Final Contract Report

State and Regional Demonstration in Health Information Technology: Utah

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HEALTH IT

Final Contract Report

State and Regional Demonstration in Health Information Technology: Utah

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Preface

This project was one of six State and Regional Demonstrations in Health Information Technology (IT) contracts funded by the AHRQ Health IT Portfolio. The goals of the projects were to identify and support data sharing and interoperability activities aimed at improving health care for patients and populations on a discrete State or regional level. These States and their respective health information organizations (HIOs) are as follows:

- Colorado: Colorado Regional Health Information Organization (CORHIO)
- Delaware: Delaware Health Information Network (DHIN)
- Indiana: Indiana Network for Patient Care (INPC)
- Rhode Island: current*care*
- Tennessee: Mid-South e-Health Alliance (MSeHA)
- Utah: Utah Health Information Network (UHIN)

For more information about these projects, including a cross-project summary of lessons learned, please visit http://healthit.ahrq.gov/stateandregionalhie.

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Executive Summary

Background and Purpose

This report summarizes the progress and evolution of this project. It also describes the methods used to achieve the project goals and objectives, provides key deliverables, and summarizes our results, findings, and lessons learned to date.

Results

As of August 31, 2011, 13 facilities (11 hospitals, one large clinic group, and one independent laboratory) have sent more than 8 million clinical messages to the edge servers. Although the use of the Clinical Health Information Exchange (cHIE) by other end users to retrieve that information has not reached the stage where its effects on patient safety and quality of care can be measured, interviews with clinics and hospitals show that, in spite of the delays in its implementation, enthusiasm and expectations for the cHIE remain high.

Recommendations for Future Research

With respect to evaluation and research, a great deal has been learned in the course of this project. The evaluation plan has changed dramatically as the result of delays and changes in the implementation, and the most important lesson learned is that any plan for evaluating a developing health information exchange (HIE) must be flexible and adaptable. It should be an expectation that the evaluation plan will change and evolve over time. Part of that flexibility should include adapting the evaluation to take into account, as far as possible, the needs and interests of the many and various entities with a stake in HIE.

With respect to research, given the complexity of HIE, the fact that it is occurring in the real world, where the landscape is constantly changing and shifting, it would be unreasonable and misguided to expect that the benefits of HIE could be rigorously and definitively proven using the most stringent methods of research. It is not hypothesis testing in the strict sense, nor can it be. We lack the control needed to test such 'hypotheses' and in attempting to force the evaluation into the constraints imposed by rigorous hypothesis testing and the need for definitive proof, we would focus our attention and energy on the wrong areas.

This is not to say that it is not possible to evaluate the effects of HIE on health care. Evaluation should be a central part of any HIE implementation. But the evaluation should be practical and realistic in its ambitions and scope. Ongoing formative evaluation should be used to guide, inform and track the development and implementation of HIE. Formative evaluations and qualitative analyses, including program evaluation methods, should be a major part of the evaluation. Qualitative data can be a rich and valuable source of information that can be used to guide and monitor the project as it develops. Evaluation of outcomes should not wait until HIE is fully mature and functioning and widely used, but rather should measure outcomes, on an ongoing basis, to the extent possible with the data that is available, while recognizing and acknowledging the potential limitations of such an approach.

Background and Purpose

This report summarizes and documents the progress and evolution of this project and describes the methods used to achieve the project goals and objectives, provides key deliverables, and summarizes our findings and lessons learned.

Background on the Project and Local Environment

Local Environment

The State of Utah has a long history of health information technology (IT) initiatives, and from the start of this project in 2004, the health IT environment has continued to evolve. In 2004, HealthInsight conducted a survey of the State's approximately 350 clinics providing primary care, to assess their current state of health IT adoption and future plans regarding health IT. The results of that survey showed that of Utah's approximately 350 primary care practices about 30 percent were using electronic health record (EHR) systems. [1] Since that time there have been multiple initiatives in the State to assist outpatient practices in adopting and effectively using EHR systems, resulting in EHR adoption rates much higher than the national average. The most recent environmental scan in June 2009 found that approximately 61 percent of all primary care practices had EHR systems. This is more than twice the national rate. In addition, it was estimated that 22 percent of specialty practices were using EHRs.

Among the initiatives between 2004 and 2011 promoting EHR adoption and effective use are—

- Doctors Office Quality – Information Technology (DOQ-IT) demonstration project (2004 –2008).
- Medicare Care Management Performance (MCMP) pay for performance demonstration project (2007–2011). The DOQ-IT and MCMP projects were managed by HealthInsight and focused exclusively on primary care clinics. Approximately 125 clinics worked with HealthInsight in these two initiatives.
- Utah Medical Association (UMA) and Utah Department of Health (UDOH) funding to HealthInsight to provide DOQ-IT like support for specialty clinics (2006–2009). As a result of the UMA and UDOH funding approximately 80 specialty clinics received assistance in selecting and adopting EHRs.

In 2010, HealthInsight was designated as the health IT Regional Extension Center (REC) for Utah and Nevada. In the course of this work, HealthInsight is assisting and supporting Utah's health care providers in achieving financial incentives for attaining Meaningful Use with their EHR systems. The Meaningful Use criteria include the exchange of clinical information via HIE. In Utah approximately 200 primary care clinics are working with the

[1] Utah Statewide Clinical Health Information Strategic Plan. Available at http://health.utah.gov/phi/ehealth/UT_HIE_StrategicPlans_March2010.pdf

REC to achieve Meaningful Use. Approximately 90 percent of these clinics already have an EHR; approximately 10 percent will be adopting an EHR.

Beacon Project. In 2010, Utah was named one of 17 Beacon Communities by the Office of the National Coordinator for Health Information Technology. This effort will engage the health care community in the Salt Lake area to demonstrate that health IT can be used to improve the quality and efficiency and reduce the cost of health care. A portion of the Beacon funds have been set aside to reimburse clinics for the costs associated with interfacing their EHRs with the cHIE.

Formation of the Project

The Utah Health Information Network (UHIN) has been in existence since 1993. UHIN has served two primary purposes: The convener for the community in creating standardized administrative (X122 billing)[2] transactions; and a hub connection (UHINet) that clinicians and payers in the State and across the country can use to exchange administrative transactions. The mission of UHIN is to decrease the administrative cost of health care.

By 2005, the governance and sustainability model for administrative transactions was quite mature. UHIN is governed by its members and as a result the associated costs in supporting the UHIN infrastructure are kept at a reasonable rate for its members. Administrative transactions which are standardized by UHIN (the community) become part of State mandated rule.[3]

The majority (90 percent +) of the providers in the State are already connected directly or indirectly to UHIN in exchanging administrative transactions.

The community desired to exchange clinical data in a similar manner to the exchange of administrative data via UHIN systems. This includes standardizing clinical exchange transactions to streamline interoperability.

By 2003, UHIN had existed for over 10 years as a successful community enterprise to exchange administrative data. The consensus was that exchanging clinical data would require some modification of UHIN's infrastructure, business and security practices. Accordingly, the UHIN infrastructure and business structure would be updated to address these requirements.

In 2004, UHIN applied for and received a State and Regional Demonstration in Health Information Technology contract, which led to the formation of the project to Improve Communication Between Health Care Providers via a Statewide Infrastructure. This project has played a significant role to update the UHIN system infrastructure to be able to exchange clinical data.

Project Goals and Objectives

The goal for this project was to improve the quality and reduce the cost of health care by improving communication (clinical data and messages) between individual health care providers. We plan to expand and enhance our successful model of serving as a statewide,

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[2] http://www.x12.org/x12org/about/faqs.cfm

3 http://www.rules.utah.gov/publicat/code/r380/r380-070.htm

self-sustaining, not-for-profit transmittal hub by appropriately communicating clinical data in the form of simple[4] and intelligent[5] messages.

There were several specific aims that we planned accomplish in order to achieve this goal:

- Adapt UHIN infrastructure to exchange clinical data
- Encourage adoption of EHRs and leverage other efforts
- Develop a sustainability model, going forward
- Exchange clinical information electronically:
  - Phase 1 - Develop simple messaging capability
  - Phase 2 – Develop intelligent messaging capability
- Evaluate the impact
  - Conduct analyses of the role of the Medicaid program
  - UHINt[6] Adoption Evaluation – This evaluation captured the sender/receiver user experience in using UHINt, which is application software used for administrative exchange that was enhanced for clinical exchange. This also captures the UHIN staff perspective of the UHINt adoption experience.
  - Clinical Health Information Exchange (cHIE) Evaluation – To provide more HIE functionality, UHIN moved to a commercial off-the-shelf clinical exchange platform. This new platform replaced the UHINt functionality. The cHIE evaluation is an evaluation regarding early implementers of the cHIE. This will include baseline and post analysis.
  - Final Impact Report – A summary of the Utah Statewide Regional Demonstration (SRD) final impact analysis.

Governance

UHIN governance structure before clinical exchange. In 2005, UHIN was a not-for-profit entity. UHIN would convene public and private entities together in the development of administrative standards, which become a part of State rule. The UHIN Board was primarily payer based with some large physician groups/organizations also represented.

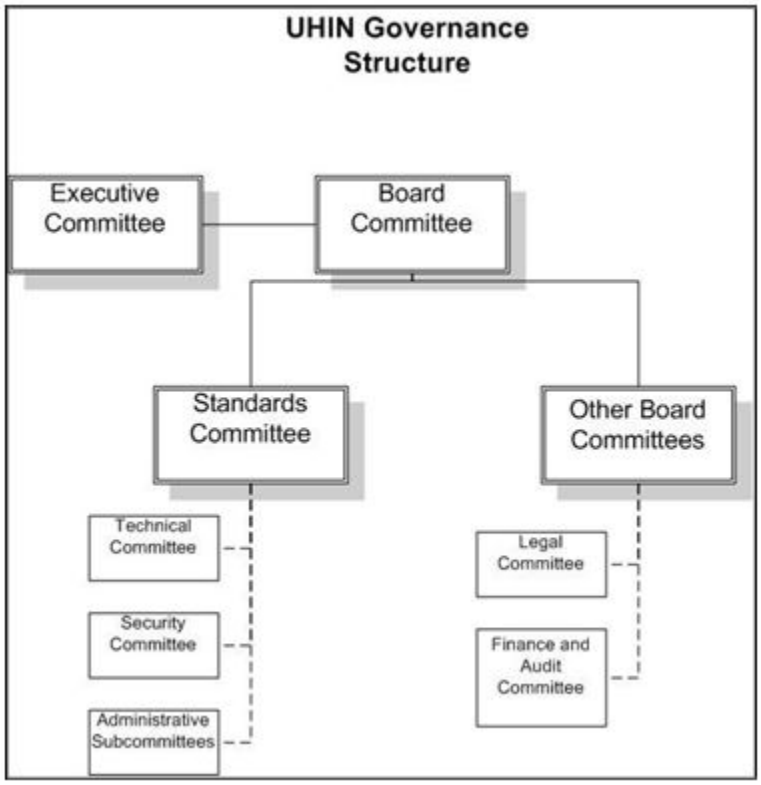
UHIN committees, subcommittees, and workgroups work on a consensus model.

