHEC worked with HealthKey to build a PKI model in Minnesota to support healthcare data exchange. The organization also initiated MedNet, a private, non-proprietary, statewide, public-private health care telecommunications network in Minnesota, which is exchanging both administrative data and an exchange of certain kinds of public health data.

Functionality
The PKI / HealthKey project focused on the following items:
- Directory Services
- Secure exchange of confidential information
- Secure encryption of e-mail

- Digital signature of e-mail
- Digital signature for other documents.
- Reduced sign-on requirements
- Secure access to web pages via smartcards and/or certificates

This built on an earlier three state effort with Washington and Massachusetts.

Data Being Exchanged

The public health data exchange enabled by MedNet involves secure email and file transfers from providers to the state public health department. Specifically:
- Lab reporting -- The exchanges started with proprietary standards and are now in the process of switching to HL7 standards
- Birth reports – These are also being done through a system of propriety standards, but they are also working to transition these to HL7
- Death reports from funeral homes
- Reportable events – For a lot of providers reporting is still being done by paper. They are moving towards getting these automated.
- Disease registries – used by public health for surveillance purpose. This is also being transitioned to HL7
- Trauma registries

Organizations Involved

The HealthKey Bridge project involved the Health Department, Department of Human Services (Medicaid), Falls Church, Virginia based Mitretek Systems, Inc and Saint Paul, Minnesota based VisionShare, Inc.

MedNet involves a large number of major health systems, payors and government entities in Minnesota.

Political and Organizational Roadblocks and Solutions

In the HealthKey effort around PKI models, MHDI found that security needs to be broken down into doable pieces; that "one size fits all" does not apply.

MHDI has learned that data exchange needs to respond to specific business needs, otherwise it will not happen. Further, it will take years to get adoption of standards and security tools, and that we wouldn't be able to transform the healthcare industry in a short timeframe.

MHDI has also learned from their public health data exchange work that there is a critical path to creating a bridge between private and public sector; and that this is where effort needs to be put now. Before September 11, 2001, the focus was on private sector exchange, and now the focus is on public-private collaboratives. The next generation of HealthKey efforts will focus on models for secure public and private exchange of data.

Technical Roadblocks and Solutions
In order to move towards interoperability, MHDI chose to build a "bridge" system that allowed interoperability between digital certificates issued by certification authorities (CAs) used by healthcare organization doing business as trading partners.

The use of a healthcare Bridge CA (the "HealthKey Bridge"), jointly developed by Mitretek Systems, VisionShare and the Institute enabled information security vendors to create interoperable systems. The HealthKey Bridge model connects disparate security infrastructures through security authentication standards – thus allowing proprietary vendors of PKI services to interact. In this model, local healthcare organizations worked with their CA and PKI vendors to have them agree to use the same standard to interconnect through the HealthKey Bridge.

What they found was that there wasn't a current business need to implement this level of security. Because HIPAA does not require PKI, this depth of security is more of a risk management solution that organizations will get to years down the road. They also found that some models, such as encryption, were less expensive and were more immediately useful.

MHDI also found there was significant disparity of IT systems on different platforms, and that made the PKI effort was extremely resource intensive. Vision Share, however, has taken a simplified version of the model and sold it to healthcare and other industries. In the HealthKey model, MHDI and its partners were implementing PKI on healthcare systems' existing servers and infrastructure. Vision Share pre-programs a server and has all outgoing email run through that server – reducing the cost of implementation significantly.

Project Status
The technology demonstration of PKI was completed in 2001, and Vision Share is now moving forward with a simplified version of that work. They are also continuing to exchange and standardize clinical data between public health and providers.

Future Plans
In addition to their standardization efforts, they are also looking at building the business reasons for clinical data exchange, and try to address them. Most of the organizations in MedNet are still in the process of implementing EMR so a lot of information is not electronic yet. MHDI is convening CIOs to assess the state of EMR within Minnesota. The step they are currently looking at is determining strategies to promote adoption of EMR. The next step would be to ensure secure exchange of clinical data.

Massachusetts Health Data Consortium

Contact and Follow-up Information
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Background
MHDC began in 1978 and is funded through membership (65%), conferences and seminars (15%), data products (15%), and grants (5%).

Description of the Group's Work
The Consortium currently conducts the following activities:
- Collects data, creates data products for facility use, and produces pre-formatted comparative reports in the following areas:
  - Ambulatory (Observation Stays & Emergency Dept.)
  - Inpatient Case Mix & Charges
  - Physician demographics
- Educates through information exchange events
  - CIO Forum
  - Security and Privacy Officers' forums
  - Webmasters' forums
  - Data managers & Users Forum
  - Information about HIPAA
  - Conferences and meetings on Quality Improvement & Patient Safety
- Performs health services research
- Numerous concurrent projects including focuses on collaborative learning and research regarding:
  - HIPAA (technical assistance and access to resources)
  - Cost and access to care (Conferences and series, working groups, measurements)
  - EMR (access to resources)
  - eHealth (access to resources -- research)
  - Patient safety and CPOE
    - Technology survey
    - Input from members on current initiatives
    - Sharing results with government
    - Technical assistance
    - Access to Resources
  - Physician Directories online – participating in research with Commonwealth Fund and also providing access to further resources

- o Physician Patient email -- examining capabilities of secure online transactions through group's CIO forum. This effort is led by John Halamka. MHDC also provides access to further resources in this area.
- o Public Health & Bioterrorism – They provide access to online and literature resources, and also participate in HealthKey.
- o Quality and Verification of Health Information -- access to resources
- o Quality Measurement / Outcomes -- access to resources, presentations

Functionality

The Consortium's CIO Forum facilitated the creation of the New England Healthcare EDI Network (NEHEN)—which now generates over 1.5 million HIPAA-compliant transactions a month among more than 20 major healthcare organizations.

Data Being Exchanged

NEHEN processes eligibility verification, referrals, and claims status inquiry.

The Consortium has initiated a new entity (Mass-S.H.A.R.E.) with the objective of creating a community-wide approach for access to clinical data held by each enterprise. The first data to be accessed will be prescription histories.

Since 1978, the Consortium has obtained a variety of data from providers, health plans and government agencies and converted them into Comparative analyses.

Organizations Involved
Their CIO Forum membership includes 33 Healthcare organizations and 9 technology companies or consultants. Each initiative involves various leaders in their membership and others exchanging data around the country. Total membership is over 135.

Organizational and Political Roadblocks and Solutions
Through MHDC's numerous successful efforts, they have found that their niche is inter-enterprise, collaborative projects. Further, any project that has a clear business case and ROI moves quickly. MHDC has focused on finding projects that are on the 'hot list' of their membership. Currently, those include: Patient Prescription History in the Emergency Department and Administrative Simplification for prompt provider payment. In general, MHDC has found that if there's a reimbursement connection, the project will be ranked higher in obtaining committed resources.

They've also found that:

- An organization cannot always keep the savings that they expect at the beginning of an effort, and this is may discourage some participants.
- Organizations often do not get rewarded for lowering costs.
- Historically, there is a lower level of funding for IT than in other sectors, but once IT gets funding, there is much competition for the resources.
- The IT Department and User departments should continue to show return on investment and make a business case for senior management.

Technical Roadblocks and Solutions

In a recent effort, the CIO Forum of MHDC investigated a set of security technologies for messaging. They wanted to exchange patient-specific data via the Internet, privately and securely. However, cost and administrative barriers to implementing full PKI were prohibitive -- given the need to issue individual level digital certificates to large numbers of people, training new users can be prohibitive.

Instead, the CIO Forum took an organization-to-organization (server-to-server) approach and identified a group of vendors - encouraging them to offer inter-operable, Secure/Multi-purpose Internet Mail Extensions (S/MIME) products that simplify secure emails. The Forum got vendors to work together to demonstrate that their Internet encryption products could work seamlessly with one another. Over a 3-month period, they conducted an email dialog and agreed on an approach, then simulated a multi-organizational email environment to demonstrate interoperability. After the testing period, all vendors were able to show ability to encrypt and decrypt email transmissions from other vendors.

The lessons they learned from this were as follows:
- A one-size-fits all solution to health data security (i.e.: PKI) is not necessary
- A group of competing vendors can work together to be interoperable
- The health data security problem can be broken down into manageable projects
- An effective convener can enable collaboration

Project Status

In the CIO forum effort, the vendors will submit this approach to the IETF for publication. The Consortium hopes to work with IETF to establish a standard methodology for exchange of encrypted clinical messages. This new standard would use a 'domain encrypting agent' and 'signing agent' to avoid having to exchange individual certificates.

Other healthcare communities have contacted the Consortium to learn more about their approach.

Status of other efforts can be obtained by accessing MHDC's extensive website and its resources, or contacting Elliot Stone or his staff.

Future Plans
The CIO Forum intends to extend its work by identifying a secure batch transfer of files as its next health data security priority. Other administrative and clinical initiatives of MHDC will continue and develop per the needs of its membership.

HealthBridge

Contact and Follow-up Information
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Background
Hospitals in the Cincinnati area have extremely low reimbursement rate, estimated at 20%- 30% below other mid-western metropolitan areas. The financial pressure being felt by these hospitals has spurred them to look for ways to develop standardized clinical exchange in order to lower their operating costs. HealthBridge began by providing access to existing clinical systems through an intranet and has subsequently moved to the Internet to provide access to systems at 17 regional hospitals. HealthBridge also installed a community-wide messaging platform so physicians and their staff can use one electronic in-box to view radiology, lab, and transcription data regardless of which organization it originated in.

Description of the Group's Work
HealthBridge connects hospitals and physicians securely and outsources electronic and non-electronic communications. HealthBridge provides electronic access to PACS systems, electronic chart completion, Hospital Information Systems at 17 hospitals, hospital EMR's and administrative tools for hospitals and physician offices. HealthBridge operates a secure portal and Internet security and authentication for the community.

Functionality
Current functionality includes:
- Secure portal access including Internet authentication and usage reporting
- Access to key existing hospitals applications (both web enabled and non-web enabled)
- A single electronic in-box for hospital radiology, lab, transcription and ADT for 17 hospitals
- Physicians also have the option of using the community in-box for internal transcription
- Insurance eligibility checking, on-line referrals, UPIN search
- Outsourced community faxing for physicians who do not wish to use electronic tools
- Outsourced community printing to share the cost or printing across all hospitals systems (for printed reports, HealthBridge can consolidate

printing across the 17 hospitals, MRI Centers, local and national labs, and send one envelope)

- EMR feed – HealthBridge provides a single feed with one interface to EMR's for lab, radiology, transcription and ADT for all participating organizations
- Currently sending 6 million reports annually through messaging system; will be 14 million by end of 2003

Data Being Exchanged

Laboratory, Radiology, and Transcribed Reports and Patient Demographics and Insurance for the following health systems:

- Mercy Health Partners: (Anderson, Clermont, Fairfield, Western Hill, Mt Airy)
    o Email of lab, radiology, transcription ADT
    o Physician Access
    o Scheduling
    o Radiology images
- Health Alliance (Christ Hospital, University Hospital, St. Luke's East/West, Jewish)
    o Email of Lab – Radiology, Transcription and ADT in Q3, 2003
    o Last Word Clinical Information System
    o Alliance Laboratory Services
    o IDX billing
    o EMR's at University, St Luke's E/W
- TriHealth: (Bethesda and Good Samaritan Hospitals)
    o Email of Lab, Radiology, Transcription Cardiology
    o Access to CIS, Meditech
- Drake
    o Access to Keane First Coat Clinical Information System
- Children's hospital
    o Access to SMS Clinical Information System
- St Elizabeth Medical Center (North, South and Grant County)
    o Email of Lab, Radiology, Transcription
    o On-line chart completion
    o PACS system
    o Access to HBOC Clinical Information System
- Other
    o On-line EKG's and pace maker recall tracking
    o Local and national lab email
    o Billing data access for physician offices
    o Local and national lab electronic access
    o Office based transcription in electronic in-box
    o EMR insertion

- o Physician office internal lab system to electronic messaging system
- o Outsourcing of non-electronic results for are organizations to reduce cost during transition to electronic
- o Conversion of HL7 reports to Microsoft Word, flat file, etc

Insurance Information from the following managed care organizations:

- Numerous insurance companies
- Medicaid
- Medicare in 2003
- Uninsured grant tracking

Organizations Involved
- Children's Hospital Medical Center
- St Elizabeth Medical Center
- Health Alliance of Greater Cincinnati
- Mercy Health Partners
- TriHealth
- Academy of Medicine
- The Greater Cincinnati Health Council
- Employer Representatives
- Community Representatives

Political and Organizational Roadblocks and Solutions
HealthBridge's biggest organizational problems were in getting players to play together and getting a critical mass of content online so people would actually use the product.

Technical Roadblocks and Solutions
From a technology standpoint, they struggled with web enabling applications that were not currently web enabled. Standardizing interfaces was also a challenge, as was developing a repeatable methodology for integrating clinical applications.