- Board and Executive Committee – Approve standardized administrative transactions and UHIN policies. Responsible for the strategic direction of UHIN. Board seats were initially purchased with a single individual representing an organization.
- Standards Committee – Subcommittees create standardized administrative transactions and policy regarding UHIN systems and systems connecting to UHIN systems (e.g., Security, minimum hardware requirements).

[4] Simple messages - Are those messages with a known destination (e.g., provider-to-provider messages)
[5] Intelligent messages – Report delivery of messages and query clinical data of a patient.
[6] UHINt – UHIN updated baseline application tool to exchange simple messages (administrative and clinical).

- Other Board Committees – Legal Committee creates and updates the Electronic Commerce Agreement. Finance and Audit approves pricing and budget and reviews the UHIN financial audits.

Figure 1. UHIN governance structure 2005 (prior to the AHRQ contract)



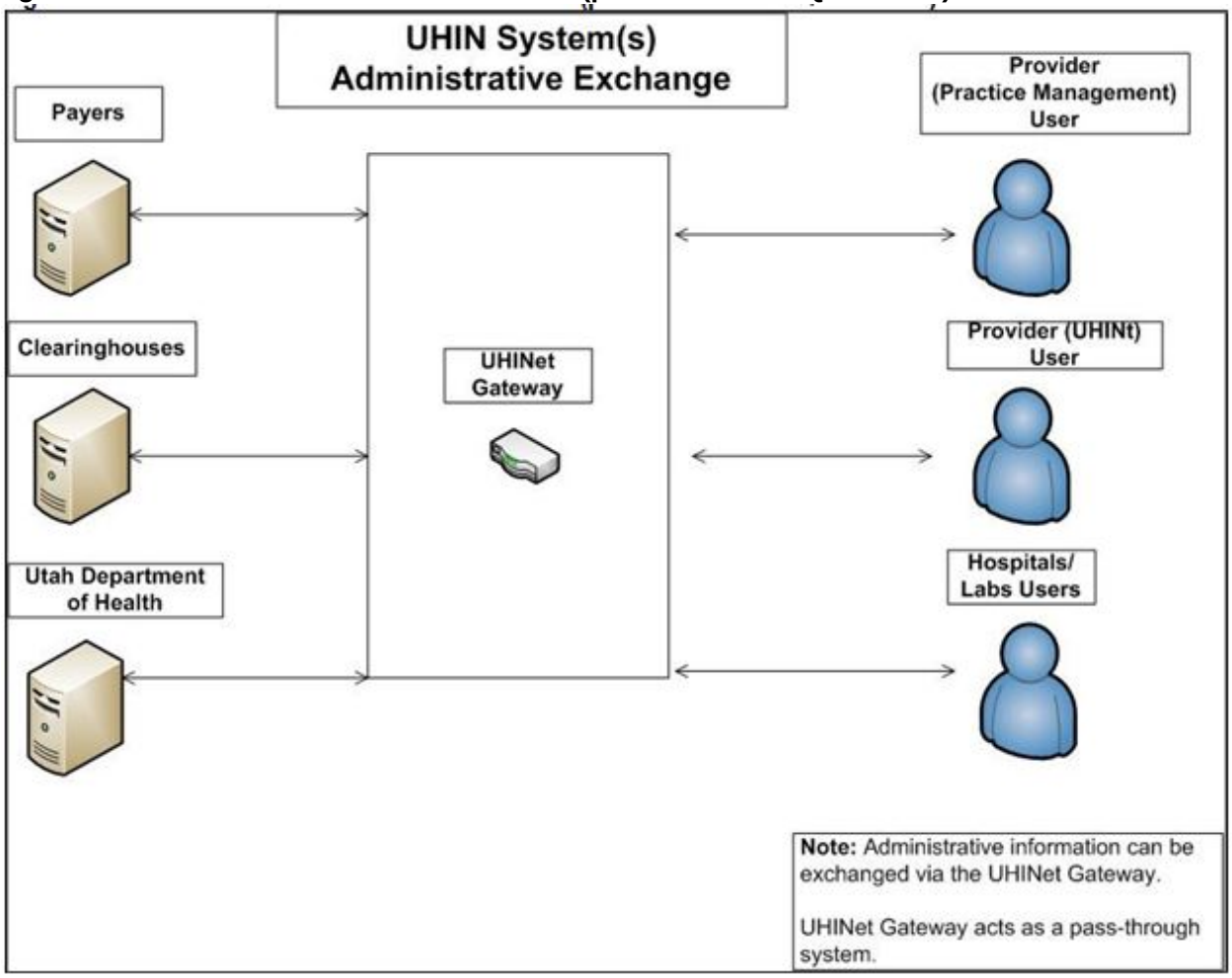
Finance

Sustainability Plan. Prior to the AHRQ contract, UHIN was created with initial investment by Board members and a small grant by the State. Ongoing operations were fully funded based on services provided and paid for by members. The overall costs and expenses to run the UHIN administrative exchange in 2004 was just under $2 million annually. Approximately 49 percent of costs were for supporting services.

Technical Infrastructure

UHIN infrastructure before Clinical Exchange. The UHIN gateway (UHINet) allowed for the exchange of administrative (billing) information between entities. The gateway acts as an electronic post-office whose primary function was authentication of the system user and routing administrative information (X127 formatted data) between entities. A baseline application (UHINt) tool is used by some providers to exchange administrative information.

Figure 2. UHIN Technical Infrastructure 2005 (prior to the AHRQ contract)



[7] http://www.x12.org/x12org/about/faqs.cfm#b1

Business and Technical Operations

UHIN Organization Structure 2004 (prior to the AHRQ contract)

Executives (2)
- Director
- Assistant Director

Standards Team (1)
- Standards Manager

Project Team/Quality Assurance (2)
- Project Manager
- Quality Assurance Analyst

Member Relations (Customer Service) (2)
- Marketing Manager
- Education Coordinator

Operations/Accounting (1)
- Office Manager

Total Staff: 8

UHIN's technical operations are outsourced to a couple of different organizations. The data centers are hosted at two different locations in Utah.

Legal/Policy

In 2005, UHIN and it members used a single business agreement called an Electronic Commerce Agreement (ECA). This agreement was created by the community several years ago for administrative exchange. By signing the UHIN ECA, members could exchange administrative data with any of the entities connected to UHIN. A member did not have to sign a separate business agreement with each of the entities connected to UHIN to exchange administrative data. A few minor changes were made to implement the clinical exchange. The majority of policies created by the community involve the Standards and Specifications.

In the UHIN context, UHIN Standards are implementation guides which become a part of Utah State rule. UHIN Specifications are implementation guides and policies that UHIN members agree to abide by which do not become a part of State rule.

UHIN convenes community member stakeholders who representing various organizations to create/update UHIN Standards and Specifications. These Standards and Specifications are created by UHIN committees and go through a formal approval process, which includes the following:

- Specific committee approval
- Standards approval
- Executive approval
- Board approval

State approval (for Standards)**.** UHIN community stakeholders created policies (e.g., security, hardware, and network requirements) that UHIN and its members agreed to abide by.

Results

Governance

With the addition of clinical exchange UHIN's purpose remains the same as it was originally. However, the clinical component provides additional complexities. Clinical information exchange is at a stage now where administrative exchange was when UHIN first started. Similar to administrative transactions, clinical messages are standardized by UHIN (community) and become part of Standards for Electronic Exchange of Clinical Health Information State rule.[8]

With the addition of clinical exchange, UHIN has needed to make changes/additions to the governance model and UHIN agreements.

Identifying Partners and Other Stakeholders

As the clinical exchange has evolved over the contract period, UHIN found that many organizations have distinctly different individuals who represent the clinical side versus the administrative side of the organization. Because of this dynamic, the creation of new committees and educating individuals to participate in a consensus model has taken some time to bring up to speed. Stakeholders (e.g., hospitals, clinicians) who have not played as large of a role previously in UHIN governance are now taking a larger role in the governance model.

Clinical councils have begun in specific geographic locations, with the meetings being held in that geographic location. This has brought a new "local" perspective to the entities involved and provides them with an opportunity to coordinate the cHIE participation and status in their area.

UHIN is now the State-designated Health Information Exchange (HIE) and is officially a 501(c) 3 nonprofit organization. UHIN continues to convene public and private entities together in the development of administrative and clinical standards (implementation guides). The UHIN Board continues to make strategic decisions on what services UHIN should provide to its members. The Board has grown larger and now incorporates more clinical individuals and organizations.

Formation and Usefulness of the Technical Advisory Panel

Initially, the Technical Advisory Panel was called the Clinical Exchange Committee (CEC). This committee consisted of individuals representing hospitals, laboratories, payers, Utah Department of Health, consumers, and clinicians. This committee met monthly and was very instrumental in identifying possible clinical messages to exchange for simple messaging capability (phase 1). This committee was initially charged with developing a plan to address the following goals:

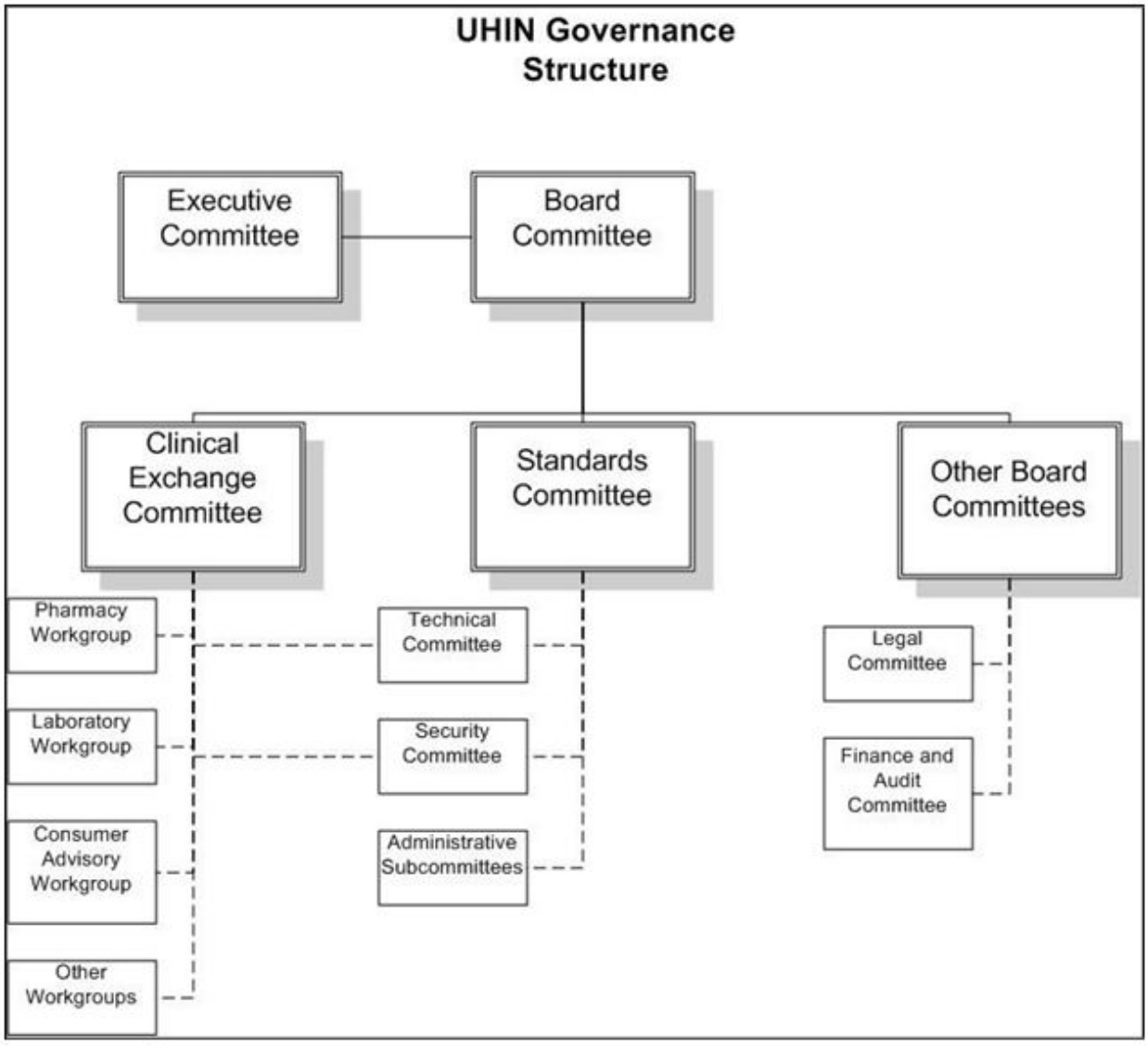
[8] http://www.rules.utah.gov/publicat/code/r380/r380-070.htm

- Improve quality of care; improve patient safety
- Bring economic value to the community – be self-sustaining
- Deal with access questions.
- Make the system accessible to all providers.
- Use open standards to create a nonproprietary system.
- Identify the patient.
- Operate a peer-to-peer system.

It was determined that for phase 1 simple messaging may help identify possible value propositions for community members.

The governance structure for administrative and clinical was kept separate where possible (e.g., Clinical Exchange Committee and Standards Committee).

Figure 3. UHIN governance structure 2005 to 2007

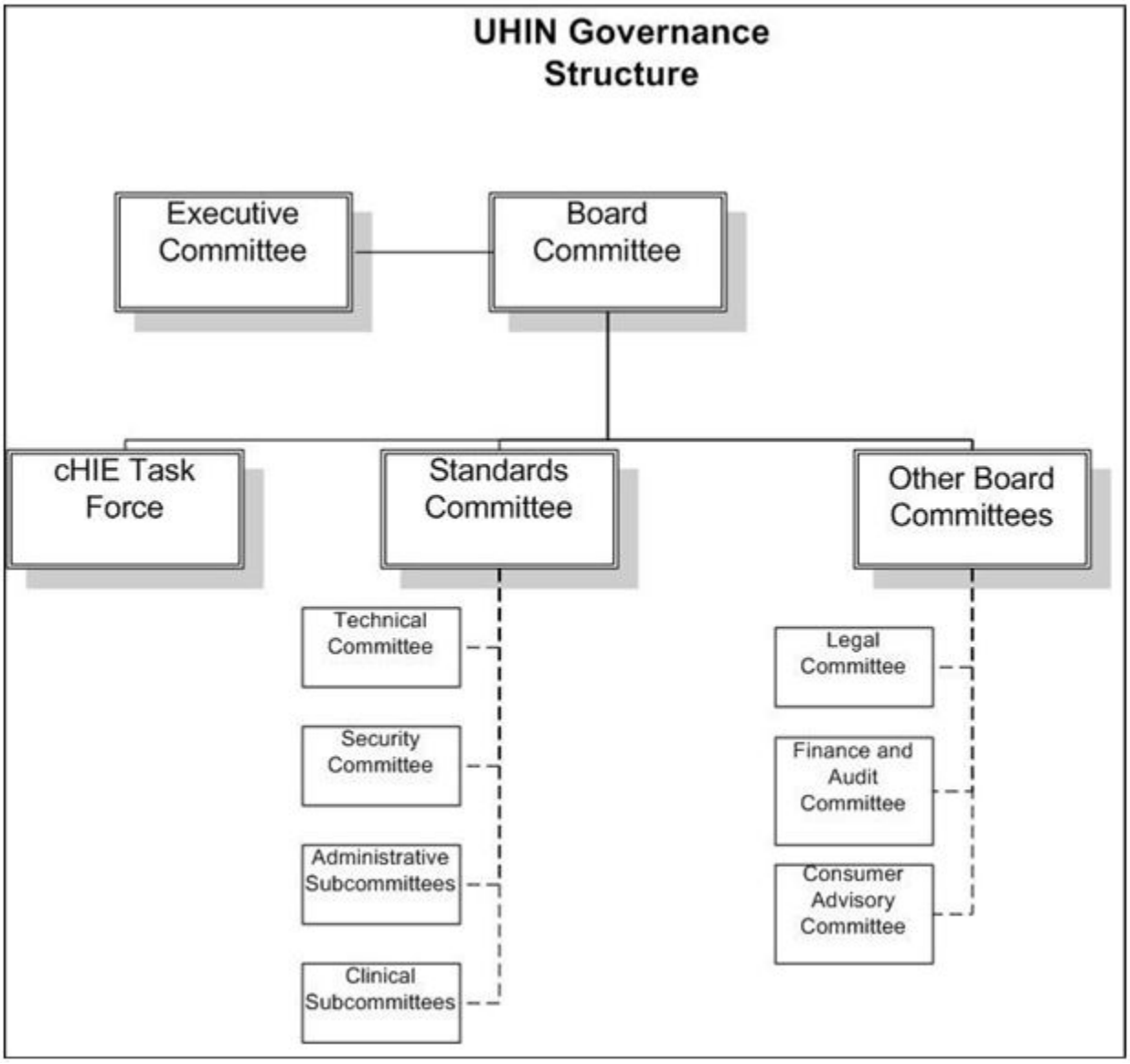


Then, the governance structure for administrative and clinical was combined under a single Standards Committee. A special board appointed cHIE Task Force was created to assist in getting the cHIE (develop intelligent messaging capability) off the ground and in selecting a new clinical exchange platform.

Other governance changes are as follows:

- Board and Executive Committee – Approve standardized administrative and clinical transactions/messages and UHIN policies. Continue to be responsible for the strategic direction of UHIN.
- Standards Committee – Subcommittees create standardized administrative and clinical transactions/messages and policy regarding UHIN systems and systems connecting to UHIN systems (e.g., security, minimum hardware requirements).
- cHIE Task Force – Created by the UHIN Board, helped create the Request for Proposal (RFP) for the new clinical exchange platform, select the vendor and identify message types for exchange.
- Other Board Committees – The Healthcare Consumer Advisory Committee provided a focus group which provided input from individuals/organization perspective in having their information shared on the cHIE.

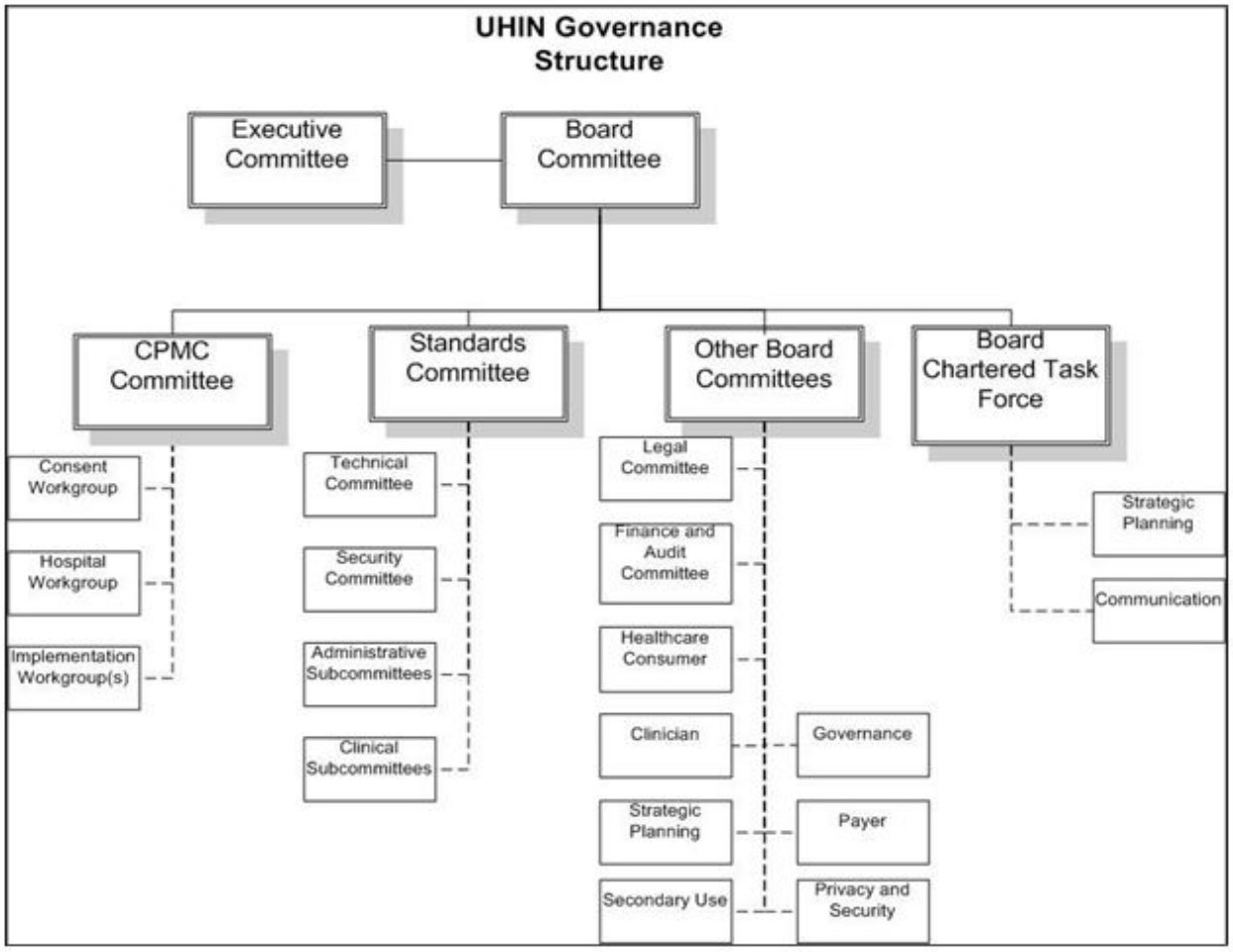
Figure 4. UHIN governance structure 2007 to 2009



Other governance changes are as follows:

- The Community Program Management Committee (CPMC) has played a key role in the planning, operations and developing procedures of the cHIE. The cHIE Task Force was incorporated into CPMC.
- Other Board Committees –The Clinician and Healthcare Consumer Committees have been added and provide input on policies and services.
- Board Chartered Task Force – Focus groups have been added which have a specific function and goals.