Project Status
The web-enabled data exchange application currently has 4,000 users, including 425 Group Practices. HealthBridge has over 7,000 physicians identified in the clinical messaging application. Within the clinical messaging product, they have completed three out of five major systems. One will be completed within three months. National and local labs are in integration. Two office-based transcription companies have integrated to the messaging application. One internal physician lab is in integration. Three practices are in integration for

direct EMR access. The first nursing home has been signed and is receiving results electronically.

Future Plans
Future plans include:
- Connecting rural hospitals
- Expanding on-line products that will increase efficiency and reduce costs
- Providing access to Medicare eligibility
- Creating a community-wide standard for handhelds including access to clinical messages from a single device from your home, office and physician lounge
- On-line lab ordering
- Single sign-on for all applications
- Biometric authentication for signing reports and physician access to various hospital facilities
- Porting services to other communities interested in sharing and reducing common infrastructure costs
- Connecting other key players in healthcare such as additional nursing homes, pharmacies and MRI Centers
- Continue to reach and connect the physician community to HealthBridge.
- Expanding existing Clinical Messaging platform to more doctors and create physician-to- physician electronic communication.
- Patient to physician electronic communication

CareScience

Contact and Follow-Up Information
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Background

In 1999, a community of health care providers in Santa Barbara County, CA approached the California Healthcare Foundation (CHCF) with a proposal to exchange data between Santa Barbara healthcare stakeholders.

CHCF asked Dr. David Brailer, Chairman and CEO of CareScience, a leading care management company, to conduct a feasibility study to determine whether the proposed Santa Barbara project was viable. Following an initial assessment, Dr. Brailer and his team at CareScience worked with community leaders to craft an implementation plan that developed a collaborative working structure, a community-wide clinical information sharing technology and a business plan. Based on this initial plan, CHCF provided a $10 million dollar grant to the project over a three-year period. CareScience Inc., a leading provider of healthcare information care management tools was also contracted to manage the project and build the technology.

The first step CareScience took was to set up a certification program for third party vendors in Santa Barbara in order to educate the community about technologies and adherence to well known industry standards. Through this program they were able to weed out vendors that were not meeting standards for interoperability and security for compliant clinical data exchange.

Description of the Group's Work
The Santa Barbara County Care Data Exchange™ is a community-wide initiative designed to improve the quality, clinical efficiency, and safety of health care by making inter- and intra-organizational, patient-specific information more readily available at the point of care. The initiative also hopes to establish a new business model for sharing investments in information systems within a community setting. The Care Data Exchange brings together leading public and private health care organizations throughout Santa Barbara County.

The community project is comprised of 10 healthcare organizations clustered into four Care Data Alliances. Led by an anchor organization, each Care Data Alliance developed its own set of data-sharing goals based on the strategic interests of its members. In order to govern the effort, CareScience formed a central

policymaking body called the Exchange Council that includes senior administrators from each anchor organization. The Council meets regularly to establish consensus on business rules and technology standards for the entire initiative. A Technical Advisory Committee, consisting of technical representatives from each Alliance as well as a Clinical Advisory Committee, consisting of clinical representatives from each Alliance were also formed to help guide technical requirements or data sharing and inform usability and adoption practices for physicians.

Functionality

The technology developed for the Santa Barbara Care Data Exchange offers the following features and functionality:

- *Identity Correlation Service* - correlates multiple patient identities across disparate systems.
- *Information Locator Service* - identifies where clinical data resides on a correlated patient, and accesses requested records for an authorized user.
- *Access Control Service* - supports HIPPA compliance by enabling user-defined security rules, including role-based access and logging of all data access events.
- *Clinician and Consumer Portals* - gives clinician end-users the ability to perform customized patient searches and locate clinical results while using a browser-based user interface. The consumer/patient portal gives views of the same information and is managed by the patient's caregiver.

Data Being Exchanged
- Lab Results
- Radiology Results (Images, Voices, File/Dictation, Reports)
- Pharmacy Results (Medication History)
- Medical Record Transcription
- Administrative data (Eligibility, Referrals, Authorizations)

Organizations Involved

The Santa Barbara County Care Data Exchange is a community-wide project that includes more than 75 percent of leading healthcare providers in Santa Barbara County, California. The following organizations have participated in the Santa Barbara County Care Data Exchange:

- Santa Barbara Regional Health Authority
- Santa Barbara County Public Health Department
- Sansum - Santa Barbara Medical Foundation Clinic
- Cottage Health System
- Catholic Healthcare West, Marian Medical Center

- Midcoast IPA
- Lompoc Valley Community Healthcare Organization
- Santa Barbara Medical Society
- Pueblo Radiology Medical Group
- Unilab
- University of California, Santa Barbara

Organizational and Political Barriers and Solutions
Through the course of the Santa Barbara Care Data Exchange project, CareScience had to identify and come up with solutions for the following political and organizational roadblocks. They suggest that these are the sorts of questions most clinical data exchange efforts will face.

- Physician Adoption Issues
  - Typically, physicians practice at 2-3 facilities
  - Physicians require information from multiple sources to change behavior
  - How can fragmented data be translated into a patient-centric view
  - How does information get to *the point of care when needed*?
    - Office, clinic, lab, hospital, ER, home, etc.
  - How do you ensure accurate, up-to-date information?
  - How is information access controlled and protected?
    - Confidentiality, liability, compliance
- Organizational Issues
  - Which organizations should participate in the project?
    - Health systems
    - Ancillary providers
    - Pharmacies
    - Physicians
    - Public organizations
    - Health plans
  - How should the data sharing organization be structured?
    - Loose confederation
    - Formal legal entity
  - What mechanisms should be used to expand data sharing participation after start-up?
- Financial Issues
  - What are the direct and indirect costs of participation in data sharing (both initial and ongoing costs)?
    - Internal Systems
    - External Integration
  - Who bears the financial burden?
    - Health Systems
    - Physicians
    - Health plans

- - Other (e.g., philanthropies, government)
  - o What type of financial model would encourage maximum participation?
    - Participant model
    - Sponsor model
    - Transaction or metric based?
- Financial and Strategic Issues
  - o What are the economic benefits, and who gets them?
    - Reduced capital expenditures
    - Direct reduction of "result" dissemination
    - Reduced duplication of tests, therapies, admissions
    - Increased productivity (physician, staff)
  - o What are the strategic benefits?
    - Better quality of care, patient safety, population health analysis and management
    - Patient and consumer satisfaction
    - Improved physician relations
    - HIPAA readiness and integration synchronization
- Implementation Issues
  - o What information can and should be made available for data sharing?
  - o How are joint implementation processes adopted and enforced?
  - o How does data sharing affect ongoing internal technology deployment plans?
  - o What is the role of point-of-care vendors in data sharing implementation?
  - o Who will be the data sharing users, and how should they be trained and supported?
- Governance Issues
  - o How many layers of governance are needed to balance participants' need for control with efficient decision-making?
  - o Can participants veto business decisions regarding data sharing?
  - o Who sets priorities?
    - Technical
    - Clinical
    - Financial
    - Strategic
  - o Who creates and enforces data access rules and compliance?
- Physician Relations Issues
  - o How should data sharing be coordinated with other physician-oriented efforts among participants?
  - o What physician needs and desires should be given priority?
  - o How will data sharing influence the adoption by physicians of point-of-care technology?
  - o How can physician attention and support be gained?
  - o How should physician fears be addressed?
    - Physician-patient relationship