Figure 5. Current UHIN governance structure (major components adopted in 2010)



Lessons Learned About Governance

- Importance of including independent clinicians on the Board to provide a voice in the direction of the cHIE.
- Ensure that a business case for each new function is developed and vetted to ensure community buy-in.
- Transparency is critical when discussing complex issues (e.g., patient consent to have their health information accessible in the cHIE).
- Importance of developing oral and written consistent message/updates to the Board and various community committees.
- Involving all stakeholders to provide input and direction regarding secondary use of the information on the HIE.

Conclusions

The consensus model is successful due to the culture in Utah. However, it may take time for entities to speak their mind (e.g., consent) about their real concerns and what will adequately address their immediate concerns and needs.

As hesitation is observed with entity representatives, it is important to investigate their real concerns so issues can be identified sooner. If concerns are not identified early on, implementation may be delayed.

Finance

Administrative and Clinical costs are both included in the information contained in Table 1. HIE costs. Definitions of Table 1 column headers:

- **Initial HIE -** These costs include one-time hardware purchases and software development of the system as it relates to third party contracts. This includes the gateway and baseline tool. In 2005 and 2006 the gateway was enhanced for clinical data. 2006 was the beginning of the baseline tool development, which includes 2007 and part of 2008. At the end of 2009, the software for the clinical health information exchange was purchased.
- **Ongoing HIE -** These costs include ongoing maintenance and support of the system as it relates to third party contracts. This includes the gateway and baseline tool.
- **Administrative -** These costs include all administrative expenses (office supplies and equipment, rent, employee benefits, travel).
- **Salaries -** These costs consist of employee salaries only.
- **FTE -** Number of full time employees.

Table 1. HIE costs (2004 to 2011)

Yearly Summary by Category						
Year	**Initial HIE**	**Ongoing HIE**	**Administrative**	**Salaries**	**Total**	**FTE**
2004 Sept.- Dec.	$47,390.12	$138,464.61	$101,196.44	$192,746.58	$479,797.75	10*
	10%	29%	21%	40%		
2005	$496,749.99	$662,514.29	$405,559.08	$652,234.79	$2,217,058.15	11
	22%	30%	18%	29%		
2006	$749,741.11	$670,730.15	$543,940.25	$753,399.57	$2,717,811.08	11
	28%	25%	20%	28%		
2007	$612,381.60	$771,955.42	$554,488.24	$914,306.67	$2,853,131.93	15
	21%	27%	19%	32%		
2008	$242,712.15	$931,656.30	$684,551.24	$1,059,267.45	$2,918,187.14	19
	8%	32%	23%	36%		
2009	$1,148,411.23	$1,872,022.61	$891,965.88	$1,308,640.25	$5,221,039.97	22
	22%	36%	17%	25%		
2010	$103,505.28	$2,923,958.45	$1,021,634.96	$1,817,722.15	$5,866,820.84	31
	2%	50%	17%	31%		
2011 (Jan - June)	$36,042.97	$1,051,522.99	$575,320.18	$1,013,142.83	$2,676,028.97	32
TOTALS:	$3,436,934.45	$9,022,824.82	$4,778,656.27	$7,711,460.29	$24,949,875.83	
	14%	36%	19%	31%		

*Two employees added after AHRQ contract was received in 2004.

Initial Sources of Funding

There have been several different initial funding opportunities available for clinical exchange, these include the following:

- AHRQ State and Regional Demonstration Project (Awarded September 2004): $5 million.
- Utah Department of Health Local Health Information Infrastructure (LHII) (2-year grant awarded 2004): $660,000.
- ARRA HIE CA Grant – Utah Department of Health (Awarded February 2010): $5,051,366.
- Beacon Grant - HealthInsight (Awarded May 2010): $1,423,505.
- VA Grant – Department of Veteran Affairs (Awarded July 2010): $1,085,241.
- Master Patient Index Grant – University of Utah (Awarded September 2009): $285,978.
- REC Grant – HealthInsight (Awarded July 2010): $195,000.
- UNS-cHIE Exchange Grant – Utah Department of Health (Awarded September 2009): $96,000.
- CHIPRA Grant – University of Utah (Awarded July 2010): $73,332.

Developing and Implementing the Sustainability Plan

Approaches to Sustainability-Components for sustainability include:

- Not-for-profit-501(c)(3)
- A competitive pricing model for products and services
- Broad-based coalition
- Development of community State standards (implementation guides)
- Gateway services and baseline tools

Pricing Model Development

- The community decided on pricing based on an equal share of the clinical costs spread amongst clinicians, hospitals, and payers
- The clinical pricing model was first implemented at the beginning of 2010

Current Clinical Pricing Structure

- Payers:
    - Per Member per Month (PMPM) Option: a maximum of 8.5 cents per member per month max cost with a 250,000 member cap.
    - Click Fee Option: a maximum of 21 cents per 837 or claim (this would be in addition to the existing administrative fee). If a payer were to opt for the Click Fee option, they would be subject to the same annual fee maximum they would have been billed if they had opted for the PMPM fee option (in other words, the payer would not be charged more if they used the click fee option than if they had used the PMPM option).

- Hospitals – Fee based on the annual number of discharges.
- Clinicians – Clinical membership fee based on number of clinicians in office.

Table 2. Clinical membership fee

# Clinicians in Office	Annual Membership Fee
<1	$300
1	$600
2-9	$1,000
10-24	$2,000
25-49	$6,580
50-100	$10,528
100-200	$16,108
Over 200	$28,189

  - Safety Net Providers - Charged at the "1 Clinician" fee category.
  - Home Health Providers - Charged at the "<1 Clinician" fee category.
- Long-Term Care – Fee based on licensed beds per organization.

Table 3. Long-term care fee

# Beds	Annual Fee
<25	$150
25-49	$225
50-99	$400
100-199	$600
200-399	$900
400-799	$1,500
800-1,599	$2,560
>1,600	$4,640

- Independent Laboratory Pricing for Results Delivery (only) – $10 per ordering provider per month by individual lab. This is based on the number of providers receiving results/month, not based on the number of results.
- Pharmacy – Based on brick and mortar location(s)

Table 4. Pharmacy fee

Locations	Annual Fee
1	$300
2-9	$600
10-20	$1,200
21-30	$2,400
31-50	$4,800
50-100	$9,600
>100	$16,000

Lessons Learned About Finance and Sustainability

Sustainability Plan. Clinical data exchange has more business, technical and political dynamics then administrative exchange. As a result, by adding clinical data exchange products and services the overall costs have increased nearly threefold from 2004 and the number of employees has increased fourfold. We are in start-up mode as it relates to clinical exchange and we believe that the overall costs may decrease as clinical exchange matures.

UHIN has been fortunate that most payers have been willing to pay their share of clinical fees as we are in start-up mode.

In order for many users to find value in utilizing the cHIE, it is important that the cHIE contains clinical information from a majority of the data sources in the State. We have been busy filling the wells (e.g., have data sources provide clinical information to the cHIE) with clinical data and have learned that this takes some time to fully interface with all of the data sources.

With the change in the cHIE consent model to an opt-in approach9 this has delayed one of the primary uses (query a patient's clinical information from various data sources) that many individuals/organizations see value in using the cHIE. In addition to filling the wells, it is critical that consent is collected from mass number of patients.

Conclusions

It is important to quickly identify how the HIE brings value to entities; this can be unique to each entity.

Understanding the stakeholder's value equation accomplishes the following:

- Helps determine the roadmap for HIE implementation
- Helps provide an expectation to stakeholders of when they can begin seeing HIE value

Helps determine baseline measures so the impact/value of the HIE can be measured

Technical Infrastructure

Selecting Technical Infrastructure Design

The UHIN Board chartered a cHIE Task Force (which consisted of data suppliers and data users) whose primary purpose was to complete a Request for Proposal (RFP) for a Clinical Exchange system. The list of functionality and components was primarily created by the cHIE Task Force. Input was received regarding the RFP from physician, hospital and technical committees. Also, components from other HIE RFP's were incorporated.

The Technical Advisory Panel (Clinical Exchange Committee) initially had the desire to exchange intelligent messages (phase 2) but understood that this could not be implemented quickly and there was a limited number of HIE vendors in the market. Also, based on the UHINt adoption pilot/evaluation experience this confirmed the ultimate desire of the community of a more sophisticated system was needed for clinical exchange.

Some important components when selecting technical infrastructure included:

[9] Before a patient's clinical information can be queried in the cHIE by an authorized provider, the patient must provide global cHIE consent.

- Contract with a single vendor
- A mature “off the shelf” solution
- A complete clinical exchange solution including a baseline clinical tool for users
- Federated repositories
- Able to have opt-in/opt-out consent
- Scalable solution
- Clinical transformation ability
- Robust Master Patient Index
- Report delivery and query functionality
- Redundant/failover architecture
- Robust logging and reporting capabilities
- Positive existing customer testimonials
- On-site visits of existing customer installations

Role of stakeholder preferences/opinions. The community stakeholders were intimately involved in the creation of the Request for Proposal (RFP) of the clinical exchange infrastructure. The RFP included use cases and functionality preferences that the stakeholders wanted.

After the vendor was selected, community stakeholders continue to be involved through the various UHIN committees with system enhancements requests.

Selecting a Vendor

Community stakeholders were involved in the creation and reviewing/scoring RFP responses and in attending vendor demonstrations. For the top vendors, selected stakeholders performed on-site visits of existing customer installations to get first hand feedback from users of the vendors system.

In addition, the top vendor’s Master Patient Index was tested by using a known identity data set.