- Profiling
- Patient-stealing
- Communications Issues
  - Should the data sharing initiative have an identity separate from the participants?
  - What messages should be aimed at key constituencies?
    - Local opinion leaders
    - Physicians
    - Trading partners
    - Elected community leaders
    - Media
    - Consumers
  - What mechanisms should be used to establish positive support for data sharing?
  - What contingency plans will be needed for handling negative messaging?
- Legal and Regulatory Issues
  - How does HIPAA Privacy Regulations affect data sharing?
    - Business Associate Relationships
    - Regulating Uses and Disclosures of PHI
    - Verification
    - Notice of Privacy Practices - Implementation
    - Access of Individuals to their PHI
    - Amendment of PHI
    - Accounting of Disclosures
  - How does proposed HIPAA Security Regulations affect data sharing?
    - Data integrity, confidentiality and availability
    - Unauthorized access to data transmitted over a network
    - Electronic Signature
- How will the data sharing effort be rolled out given competing priorities (leadership commitment versus other projects)
- CareScience addressed these issues by setting up the governance structure that was described above:
  - Each alliance did its own planning as to what to kind of data to exchange.
  - The Clinical Advisory Committee surveyed physicians on their fears and incorporated solutions into their overall adoption strategy.
  - Heads of each Alliance sat on a countywide Executive Council that worked with the Technical and Clinical Advisory Committees to address synergies.
  - There was some difficulty getting the groups to organize into alliances, but ultimately they did.
- CareScience certified third party technology products that only used secure and open standards for clinical data exchange.

Technical Roadblocks and Solutions
The Use of Data Standards

CareScience dealt with data standards issues by utilizing standards as much as possible and designing custom interfaces when there were no other options. The Care Data Exchange technology takes advantage of whatever standardized data streams are already in place at the participating organizations' sites. CareScience used different third party products, such as Apelon or other clinical terminology servers, to normalize data vocabulary when required. They also actively engaged vendors in discussion of core data exchange issues. Those vendors who followed a process of total customization for their customers and would not invest in widely accepted standards were excluded from the approved list of vendors that the community could use. Finally, CareScience primarily focused on HL7 and HIPAA transaction standards as its benchmark for interoperability.

Controlled Data Access

CareScience adopted distributed network to help assuage community fears about data ownership and confidentiality. The Care Data Exchange allows each participating organization and/or enterprise-wide department to maintain local control over their own data. Results are accessed from multiple systems but the source data remains with the department and/or enterprise organization that stewards it and access to clinical results are released only after authorization is confirmed with a data originator.

In order to preserve the ability for participating organizations to maintain local control over their data, CareScience employed the use of peer-to-peer (P2P) technology to access cross-enterprise patient records. A P2P architecture is a network in which information resides on individual computers and servers but is accessible to all authorized users within a network. Instead of having to place all shared files in a central database housed on a server or a clinical data repository, members of a P2P network access files from each other's individual computers using the Internet or a secure Virtual Private Network (VPN) connection. Information authorized for release is sent in encrypted form directly from the data originator to the data requester. This type of technology gives users local control over their data. Data remains on all of the participating organizations source systems, but is available to network participants via the peer-to-peer file sharing protocol. This way the Care Data Exchange can offer users a highly scalable model with a marginal growth cost for cross-enterprise data sharing. It securely locates clinical results across the enterprise and displays the results in a form to be used by multiple types of healthcare professionals for the purpose of appropriately treating the patient.

Patient Privacy

The Care Data Exchange helps healthcare organizations comply with the HIPAA Federal Patient Privacy regulations by offering a contracting model that defines

data sharing policies for cross-enterprise data sharing arrangements. Users can access the appropriate patient information through the Internet but are restricted based upon certain access privileges. A built-in patient consent tracking feature facilitates patient consent via administrative management and maintains consent logs for audit purposes.

Cost Barriers
The Care Data Exchange leverages historical investments in legacy systems by using public Internet connectivity and P2P technology to access results from heterogeneous systems. This eliminates the need for costly hardware or integration software that synchronizes and replicates data to multiple source systems. Participants need only a Web browser and an Internet connection to access clinical results

The Santa Barbara County Care Data Exchange project will publish results from its findings in the summer, 2003. But, the project leadership has shared preliminary conclusions with Connecting for Health that are highlighted here:
1. The payback of moving from expensive paper-based processes to electronic labor-free, low cost transmissions is more than 2 to 1.
2. Clinical data sharing simplifies workflow in physicians' offices by making information accessible all in one place electronically. Benefits are realizable in the near-term, even without infrastructure such as EMR and CPOE.
3. Lastly, data sharing has direct quality and service benefits that include more appropriate utilization and more timely treatment, as information is made readily available to clinicians.

Project Status
The development of the Care Data Exchange is in its third year. Business rules, data sharing standards, and a technical implementation plan have been developed. A pilot test of the system began in the spring of 2002. The system became fully operational in fall of 2002.

Future Plans
CareScience is now doing a feasibility study in Sonoma County, and is also working with Johns Hopkins and Seattle to see if they can replicate the work they have done in Santa Barbara, CA.

California Information Exchange (CALINX)

Contact and Follow-up Information
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Background
CALINX (California Information Exchange-Linking Partners for Quality Healthcare) began in late 1996 as a broadly based effort among California businesses, physicians, health plans, hospitals and health care systems. All stakeholders agreed to collaborate on standards, cooperate on implementation and compete on quality. The Pacific Business Group on Health (PBGH), National IPA Coalition (NIPAC), and the California Association of Health Plans (CAHP) managed this effort in collaboration with the American Medical Group Association (AMGA), California Healthcare Association (CHA), and California Medical Association (CMA). Project costs from 1997 to 2000 were supported by a grant from the California HealthCare Foundation based in Oakland, CA.