Deployment of Technical Infrastructure Design

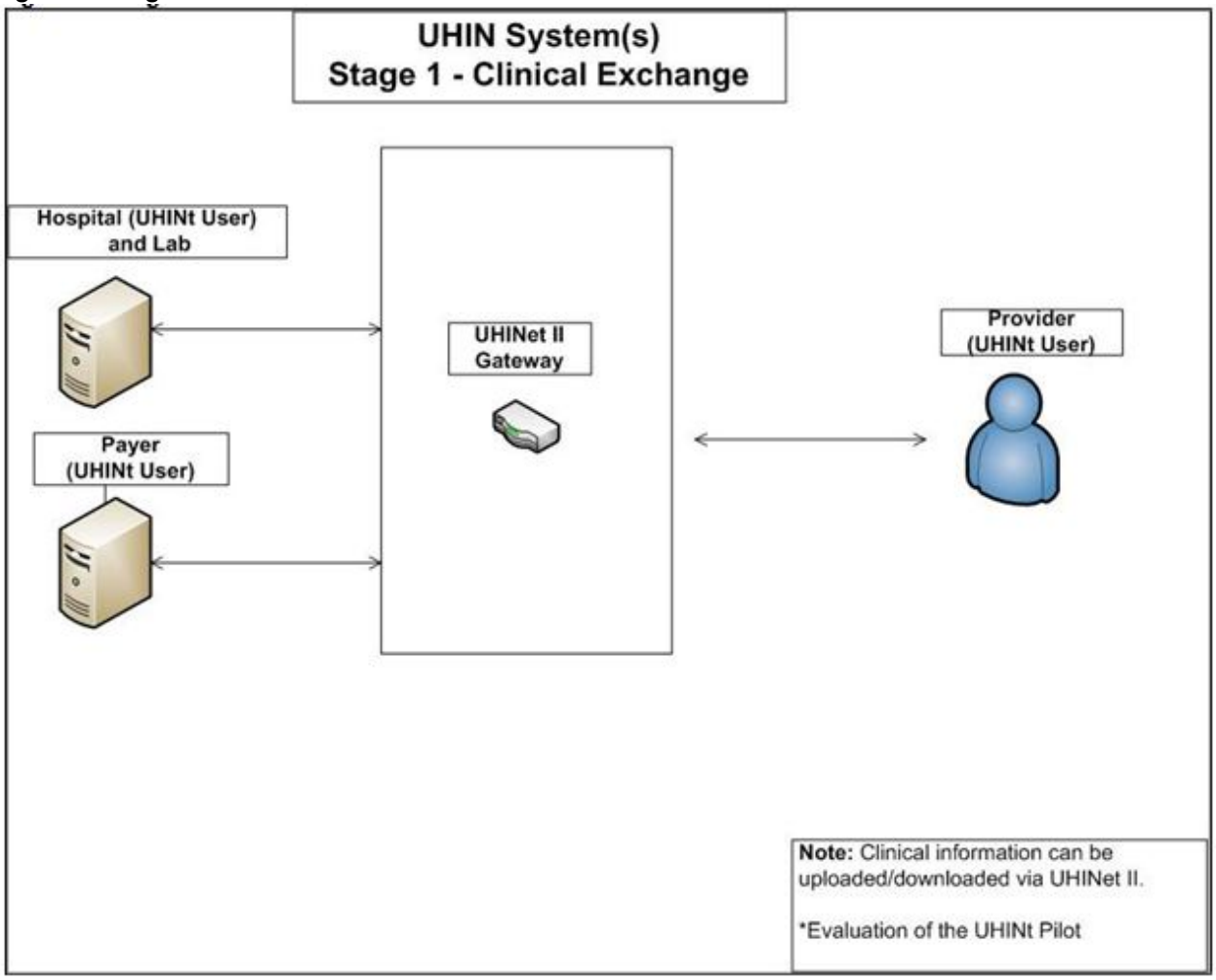
Initially we tried to leverage a single connection, to exchange administrative and clinical data. While possible, we found from the user experience, that this would not meet the needs of all stakeholders. A more sophisticated system was needed to meet the needs of our stakeholders.

Included below are the evolution stages of the deployed technical infrastructure design.

Stage 1- Initial Clinical Exchange approach via existing (upgraded) UHIN infrastructure

The UHIN gateway (UHINet) was upgraded (UHINet II) to a Web Services design and architecture. This allowed for the exchange of not only administrative (billing) information via the UHIN gateway, but also the exchange of clinical information and attachments. In addition, the baseline application (UHINt) was a tool used by some providers to exchange administrative information. This tool was upgraded (UHINt 2.5) to allow for entities to have simple messaging capability to exchange clinical information and attachments. Stage 1 was used for the UHINt Adoption Evaluation or simple messaging capability.

Figure 6. Stage 1 UHIN technical infrastructure



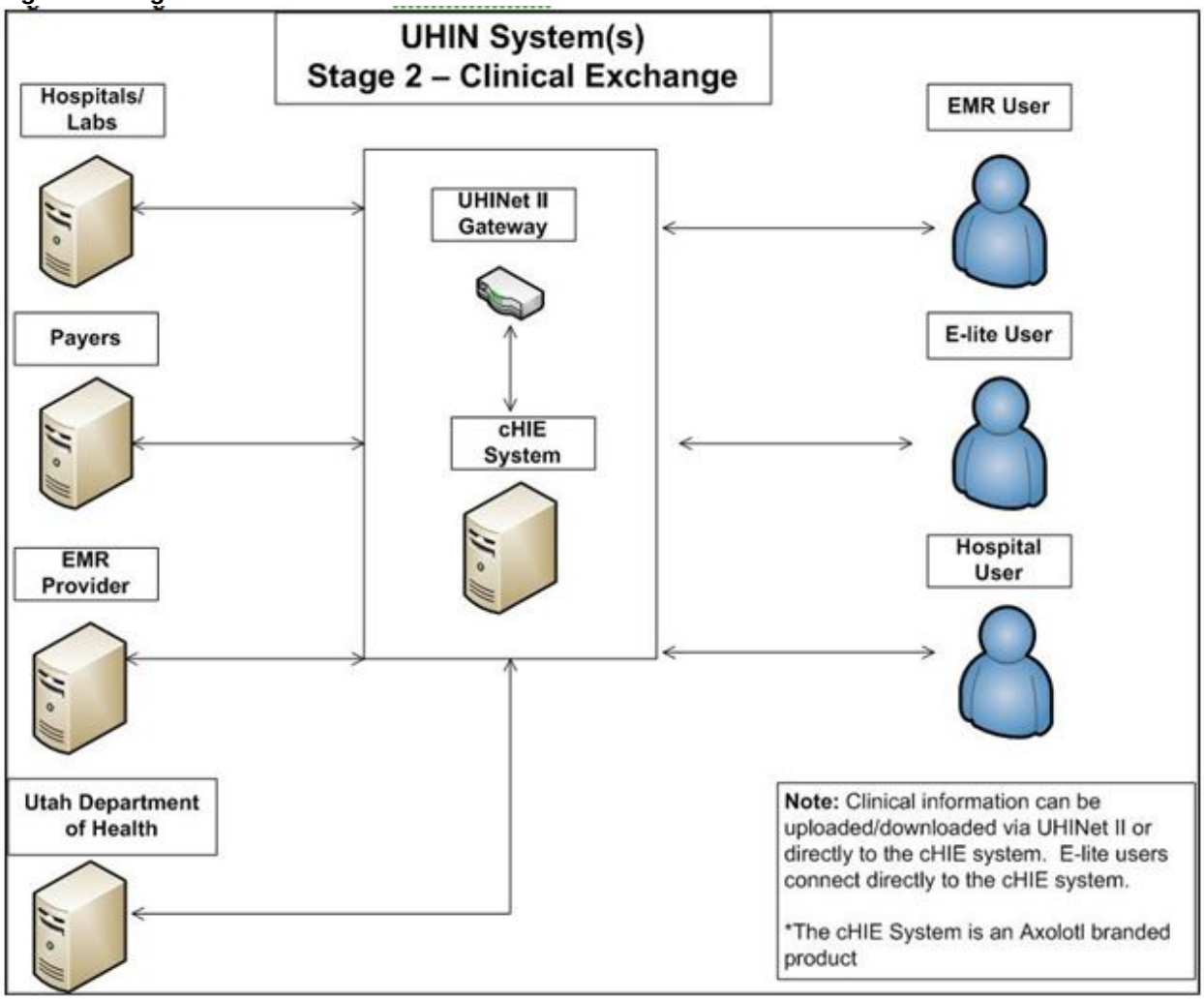
Stage 2- Interface existing UHIN infrastructure with new UHIN Clinical Exchange infrastructure

It became very apparent during stage 1 that a more intelligent messaging capability was desired by health care providers. The intelligent message capability includes the capability of not only simple messaging capability, but the ability to do report deliver and query clinical records for a specific patient. The UHIN Board of Directors decided to purchase a new

clinical exchange platform (Axolotl Elysium) and baseline provider exchange tools that had intelligent message capability.

To help entities leverage their existing UHIN gateway connection to the new clinical exchange platform (Clinical Health Information Exchange or cHIE), an interface was developed between the two systems to allow for the upload/download of messages between the two systems.