Description of the Group's Work
In an effort to move towards standardized exchange of data between employers and health plans and between health plans and physician groups, CALINX convened work groups to establish detailed data standards and rules for data exchange in certain clinical and administrative areas. To conform to HIPAA and related standardization initiatives in other parts of the country, CALINX data standards were based on ANSI and other well-established national standards. CALINX also managed pilot efforts to demonstrate the cost-effectiveness of exchanging data using those standards in a secure, private way.

Functionality
CALINX (California Information Exchange -- Linking Partners for Quality Healthcare) is a statewide initiative with five principal objectives:
- Improve the completeness and accuracy of health information
- Promote the adoption of data standards and implement electronic data exchange
- Encourage stakeholders to share the information needed to make good health care decisions, monitor patient populations, and support value-based purchasing
- Improve inefficient information systems and provide for the open, secure exchange of information among trading partners
- Protect the privacy and confidentiality of individuals while balancing the need to monitor health care performance and quality.

- To these ends, participating organizations agreed to collaborate on defining data standards compatible with HIPAA and to cooperate on implementing those standards in the California market.

Data Being Exchanged

CALINX agreed on data standards and Rules of Exchange for the following areas:
- Eligibility
- Enrollment
- Member ID card
- Encounters
- Clinical Lab Results
- Pharmacy

Organizations Involved

Partners
- Pacific Business Group on Health (PBGH)
- National IPA Coalition (NIPAC)
- California Association of Health Plans (CAHP)
- American Medical Group Association (AMGA)
- California Medical Association (CMA)
- California Healthcare Association (CHA)

Oversight Group (Executive Leadership)
- Bruce Bodaken, President & CEO, Blue Shield of California
- Peter Lee, JD, Executive Director, Center for Health Care Rights
- Jack Lewin, MD, Executive Vice President and CEO, California Medical Association
- Robert Margolis, MD, California Association of Provider Organizations
- Nancy Oswald, PhD, President, National IPA Coalition
- George Perlstein, MD, American Medical Group Association
- Patricia E. Powers, President & CEO, PBGH
- Bruce Spurlock, MD, Executive Vice President, California Healthcare Association
- Ron Williams, President & CEO, Blue Cross of California
- Walter Zelman, President & CEO, California Association of Health Plans

Demonstration Pilot Participants

For Enrollment (first tier implementation):

Employers-APL, Ltd., CalPERS, PacAdvantage, Safeway, SBC, Southern California Auto Club, University of California

<u>Health Plans</u>-Aetna, Blue Shield, Blue Cross, Health Net, Kaiser, Lifeguard,
Pacificare, United, VSP

For Pharmacy:

Project Site	Health Plan	Physician Group
1	Blue Shield	ProMed
2	Health Net	Monarch
3	PacifiCare	Santa Clara County IPA

For Encounters:

Project Site	Health Plan	Physician Group
1	Blue Cross	Huntington Provider Group
2	Blue Shield	Health Care Partners
3	Health Net	North American Med. Mgmt
4	PacifiCare	Lakeside Health Care

Political and Organizational Roadblocks and Solutions
- Standardization - The major roadblock to moving from a pilot stage to an adoption stage was the lack of market business case for adopting standards if the parties were already using electronic data exchange.   When trading partners are exchanging data using proprietary formats, they are not motivated to invest the resources to make changes.
- Executive Sponsorship – It is important to maintain executive oversight of the project at all trading organizations to ensure a commitment to project deadlines.
- Dedicated Resources – As with most projects, assigning a project lead that is dedicated to the achievement of the project, as well as assigning sufficient IS resources, will improve the likelihood of timely success.
- Scheduling the project – Ensure sufficient resources are assigned to support the project and do not divert them to other organizational priorities until this project is completed.
- Involving business unit leadership – Aligning the needs of the business units with the implementation effort will ensure that the business units are successful in obtaining the data needed. There is an apparent disconnect between those that use the data and those that acquire the data. The business unit leaders need to be aware that it is possible that additional data elements are being submitted, but not stored in their system.

For the enrollment transaction set
Potentially the most successful venture was adoption of enrollment standards by select members of the PBGH purchaser coalition. Inspired employers, with

their purchasing might, persuaded health plans to assist and accept their standardized data feeds. The biggest enabler was electronic standardization by CalPERS, involving most health plans in California early on in the project cycle. A number of employers joined forces after the first tier described above, and the work group continued meeting until early 2002.

For the pharmacy data exchange effort
- The most significant barrier was timing. The implementation of the demonstration projects coincided with the Y2K readiness programs for plans and physician groups. Therefore, the ability to obtain system-programming resources was challenging. This created substantial delays in the project.
- Additional barriers identified by the plans included overcoming concern about use of data, staff turnover and other internal priorities which resulted in a difficulty in assigning dedicated resource support to the project.
- The additional barriers reported by the groups included time and resources, training and not having the required skill level to manipulate the data efficiently, as well as not receiving technical support from their trading partner.
- The recommendations from the participants to overcome these barriers included:
    o Developing a solid contract with each trading partner concerning use of the data
    o Assigning dedicated resources to the project until it is completed, despite changing priorities
    o Obtain an MS Access database shell from an organization that has already created one, or assign a high-level programmer to establish the database.

For the encounter data exchange effort
- Again, timing and the demands of large alternate projects (at the time Y2K, but could have been HIPAA or something else of similar magnitude)
- Additional barriers identified by the plans included priority conflicts with developing X12 compliant programs, coordination of project implementation across multiple internal departments and the use of a vendor which, in this case, negatively impacted the communication process.
- The additional barriers reported by the groups included timing due to a system conversion, working through problems with the vendor (as described above), and the inability to obtain complete and timely encounters from physicians.
- The recommendations from the participants to overcome these barriers included:

- o Assigning a business unit owner as project lead to establish priorities within the organization.
- o Assigning dedicated resources to the project until it is completed, despite changing priorities
- o Meet with vendor and trading partners to develop an implementation plan and review formats and issues unique to each entity.
- Finally, the facilitation offered by 2C Solutions and CALINX has been essential in moving the project forward. The lack of dedicated resources among the project participants requires project leadership and management.

For the lab data exchange effort

Laboratory Motivation -- While the laboratories were interested in the project, they did not have sufficient motivation to justify the priority of this project internally. The laboratories were very much customer driven and had difficulty justifying changes that had not been directly requested by their clients. Therefore, to increase the importance of this project internally, the demands from their physician group clients need to drive this process. CALINX will need to gain the support and interest of the physician groups and have them request the laboratory participation.

Physician Group Level of Interest and Distractions-- The financial solvency issues surrounding most physician groups today are creating pressures on the groups to focus only on the critical tasks. The collection of electronic laboratory data, while recognized as desirous by some, had not been established as an organizational priority.

Project Timing-- One of the most significant barriers, as with the other two CALINX demonstration projects, was the timing of the project. Initiating a project of this nature, which required IS resource support, in the last quarter of 1999 proved impossible. Resources were dedicated to Y2K efforts and unable to commit time to this project. This delay resulted in a loss of momentum to carry forward into 2000. This was further challenged by the continued inability of the laboratories to produce an HL7 file.

Lack of Proven Value--Other clinical transaction data sets (i.e. Pharmacy and Encounter) have been widely exchanged in extremely inefficient methods. Thus, the interest in these transaction sets and the ability to show true cost savings for improving the process was fairly straightforward. Laboratory data, however, is currently exchanged in very limited instances and most physician groups are not thinking about or prepared to accept, store, process or analyze these data.

Therefore, the cost to initiate this process is additive versus a reduction as experienced with the other data sets. In addition, physician groups typically contract with only one laboratory; therefore, the desire to have standardized data sets is minimized. Once a group develops a mapping program to their laboratory record layout, they only need to maintain one program and do not have the challenges of consolidating data from disparate sources. Should a physician group change laboratories, however, the value of standardized formats would increase. Health plans, on the other hand, would have this issue in either case if they were to receive data from all of their groups.

Technical Roadblocks and Solutions

Data results and Open Issues with Pharmacy:

Project Site:	Data Exchanged
Summary	3 completed
Blue Shield ProMed	Data exchanged successfully based on CALINX standard. Blue Shield is providing all but one of the CALINX essential/conditional fields
Health Net Monarch	Data exchanged successfully based CALINX standard. Health Net is providing all CALINX essential/conditional fields.
PacifiCare SCCIPA	Data exchanged successfully based CALINX standard. PacifiCare is providing all but one of the CALINX essential/conditional fields.

Systems Used, Pharmacy-- A variety of systems were used by the health plans to store and retrieve Pharmacy data. Most are proprietary systems, although one plan is running on an external software package. The systems include:
- RX Claims running on an AS400
- Oracle 8 for Data Warehouse and Business Objects and Access for queries
- Proprietary In-house system

All plans ranked their systems capabilities high (a 10 on a Scale of 1 to 10) in terms of ability to meet data exchange requirements. The strengths included the flexibility of the system to store data elements (with the one exception that Rx Claim does not store the PCP name) and the ease of processing data. There were no to limited weaknesses.

The groups commonly use Microsoft Access to store and report on Pharmacy data. One group uses a more robust program – Visual Basic and MS SQL Server with Crystal Reports as a reporting package. The system capability of the groups ranged from 6 to 9 for those using Access and 10 for the group using Visual Basic. A group using Access expressed the need to move data to a server to

improve processing speed. The strengths reported included ease of importing into Access and flexibility in Visual Basic. Weaknesses expressed were a difficulty in handling reversals and resubmissions in Access and the storage requirements for Visual Basic and SQL Server.

Use of Vendors, Pharmacy-- Health plans are not currently using vendors to submit Pharmacy data to groups. In all cases, there are no plans for doing so in the future, although one plan is considering delegating data submission to their Pharmacy Benefit Manager (PBM). The concern among the plans in using a vendor is the inability to control the quality of data.

The groups, while not receiving data via vendors today, would prefer to receive all data from a single source. Therefore, if the plans were willing to establish a standard vehicle for submission of data, the groups would find it easier to administer.

Data results and Open Issues with Encounter Data:

Project Site:	Data Exchanged
Summary	3 of 4 sites completed; 1 partial
Blue Cross HPG	Data exchange is on-going, however, data is being exchanged based on HPG's old format; (HPG is not sending 10 of 39 essential/conditional fields. They are unable to provide the 10 required/ conditional fields that are currently lacking, without "major modifications to HPG's core business system." HPG is submitting the X12 ANSI 837 required by Blue Cross via use of a clearinghouse to translate the file.
Blue Shield HCP	Data is being provided in CALINX format. However, data content is incomplete. HCP is not providing 9 of 39 essential/conditional fields. All programming changes were halted until after Jan 1st due to Y2K. Difficulties still exist in using ProxyMed to submit data to Blue Shield (See Use of Vendors Section)
Health Net NAMM	CALINX standardized data has not been completed between NAMM and Health Net due to the problems ProxyMed's inability to resolve the multiple submitter ID problem described in the Use of Vendor section of this report.
PacifiCare Lakeside	Data exchanged successfully for several months. The CALINX standard is in production; Lakeside is providing all essential/conditional fields.

System Requirements: Encounter Data-- A variety of systems are used by the health plans to store and report on encounter data. Most are proprietary systems running on Oracle databases.

The plans ranked their overall systems capabilities to perform the data exchange between 6 and 10 (on a scale of 1 to 10). The strengths included the flexibility of the system to accept multiple formats and media types as well as the fields captured. The weaknesses for one plan were limited to a requirement for one or more proprietary fields as well as an internal process that results in over a one-month lag time from receipt of data to reporting.

The groups used a variety of systems to store and extract their encounter data. The two groups reporting this information used STAT Managed Care and PODS (this group subsequently converted to HSD's Diamond System. When ranking their overall system capabilities, they ranged from 5 to 9 (with PODS at 5 and STAT and Diamond at 9). The reported strengths included the flexibility of fields captured in STAT and Diamond. Additionally the Diamond system was reported to have ease in extracting data from multiple modules due to its Oracle platform. The weaknesses reported for STAT were the inability to store more than 4 ICD-9 codes (although the groups question the value in this CALINX standard as most providers will not complete more than 4 ICD-9 codes on the HCFA 1500 form). The weakness reported in Diamond is the data extraction tools. The group found Crystal reports effective at pulling data, but not ideal for formatting to a flat file.

Use of Vendors: Encounter Data-- It is common practice for groups to utilize third party clearinghouses for encounter file submissions to plans. In fact, all groups in the demonstration project had previously utilized one or more vendors. Most plans accept this approach, however, PacifiCare is averse to utilizing vendors due to data quality and control issues and Health Net historically has preferred not to use vendors due to cost, however, their philosophy on this issue is changing. On the physician group side, one group preferred submitting direct to the plans because of less than optimal results from prior attempts to utilize a clearinghouse.

For the CALINX implementation, three groups utilized a vendor. Two groups had pre-established relationships and one group newly enrolled for this project. The vendor utilized was ProxyMed. One group was submitting data in the HMOIS format and ProxyMed converts the files to the X12 ANSI 837 format to comply with Blue Cross' requirement. The second group submitted files in the HMOIS format and the final group submitted a file in their proprietary format for ProxyMed to convert to the HMOIS format in order to achieve CALINX compliance.