Figure 7. Stage 2 UHIN technical infrastructure

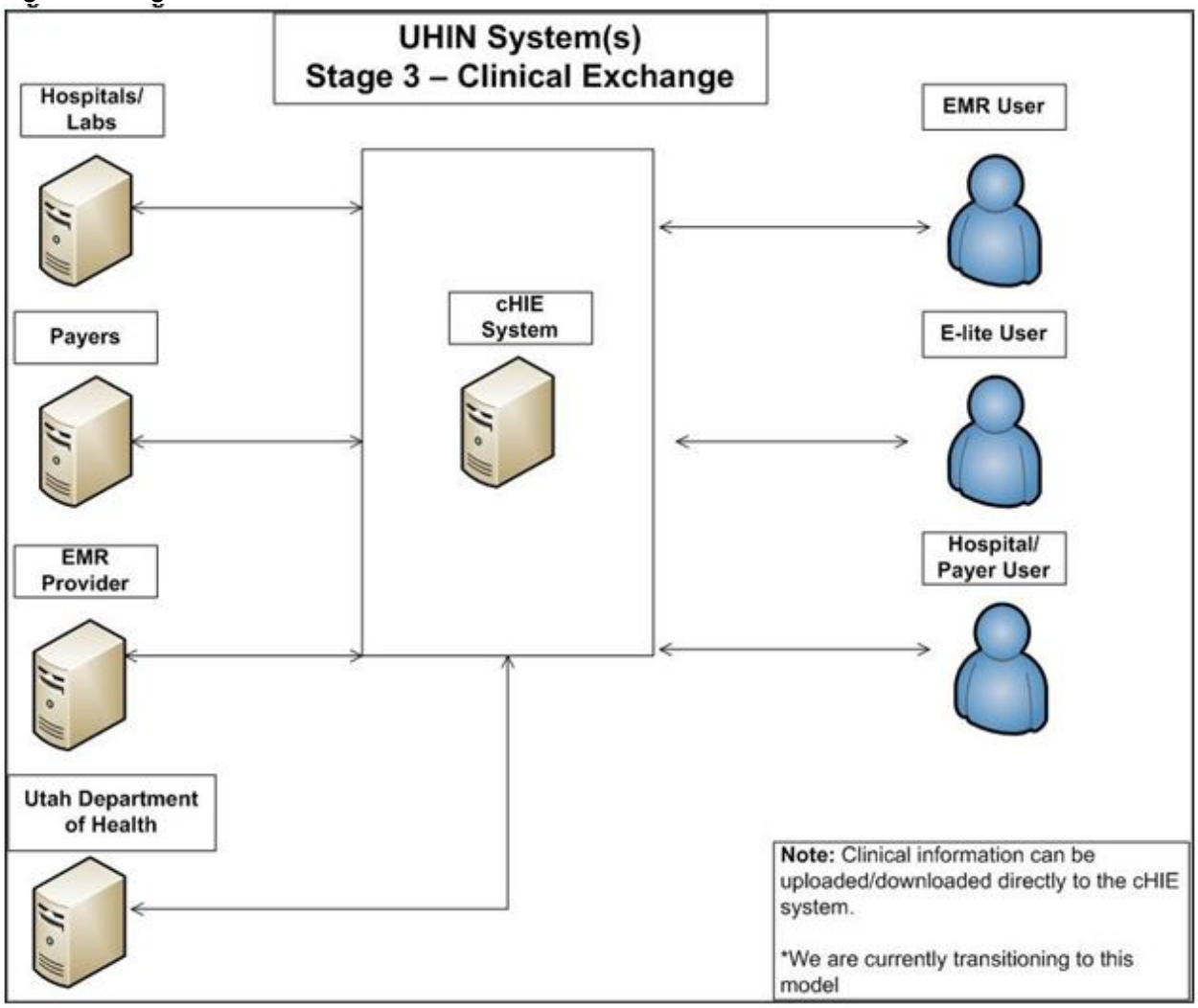


Stage 3- Current/transitioning model for clinical exchange infrastructure

Many new entities/vendors were not ready to develop Web Services connections (required for connecting to UHINet II). By connecting directly to the cHIE, entities were able to use older connection methods (e.g., VPN, sFTP), which became the preferred connection methods. It became apparent during stage 2 that it made more sense to have entities connect directly to the cHIE system to simplify the overall technical infrastructure and position entities to be able to use other future clinical exchange functionality.

We have been transitioning entities that currently are connected to the cHIE via UHINet II to a direct connection to the cHIE. All new entities connect directly to the cHIE.

Figure 8. Stage 3 UHIN technical infrastructure



Security Policy and Practices

Due to clinical exchange, we have had to update security policies. We have found that we need several new policies and procedures (e.g., privacy and security, auditing) for the community and UHIN. Auditing plays a significant role for clinical exchange and usage that we did not need to have in place before for administrative exchange. With the administrative system, UHIN did not maintain Personal Health Information (PHI) in the office or its systems. These policies and procedures are being updated/developed with assistance from community stakeholders.

UHIN has been accredited through Healthcare Network Accreditation Program by the Electronic Healthcare Network Accreditation Commission (EHNAC10). UHIN pursued and is also an accredited organization that has received Health Information Exchange Accreditation Program (HIEAP) with the Electronic Healthcare Network Accreditation Commission.

EHNAC assesses the company's health information and oversight for meeting privacy and security regulations. The accreditation program also focuses on technical performance, business processes, and resource management. In the process of a thorough, objective EHNAC evaluation, the organization discovers ways to improve efficiency, elevate quality of service, and keep up-to-date with current marketplace trends.[11]

Lessons Learned About Technical Infrastructure

When the UHIN gateway was updated (UHINet II) there was a single prescribed way of connecting using Web Services. We found out that many members/vendors were not ready for Web Services, so we have created other methods (e.g., VPN, sFTP) for connecting to the cHIE. Also, we are simplifying the complexities of interfacing with two systems (e.g.,UHINet II and the cHIE) in having members/vendors connect directly to the cHIE.

It is important to listen to community stakeholders' needs and be able to make adjustments accordingly.

Conclusions

It is important to work with community stakeholders in deciding upon the technical infrastructure and be flexible so stakeholder's needs can be met.

It has been extremely helpful to have selected a mature HIE vendor and have a user group that we can learn from other communities implementation and escalate the priority of user enhancements and bug fixes.

Business and Technical Operations

Our member relation team staff's primary role, before clinical exchange, was to maintain customers. An additional group has been added to the team, whose primary role is sales and education on the clinical exchange.

[10] http://www.ehnac.org/index.php

[11] http://www.ehnac.org/index.php?option=com_content&view=article&id=57&Itemid=14

It has been helpful to have more staff with specific roles (e.g., Electronic Health Record Integration Specialist, Communication Coordinator) to assist in the communication and implementation of clinical exchange.

Current UHIN Organization Structure

Executives (5)
- Chief Executive Officer
- Chief Operations Officer
- Chief Development and Implementations Officer
- Director of Finance
- Director of Human Resources

Standards Team (2)
- Standards Manager
- EDI Analyst

Project Team/Quality Assurance (6)
- Quality Assurance Analyst
- System Architect and Security Officer
- Business Analyst (2)
- Electronic Health Record Integration Specialist
- Government Contract Project Manager

Informatics Department (4)
- Informatics Manager
    - MPI Analyst (2)
    - Data Analyst

Customer Service/Operations (4)
- Help Desk Supervisor
    - Help Desk Representative (2)
    - Enrollment Specialist

Member Relations (6)
- Member Relations Representatives (6)

Communication (1)
- Communication Coordinator

Accounting (1)
- Accounting Coordinator

Office Services (2)
- Administrative Assistant
- Office Manager

IT (1)
- Information Technology Manager

Total Staff: 32

Developing Partnerships and Programmatic Linkages

UHIN has new/enhanced partnerships with the following organizations:

- Utah Department of Health (ARRA HIE CA and UNS-cHIE grant) – Meet weekly to coordinate efforts.
- HealthInsight (REC and Beacon grants) – Meet weekly to coordinate efforts.
- Electronic Health Record Vendors – Coordinate with provider in connecting and interfacing with the cHIE.

- The Axolotl User Group (AUG) – Share and learn from other Axolotl system HIE's across the country.
- Office of the National Coordinator (ONC) for Health IT– Share and learn from other non-Axolotl system HIE's across the country.
- The Department of Veteran Affairs (VA) – Connect with the VA and Indian Health Services.

Role of Stakeholder Preferences / Opinions on Business and Technical Operations

Community stakeholders provide ongoing feedback to UHIN through formal (e.g., committees) and informal channels regarding the direction of UHIN business and technical operations.

Identifying Data Elements for Sharing

Community stakeholders identified use cases and message types that are commonly exchanged today. The major message types include the following:

- Patient demographics (admit, discharge, and transfer messages)
- Laboratory results
- Radiology results
- Transcription reports

Community stakeholder subcommittees meet together to create Standards (implementation guides) which standardize data elements for sharing using message formats that are used by entities today. These subcommittees use national standards (e.g., HL7, NCPDP) to the extent possible. In some instances, standards need to be further constrained or more specificity added for implementation purposes of message exchange.

Implementing Data Sharing

This is quite an involved process in coordination, between in some instances up to four different entities (UHIN, the local customer, corporate customer and the vendor), there are sometimes different internal priorities and resource availability.

The major steps in implementing data sharing in addition to data agreements include the following:

- Defining the project scope of clinical exchange.
- Setting up weekly calls to report on action items and status.
- Establishing connectivity.
- Exchanging messages of test scenarios that can be expected to be sent/received to/from the HIE.
- Identifying gaps between the vendor implementation messages and the community message standards and make adjustments where possible.

- Understanding customer system limitations in message implementation exchange.
- Transforming messages, when needed, to meet the minimum community message standards.
- Move to production.

Maintenance of Technical Infrastructure

Our vendor is responsible for all system maintenance of the technical infrastructure. UHIN creates test plans for new releases and notifies the community of the system changes/downtime. UHIN solicits enhancement requests from users to our HIE vendor.

Impact on Sustainability Plan

Changing the consent model to an opt-in approach has created an additional hurdle for implementation and usage, which has slowed user adoption of cHIE. However, it has given providers an opportunity to be more involved by collecting patient consent.

Implementing a statewide HIE is a slow moving process. Some parallel business processes (e.g., results delivery, EHR interfacing) exist already for community stakeholders.

Fast pace changes in the health care dynamics especially for reporting requirements (e.g., meaningful use requirements) are taking priority over building connection to the cHIE.

There are also many enhancements (immunization registry, new MPI infrastructure) to existing products in the pipeline from our vendor and new technologies that will provide value in the future (e.g., ordering, electronic laboratory reporting, clinical analytics for entity reporting requirements).

Lessons Learned About Business and Technical Operations

It is important to involve community stakeholders in the cHIE system selection process and in implementing a technical design so their needs can be meet. Stakeholder involvement helps create a sense of ownership and builds upon the consensus model.

After the cHIE system had been selected, the vendor was purchased by an entity not trusted by the Utah medical community. This created trust perception issues as to the use of the cHIE data. This perception issue seems to be largely resolved, but it took some efforts to dispel the perception.

Conclusions

The clinical technical infrastructure is more complicated than initially thought. Selecting a mature HIE vendor was very helpful.

Federal regulations seem to be making things more complicated for HIE's. Meaningful Use has helped bring clinical data exchange to a new level, but many providers may only be meeting the minimum requirements to receive incentive monies. Meaningful Use, in many cases, has taken the vendor resources away or lowered the priority in interfacing with the cHIE.

As the Meaningful Use incentives for Stage 2 and 3 are developed, more use of exchange of data will be realized. In addition, quality reporting for the payers, including Medicare will provide some incentive for the providers to connect to the HIE to provide data.

Legal/Policy

Developing Policies

Today, UHIN and it members continue to use a single Business Associate Agreement called an Electronic Commerce Agreement (ECA) for administrative and clinical exchange of data. The ECA was updated to include more general wording to relate to clinical as well as administrative exchange. By signing the UHIN ECA, members can exchange health care information with any of the entities connected to UHIN. A member does not have to sign a separate Business Agreement with all of the entities connected to UHIN to exchange health care information.

For clinical exchange, an additional agreement was created called the cHIE Addendum. This agreement includes specific information as it relates to clinical information exchange.

UHIN community stakeholders continue to be involved in the creation of policies and procedures. There are many policies and procedures that are currently being created/updated (e.g., consent, secondary use, privacy, security) by UHIN and its stakeholders.

Role of Legal Counsel

UHIN has been fortunate in having a legal community stakeholder committee in place for quite some time that is familiar in working together and within UHIN's consensus model. In 2005, legal counsel's primary role was assisting in the creation of a legal data sharing agreement (ECA) for UHIN and its members. Now, legal counsel's role has expanded ranging from reviewing consent policies and helping draft legislation to help protect the cHIE against malpractice.

Developing Data Sharing Agreements

UHIN's legal community stakeholders are currently revising the ECA to include language from the Data Use and Reciprocal Support Agreement (DURSA) and HITECH. As a member of the Nationwide Health Information Network, it is important that the legal language used in UHIN's agreements is congruent with the DURSA.

Currently, the UHIN Security Specification includes privacy components. UHIN community stakeholders are currently in the process of developing a specific privacy policy. A special Board appointed Privacy/Security Committee has been formed to complete this task.