The use of this vendor proved difficult and increased the complexity and effort for two of the three groups. There were several contributing factors, including:

- Many plans are now attempting to differentiate the encounter submissions from groups with multiple sites. If these sites utilize the same Tax Identification number, ProxyMed is unable to differentiate the submissions. ProxyMed attempted to install an interim fix late in the project, but was unsuccessful in resolving the problem. Additional modifications were on hold until January due to Y2K freezes.
- Coordination and communication between trading partners and ProxyMed was ineffective. When problems arose with the submissions, the groups often were not aware of them until they followed up. The plans were also not aware that submissions were attempted and failed. ProxyMed reportedly posts status reports in the plans and groups mailboxes, however, it doesn't appear that the plans or groups are aware of the availability of these reports, or if they are, they do not systematically follow-up.

Even with the above problems, two of the three health plans and three of the four groups intend to use vendors to implement the CALINX standard across all trading partners. The recommendations to consider when utilizing a vendor include:

- Ensure that the vendor is contractually obligated to remain current with all HIPAA and CALINX standards, at their cost.
- Meet with the vendor as well as each trading partner to establish expectations, determine specific requirements for sending/receiving files, and establish appropriate communication channels.

Data Results and Open Issues with Lab Data

HL7 Format Complexity -- The HL7 file format is designed for a significantly broader clinical use than just laboratory results data. As such, it is a complex series of file segments attached to a header record, including repeatable fields and segments. The requirements for laboratory data involve only a very small subset of HL7 segments and files. While apparently this file format is in wide use at hospitals for multiple clinical transaction sets, its use for the minimal laboratory data set included in the CALINX standard may be an unnecessary burden to place on organizations that are currently unfamiliar with the HL7 file structure. A flat file, similar to that used for the Pharmacy data may be more readily adopted.

The ability of the laboratories to provide test result data in an HL7 format, at the time of the demonstrations, varied as follows:

- Quest Laboratory was already utilizing the HL7 format at some level within their organization
- Unilab at the initiation of the project did not believe they utilized the HL7 format, however, later discovered that it had been used within one department. Therefore, they believed that their ability to map to the CALINX standard would be simplified.
- LabCorp had no prior experience with the HL7 file.
- None of the laboratories were utilizing the Logical Observation Identifiers, Names & Codes (LOINC) coding system for coding results data. The laboratories were utilizing their own proprietary codes. The laboratories, therefore, were required to develop a mapping program from their codes to the LOINC codes. The laboratories expected to satisfy all field deemed required or conditional in the HL7 record with the following exception:

Field Specific Recommended Changes
- The Financial Transaction (FT1) Segment of the HL7 record was deemed unnecessary to include in the laboratory data submission. Very few fields in this Segment are required by CALINX. Those that are required are obtainable in other records, as follows:
  - Transaction Date: included in the MSH Segment, field # 7 Date/Time of Message
  - Transaction Type: not needed by CALINX, but required in HL7
  - Transaction code: included in OBR4; not needed by CALINX but required in HL7
  - Insurance Plan ID: this is the health plan name and number and is not stored by the laboratories. The physician groups were to populate this field from their eligibility files
  - Diagnosis Code: conditional field; not available from the laboratories at a test result level. The primary purpose for inclusion of this segment initially was to capture the diagnosis code and the health plan ID. The diagnosis code is generally not available from the laboratories and the health plan ID is never available.
  - LOINC Codes – The laboratories were struggling with the requirement to convert all laboratory results codes to the LOINC standard. Therefore, it was agreed by the participants that the laboratories would only need to convert the HEDIS-related test result codes.

Physician Groups-- None of the physician groups had experience working with the HL7 file format, nor were they currently obtaining laboratory results data. All groups would need to develop a data mapping and translation program for the HL7 file as well as an internal database for storing the data. The intent was to utilize an Access database initially. In addition, the groups would need to develop

a query program to filter the HEDIS-related test results as well as an HL7 file format for submission to the health plans. As a result, the level of effort for this project was expected to be the most significant for the groups.

Health Plans -- None of the health plans had prior experience working with the HL7 file format; however, Blue Shield had received laboratory results data directly from Unilab in the past. This data was sent in the ASTM91 format using the laboratories proprietary result codes. All plans would need to develop a data mapping and translation program for the HL7 file.

Detailed approaches can be viewed in CALINX' demonstration report and lab addendum, available at www.pbgh.org.

Project Summary
CALINX performed pilot projects for encounter and pharmacy data. Lab data were also demonstrated but delays occurred in development of standards and difficulty in recruiting workgroup participants from lab and physician groups. Enrollment standards were tested and implemented among many health plan/employer trading partnerships within PBGH.

While the demonstration projects were successful, by the end of the project in 2000 there were only four health plans and four physician groups using the CALINX Encounter standard and three health plans and three physician groups using the CALINX Pharmacy standard. The success of these standards relies on the adoption across the industry. The challenge is to move a significant number of additional plans and physician groups towards adoption of the CALINX standard. Once a critical mass has been established, other organizations will follow.

The project was burdened with timing issues. First, Y2K was resource intensive at a time when stakeholders were being asked to devote IS resources to CALINX. Then, implementation of HIPAA standardized transaction sets and privacy and security standards became all-encompassing for stakeholders. Many plans and providers recognized the reality of regulatory intervention and de-prioritized CALINX efforts.

Future Plans
Timely, comprehensive data exchange is a basic requirement of performance measurement and efficient administration. The need exists now, more than ever, for plans and providers to exchange timely, usable, comprehensive data. Importantly, the business case is reinforced by the influx of Rewarding Results programs. Additionally, technical advances since 1996 facilitate electronic data exchange. Industry leaders are starting to take the necessary steps to exert the will and collaboration required for successful data exchange.

The Foundation for Health Care Quality and The Community Health Information Technology Alliance (CHITA)

Contact and Follow-up Information
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Background
In 1998, The Foundation For Health Care Quality in Washington State undertook a 'Three State Health Information Planning Project', in collaboration with the Massachusetts Health Data Consortium and the Minnesota Health Data Institute. They engaged in an effort to evaluate the use of Internet technology to enhance and expand health care information infrastructure at community, state and, ultimately, national levels. The Three-State Health Information Planning Project was funded by the Robert Wood Johnson Foundation (Princeton, NJ) and the John A. Hartford Foundation (NY, NY). The initial planning phase of the project ended in August 1998. This three state effort was then expanded to become the five state HealthKey collaboration, also funded by the Robert Wood Johnson Foundation. HealthKey was developed to create a replicable model for Public Key Infrastructure (PKI) and other secure infrastructure models for the health care industry.   The HealthKey effort is run by CHITA, which operates under the Foundation, and was started in 1997.