Developing Liability Policy

UHIN community stakeholders are currently in the process of including updated language as it relates to liability within the data sharing agreements (ECA). In reviewing UHIN's liability insurance coverage it was determined that only a minimal increase was needed with the inclusion of clinical exchange.

Lessons Learned About Legal/Policy Development

It is vital that an HIE have a legal community stakeholder committee. The legal committee should review all policies created by the various HIE committees. Transparency is critical in this process.

UHIN's legal committee is currently reviewing and updating UHIN Privacy/Security

Policies and Procedures. To be more transparent, UHIN plans to publish part of its internal Privacy/Security Policies and Procedures on its Web site.

Conclusions

There are a lot of dynamics when several attorneys from different organizations sit in a room together to create a common legal data sharing agreement, policies and procedures. Overcoming differences and working together for the good of the community takes time to progress.

Evaluation

Developing the Evaluation Plan

When the original proposal was submitted, the actual clinical message(s) that would be transmitted had not been decided upon. Therefore our initial evaluation plan was a general outline of potential measures/outcomes that would measure the impact of HIE, in whatever form it might ultimately take in Utah, on patient safety and quality of care. At that point in time, the four potential message types being considered were—

- Medication Histories
- Discharge Summaries
- History and Physicals
- Lab Results

As the project developed it also became clear that it would be necessary to expand the potential set of measures to include operational/process measures and utilization measures. For each message type we identified possible utilization and operational measures as well as measures of patient safety and/or quality of care. From the set of potential measures in the preliminary plan we expected to choose a subset of measures for the final evaluation, once the pilot messages were decided upon.

To collect data on the operational/process measures HealthInsight developed a Document Processing Workflow Assessment Tool for hospitals and clinics. This tool allows us to estimate the costs of receiving and sending laboratory, radiology, and surgical reports and discharge summaries, and identify the circumstances in which clinical information is needed by the clinic, how well their information needs were being met, and how access to this information could be improved.

Finalizing the evaluation plan was delayed when the decision was made several years after the start of the project to move to cHIE, a much more sophisticated clinical solution. In the final evaluation plan submitted to and approved by AHRQ in April 2009, we proposed to evaluate the impact of the cHIE on the following measures:

1. Adoption and utilization of the cHIE
2. Population of the master patient index (MPI)
3. Time of availability of clinical information
4. Message processing costs and workflow for clinics and hospitals
5. Reduction in duplicate lab orders

The first four measures are utilization and process measures; the last is a clinically relevant, quality of care outcome. Measure 5 was chosen because lab reports were to be the first message type transmitted via the cHIE, and we expected that we would be able to measure its effect on reducing duplicate lab orders using payer-provided billing data. We also expected that we would be able to use data collected with the Document Processing Workflow Assessment Tool to measure the effect of the cHIE on message processing costs and workflow for a sample of clinics and hospitals using a simple pre/post study design.

In addition, it was recognized that valuable information could be gained from the failed implementation of the UHINt 2.x baseline tool. To this end, the evaluation plan included conducting semistructured interviews with UHIN staff involved in that aspect of the project, and the six pilot sites that used the tool to send or receive clinical information.

Implementing the Evaluation Plan

Since the evaluation plan for the cHIE was submitted it has continued to change and evolve. Because of delays in its implementation, utilization of the cHIE has not yet reached a level and scope where it could have any effect on clinically relevant outcomes such as duplicate lab results. Nor has it reached a stage of use where we could measure its impact of facilities' document processing costs and workflow. Therefore at this point in time, evaluation of the cHIE is limited to the first three measures listed above:

1. Adoption and utilization of the cHIE
2. Population of MPI
3. Time of availability of clinical information

In addition, in talking to facilities that have connected or will soon be connecting to the cHIE, it became apparent that valuable qualitative information could be gained by talking to users about their perceptions and experiences with the cHIE and UHIN.

Results

UHINt

Combining the information gathered from the interviews with the pilot sites and UHIN staff, the lessons learned from the UHINt implementation primarily relate to three areas:

1. Client recruitment and relations
    - In promoting a solution and recruiting potential users it is important to target the right audience. In the case of clinics, this would be the clinical staff who would be using it as part of their everyday work processes.
    - Training and formal training materials should adequately meets users' needs.
    - It is important to be able to assess and document office workflow and make the value of any tool clearly evident to providers.
2. Community and user feedback/input in the development process.
    - There should be a clear and thorough understanding of potential users' needs, expectations and work processes.
    - Starting early in the development process input from the solution's intended end users should be solicited and gathered, and this should continue through the development and design process.
    - Messages and baseline tool functionality should be tested as thoroughly as possible, before rolling out the solution to users.
    - It is important to be able to adequately address users' suggestions for improvements in an ongoing and iterative manner.

3. Uniqueness of clinical exchange.
    - Clinical data exchange and the flow of clinical data are very different from administrative data exchange.
    - The UHINt tool was a relatively simple solution that did not address the needs of more sophisticated users who need a tool that includes discrete, standardized clinical data that can be moved into EHRs and allows providers to query a patient's record across entities.

Utilization

From August 2009 through August 2011, 13 facilities (11 hospitals, 1 large clinic group, and 1 independent laboratory) have sent more than 8 million clinical messages to the edge servers (Table 5, Figures 9, and 10); more than 90 percent of all messages were sent between July 2010 and August 2011.

Currently, four message types are being transmitted:

- Laboratory results (19 percent of all messages sent)
- Transcriptions (4 percent of all messages sent)
- Radiology reports (2 percent of all messages sent)
- Admission, discharge, and transfer (ADT) messages (75 percent of all messages sent)

Table 5. Monthly message volume, total and by message type

Year/month		Laboratory Results		Transcriptions		Radiology Reports		ADT Messages		Total Messages	
		N	Cum	N	Cum	N	Cum	N	Cum	N	Cum
2009	8	969	969	-	-	-	-		-	969	969
	9	943	1,912	-	-	-	-	-	-	943	1,912
	10	907	2,819	-	-	-	-	-	-	907	2,819
	11	464	3,283	-	-	-	-	-	-	464	3,283
	12	637	3,920	-	-	-	-	-	-	637	3,920
2010	1	80,445	84,365	-	-	-	-	-	-	80,445	84,365
	2	11,635	96,000	-	-	-	-	-	-	11,635	96,000
	3	5,809	101,809	-	-	-	-	-	-	5,809	101,809
	4	5,476	107,285	-	-	-	-	-	-	5,476	107,285
	5	5,517	112,802	-	-	-	-	-	-	5,517	112,802
	6	5,389	118,191	340	340	-	-	-	-	5,729	118,531
	7	3,271	121,462	-	340	-	-	411,236	411,236	414,507	533,038
	8	4,200	125,662	1,199	1,539	1,079	1,079	558,520	969,756	564,998	1,098,036
	9	3,894	129,556	1,470	3,009	1,419	2,498	546,080	1,515,836	552,863	1,650,899
	10	81,180	210,736	1,611	4,620	1,375	3,873	274,915	1,790,751	359,081	2,009,980
	11	147,191	357,927	1,522	6,142	1,321	5,194	14,858	1,805,609	164,892	2,174,872
	12	143,466	501,393	1,557	7,699	1,318	6,512	14,946	1,820,555	161,287	2,336,159
2011	1	141,516	642,909	1,476	9,175	1,213	7,725	461,466	2,282,021	605,671	2,941,830
	2	134,823	777,732	38,465	47,640	24,895	32,620	610,435	2,892,456	808,618	3,750,448
	3	175,697	953,429	51,160	98,800	31,294	63,914	770,169	3,662,625	1,028,320	4,778,768
	4	162,701	1,116,130	44,074	142,874	26,647	90,561	693,581	4,356,206	927,003	5,705,771
	5	187,680	1,303,810	47,827	190,701	26,306	116,867	704,339	5,060,545	966,152	6,671,923
	6	68,748	1,372,558	49,152	239,853	26,990	143,857	479,954	5,540,499	624,844	7,296,767
	7	60,609	1,433,167	45,875	285,728	26,054	169,911	347,925	5,888,424	480,463	7,777,230
	8	141,214	1,574,381	49,869	335,597	28,604	198,515	500,206	6,388,630	719,893	8,497,123

Figure 9. Message volume - all clinical message types, by month

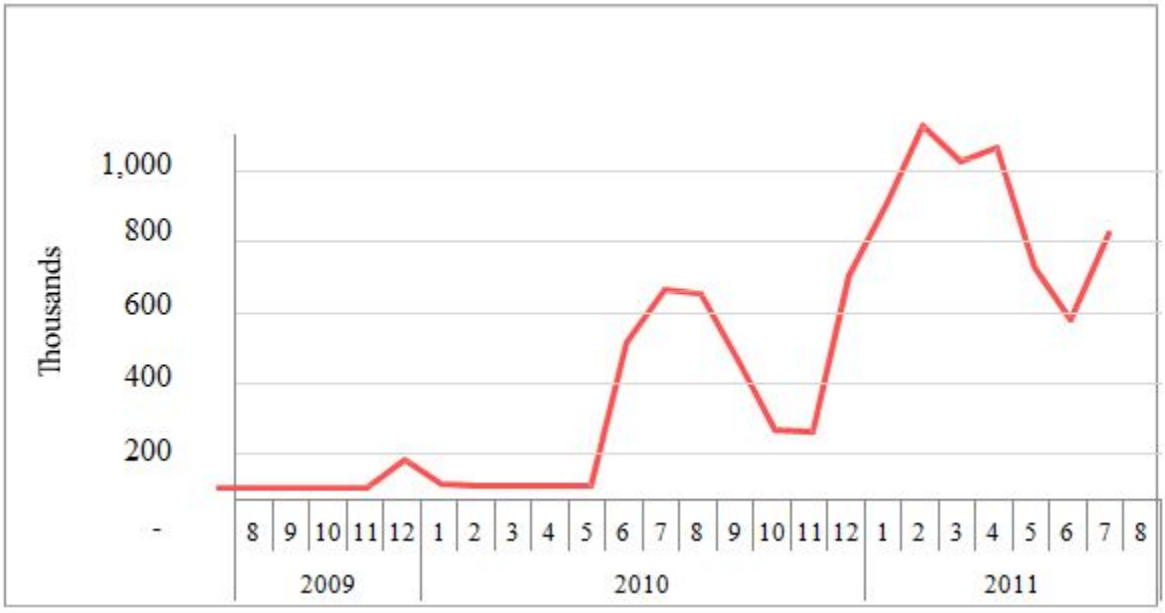
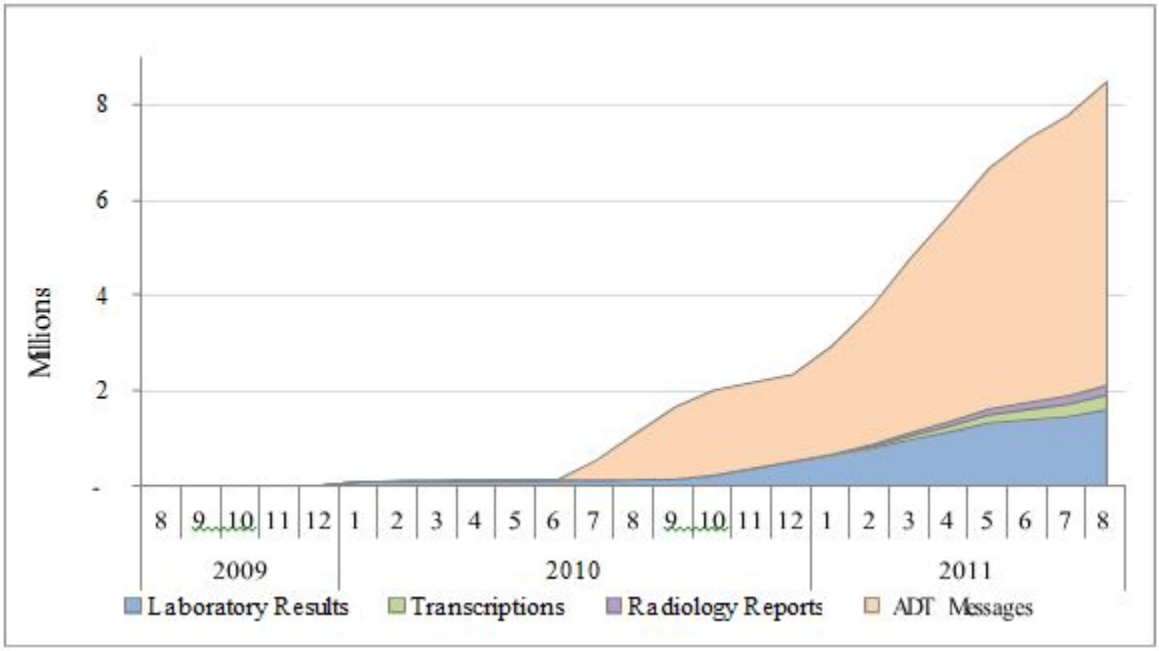


Figure 10. Cumulative messages sent, by message type



Thirteen facilities currently send messages: 11 hospitals, one independent laboratory, and 1 large clinic group. Table 6 lists the 13 sites currently contributing, with the dates they began transmitting specific message types.

Table 6. Contributing data sources

Source	Lab Results	Transcriptions	Radiology Reports	ADT Messages
Brigham City Community Hospital	Oct-10	June 10	August 10	August 10
Central Utah Clinic	January 10			
Davis Hospital				June 11
Jordan Valley Hospital				June 11
Lakeview Hospital	August 11	February 11	February 11	January 11
Moab Regional Hospital	August 09			
Mountainview Hospital	March 11	February 11	February 11	January 11
Ogden Regional Hospital	August 11	February 11	February11	January 11
PAML (Independent Lab)	May 11			
Pioneer Valley Hospital				June 11
Salt Lake Regional Hospital				June 11
St Marks Hospital	August 11	February11	February11	January 11
Timpanogos Hospital	March 11	February 11	February11	January 11
University of Utah Hospital	October 10			July 10

Population of the Secure Patient Directory (SPD) (see Table 7) began August 2009. As of August 2011, there were 471,952 records in the SPD (Table 7, Figure 11). Collection of consents began May 2011. To date there are 5,652 consent records in the SPD. Of these 76 percent are consents (n= 4,270), 16 percent (n=898) are limited consents,[12] and 9 percent (n=484) are refusals (Table 7, Figure 12).

Table 7. Population of the secure patient directory and consents (cumulative by month)

Year	Month	SPD Records	Total Consents	Consent: Yes	Consent: Limited	Consent: No
2009	9	1,281				
	10	1,589				
	11	1,777				
	12	2,123				
2010	1	18,449				
	2	20,204				
	3	21,413				
	4	51,112				
	5	53,415				
	6	54,639				
	7	143,470				
	8	190,887				
	9	226,914				
	10	254,532				
	11	263,319				
	12	268,489				
2012	1	321,469				
	2	362,457				
	3	405,026				
	4	437,419				
	5	471,952	75	54	19	2
	6	501,719	540	387	46	32
	7	523,369	2,664	2,096	374	194
	8	586,972	5,652	4,270	898	484

[12] Limited consent – Emergency only access

Figure 11. Records in secure patient directory

Figure 12. Consents (cumulative)

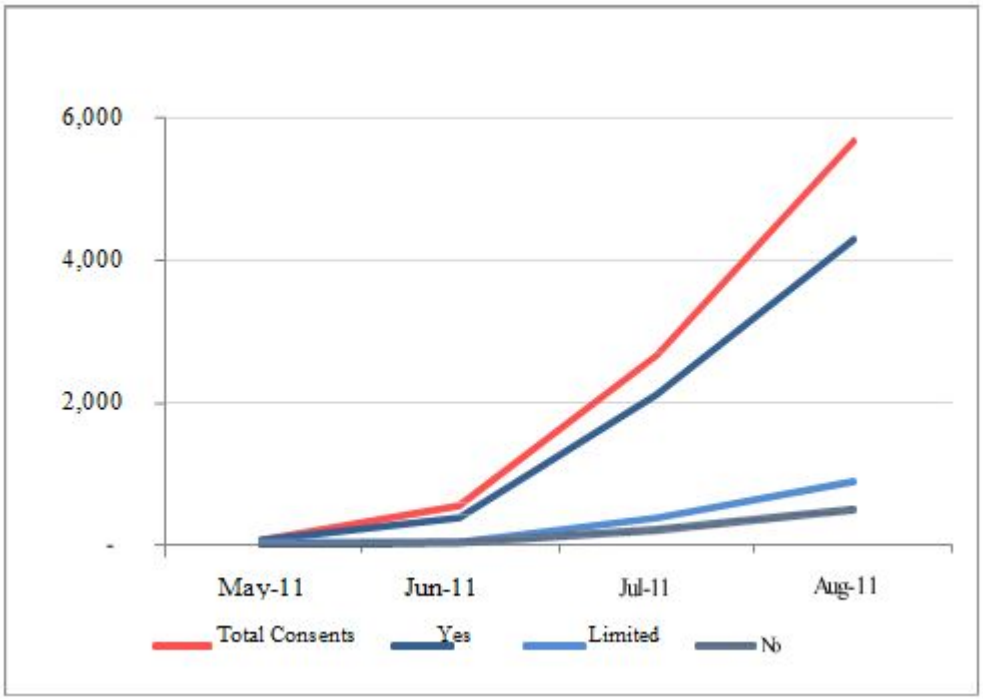


Table 8 shows the cHIE uptime, a measurement of the time when the system is available for clinicians to access clinical information on the cHIE, by month. Over the 22- month period between October 2009 and July 2011, the average uptime is 99.9 percent.

Table 8. cHIE uptime, by month

	2009	2010	2011
January		99.97%	99.98%
February		100.00%	99.98%
March		100.00%	99.98%
April		100.00%	99.98%
May		100.00%	99.99%
June		100.00%	99.99%
July		100.00%	99.99%
August		99.58%	
September		99.22%	
October	100.00%	99.47%	
November	100.00%	99.85%	
December	99.86%	99.92%	

Lessons Learned

The salient lessons learned from semistructured interviews with a small sample of clinics and hospitals that have connected, or are connecting with the cHIE are as follows:

- None of the clinics interviewed are using the cHIE for report delivery due to a variety of reasons, the most common being that clinics are waiting for their EHR vendors to create the interface with the cHIE.
- It appears that many potential users do not, or may not know that they could use the Internet to query patient information (through the Virtual Health Record [VHR]). One clinic that tried to use the cHIE for report delivery found that the process for receiving laboratory results and getting into their EHR was no better than their current process of printing, scanning, and attaching the scanned document to the patient's record in the EHR.
- Overall, the facilities interviewed are satisfied with their interactions with UHIN. Even though there have been problems and consequent delays in connecting to and interfacing with the cHIE, they recognize that it is a difficult process and delays are inevitable, especially in the early phases.

In spite of the problems, frustrations, and delays, expectations and enthusiasm for the cHIE are very high.

With regard to the first point, the delays to date have been due to a variety of reasons, from contracting with UHIN, Meaningful Use initiatives, and EHR internal resource restraints/priorities. Another contributing factor has been getting all of the data sources (e.g., hospitals and laboratories) contributing their information to the cHIE. Though significant progress has been made in this regard, it is critical that all of the large data sources are

providing all of their clinical information to the cHIE for providers to realize one of the benefits in utilizing the cHIE for report delivery.

With respect to the second point, due to the changing consent model, with patients opting in, UHIN has not yet been actively promoting the VHR as a means of querying clinical information from the cHIE.

Also with respect to the second point, another clinic had their EHR interfaced to receive laboratory results from a single data source via the cHIE. Because the data source is unable to send microbiology and send-out laboratory results electronically, the clinic has discontinued utilizing the information received via the cHIE. For these specific results the laboratory result values said “see attachment” or “send out” with no attachment sent electronically. So the clinic continues today to use the current paper/fax process in receiving laboratory results. The data source is currently making upgrades to their system and is in the processing of creating interfaces that will give them the ability to send microbiology and send-out laboratory results electronically.

Recommendations for Future Research

In the course of this project, the evaluation plan has changed dramatically as a result of several factors, primarily the delayed start of the cHIE implementation, followed by delays in the actual implementation of the cHIE and the change in the cHIE consent model to an opt-in approach. As a result, at this point we cannot measure the impact of the cHIE on quality of care or patient safety outcomes, as we had originally proposed. At this point we are limited to measuring utilization, and qualitative assessments of users' experiences and perceptions. It will take several years more before we could implement the kind of evaluation we had originally envisioned.

With respect to evaluation and research, a great deal has been learned in the course of this project, the primary lessons being as follows:

- Any plan for evaluating a developing HIE must be flexible, and it should be expected that it will change and evolve over time.
- As far as possible, the evaluation should take into account the needs and interests of the many and various entities with a stake in HIE.
- Formative analyses should be part of the evaluation, especially in the early stages, to guide, inform and track the development and implementation of HIE.
- A distinction should be made between evaluation methods for the purposes of research and evaluation methods for evaluating programs and assessing and improving operations and processes. Quality improvement methods, which use less rigorous design constraints, are more applicable to many aspects of evaluating HIE, especially with respect to the formative analyses.
- Qualitative analyses, including program evaluation methods, should be a major part of the evaluation. Particularly in the early stages, qualitative data can be a very rich and valuable source of information that can be used to guide and monitor the project as it develops.

Evaluation of outcomes should not wait until HIE is fully mature and functioning and widely used, but rather should measure outcomes, on an ongoing basis, to the extent possible, while recognizing and acknowledging the potential limitations of such an approach.