The Foundation, which focuses more broadly on improving the quality of health care, is otherwise funded by other grants and membership.

Description of the Group's Work
In addition to CHITA's role in HealthKey, the organization facilitates troubleshooting and assistance around HIPAA standards for data exchange, privacy and security, and hosts a number of workgroups around standards for administrative and claims data.

As part of HealthKey, CHITA worked on an initiative with the Washington State Department of Health (WA-DOH), local health agencies, and clinical laboratories to improve the speed and reliability of secure electronic communications containing important public health information. This project is called the *Electronic Laboratory Based Reporting System* (ELBRS).

Functionality
The Washington State Department of Health began to work with a local reference laboratory to securely encrypt disease information and send it electronically. With this process in place, WA-DOH was positioned to become a central point in the communications process, simplifying and streamlining the process. Reference laboratories would send information to WADOH and WA-DOH would communicate the information to the appropriate county health jurisdictions and CDC. The challenge facing WA-DOH was finding a way to protect the information so that only the appropriate health department would receive it. Furthermore, WA-DOH wanted to implement a solution that could be adopted as a standard by other public sector agencies and private sector laboratories. The process also needed to be consistent with national trends, especially guidelines on secure information exchange that were being developed by the CDC. Digital certificates and Virtual Private Network (VPN) technology offered an answer. In an effort to test and implement a broadly acceptable solution, the Electronic Laboratory Based Reporting System (ELBRS) project was initiated.

Data Being Exchanged
The ELBRS is used to electronically send laboratory test results, which include identifiable patient data, from private sector clinical laboratories to the state health agency. The laboratory data is then electronically distributed from the state health agency to the local health agency in the county where the patient resides. Laboratories are required under state regulations to submit this data to public health agencies so that public health can investigate the case and prevent further disease spread.

Organizations Involved
Involved in the HealthKey project are the Massachusetts Health Data Consortium (information included elsewhere in this packet), the Minnesota Health Data Institute (information included elsewhere in this packet), North Carolina Healthcare Information and Communications Alliance (information included elsewhere in this packet), and the Utah Health Information Network (currently exchanging non-clinical data).

The ELBRS component of the Washington HealthKey project involved the state Department of Health, local health agencies across the state, and two private laboratories as well as CHITA.

Organizational and Political Roadblocks and Solutions
This project was underway in WA-DOH prior to the involvement of HealthKey, and the primary organizational and political issues had already been resolved. In particular, the transition from paper-based to electronic reporting involved changes in the state's notifiable condition regulations. The changes were

necessary both to permit electronic reporting and to permit that reporting to occur through the state health agency rather than directly from laboratories to local health agencies. Local health agencies agreed to this change provided that the electronic reporting system did not in any way interfere with their ability to rapidly receive test results and initiate case investigations.

As noted below, WA-DOH became involved with HealthKey to seek better security solutions for the electronic data exchange process. CHITA and HealthKey were not only able to help with these technical issues, but were also able to assure WA-DOH that the security solutions were consistent with those being implemented by the rest of the health care industry and the rest of state government. CHITA helped accomplish this by bringing private sector health information security experts and the state's Department of Information Services to the table with WA-DOH. Together, these organizations worked to develop common, realistic security solutions. The Washington Department of Information Services went on to adopt the common model as the basis of Transact Washington, the state's primary security portal for internet-based access to state information systems.

Technical Roadblocks and Solutions
In CHITA's effort with the Washington State Department of Health, the biggest challenge was finding a way to protect the information so that only the appropriate health department would receive it. WA-DOH wanted to implement a solution that could be adopted as a standard by other public sector agencies and private sector laboratories. The process also needed to be consistent with national trends, especially guidelines on secure information exchange that were being developed by the CDC.
CHITA and WA-DOH evaluated digital certificates and Virtual Private Network (VPN) technology as solutions to the security dilemma. To assure secure communications, WA-DOH needed to do the following:
1. Find a Certificate Authority that would issue digital certificates in a manner that would be acceptable to WA-DOH, local health jurisdictions and other healthcare organizations
2. Develop and implement a disease reporting application and a retrieval process that would allow health jurisdictions to retrieve information in a secure and timely manner.
3. Develop and implement a process for deploying digital certificates to local health jurisdictions and training staff in their use.

WA-DOH was very interested in moving towards a solution that would be consistent with the security approach that other healthcare organizations were likely to take. WA-DOH participated in a Washington State Government initiative to select a Certificate Authority that would be licensed by the State to issue standard digital certificates to employees and customers of government

agencies. All agencies would accept these certificates. Digital Signature Trust (DST) was the selected Certificate Authority. CHITA facilitated discussions between representatives of WA-DOH, Washington State Department of Information Services, DST, local health jurisdictions and other organizations within the Washington State healthcare community to agree upon a policy for how individuals would be registered for digital certificates and how these certificates would be issued. DST adopted this policy.

WA-DOH collaborated with the Washington State Department of Information Services to take advantage of its VPN connections with local health jurisdictions and to develop a secure application for validating digital certificates and connecting the health department to the WA-DOH disease reporting application.

WA-DOH developed a very structured process that local health jurisdictions can follow to get digital certificates and learn how to use them.

Project Status
In the WA-DOH / CHITA effort: The group has completed development and testing of the different components of its solution. It is now in the process of implementing ELBRS with a small number of clinical laboratories and with local health agencies across the state. So far this initiative has shown some positive results. Early test results have shown that this method significantly reduces the time it takes for disease reports to reach the appropriate health agency. Disease reports are also more accurate and complete, so that public health officials spend less time making phone calls for further information. A comprehensive Public Key Infrastructure has been tested, though with a very narrow range of organizations. Through the process, WA-DOH and other participants in the healthcare community have gained a solid understanding of the issues that need to be addressed by any single organization and by the healthcare community at large. Digital Signature Trust has implemented a registration and issuance policy that takes into consideration healthcare specific needs. The healthcare community has a better understanding of certificate policy issues.

Future Plans
The same methodology that was developed for ELBRS is now being tested for other types of data and other reporters, such as collecting birth defects data from hospitals. Washington is also expanding the number of laboratories that are submitting data electronically. To further aid local health agencies, WA-DOH is developing a case investigation application that will directly import laboratory data from ELBRS, so that local health officials will be able to immediately access this critical data and incorporate it into their disease investigations.

EndNotes

Of Note:

- Though researched, UHIN and NEHEN were not included because investigation indicated that they are currently focused on sharing administrative rather than clinical data.

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