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INTRODUCTION

Diabetes is a complex, serious, and increasingly common disease. It is the most frequent cause of blindness among working-aged adults; the leading cause of non-traumatic lower extremity amputation and end-stage renal disease; and a principal cause of congenital malformations, prenatal mortality, premature mortality, and disability (Agency for Healthcare Quality and Research, 2003). Persons with diabetes are at increased risk for stroke, ischemic heart disease, peripheral vascular disease, and neuropathy (Institute for Healthcare Improvement Corporation, 2007)

The Ambulatory Health Information Exchange (AHIE) project will attempt to fill the need for easier access and communication among members of the healthcare team needed to treat the diabetic patient effectively. The AHIE will provide a seamless communication amongst different providers, ancillary services and the patient. In order to provide quality treatment for a diabetic patient, different complex processes are required to treat the diabetic patient effectively (see figure 1 below)
Figure 1: Organizations and clinical personnel required to manage a diabetic patient effectively.

The AHIE project will facilitate in the coordination of the different complex processes required to treat the diabetic patient.

**Problem Definition**

The prevalence of diabetes continues to grow. 23.6 million people, or 7.8% of the population, have diabetes, with 17.6 million being currently diagnosed and 5.7 million unaware that they have diabetes. (Center for Disease Control, 2007)

Diabetes is a very costly disease. The total estimated cost of diabetes in the United States for 2007 was $174 billion, including $116 billion in excess medical expenditures and $58 billion in reduced national productivity. The largest components of medical expenditures attributed to diabetes are hospital inpatient care (50% of total cost), diabetes medication and supplies (12%), retail prescriptions to treat complications of diabetes (11%), and physician office visits (9%) (American Diabetes Association, 2007) (see figure 2 below).
The reduced national productivity amount was $58 billion (American Diabetes Association, 2007). This indirect cost was as a result of productivity losses due to patient disability and premature mortality, time spent by family members accompanying patients when seeking care, and intangible costs (psychological pain and human suffering to the family and loved ones). The non-economic burden of distress and pain imposed on families (death, disability and economic stress) and the resulting large annual losses in economic growth affect everyone. These are the real costs of diabetes and unfortunately this cannot be quantified in financial terms.

Diabetes was the seventh leading cause of death listed on U.S. death certificates in 2006. This ranking is based on the 72,507 death certificates in 2006 in which diabetes was listed as the underlying cause of death. According to death certificate reports, diabetes contributed to a total of 233,619 deaths in 2005, the latest year for which data on contributing causes of death are available (Center for Disease Control, 2007).
Everyone in society is affected by diabetes, not just those who live with diabetes.

**STAKEHOLDERS**

In healthcare, the definition of quality can be complex and controversial, because of the different expectations of the various stakeholders. Stakeholders have been classified into two groups, internal and external stakeholders. The following tables will attempt to make it easier to understand their roles and expectations.

Tables 1 and 2 list the expectations of the internal and external stakeholders, respectively.

**Table 1: Internal Stakeholders**

<table>
<thead>
<tr>
<th>Stakeholder</th>
<th>Expectation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physician</td>
<td>Establishing diagnosis and providing appropriate treatment.</td>
</tr>
<tr>
<td>Hospital</td>
<td>Cost containment and profitability.</td>
</tr>
<tr>
<td>Patient</td>
<td>Affordable cost and quality of care.</td>
</tr>
<tr>
<td>Health Insurance Company</td>
<td>Cost-effectiveness and profitability.</td>
</tr>
<tr>
<td>Pharmacy</td>
<td>Provide prescribed medication accurately.</td>
</tr>
</tbody>
</table>
Laboratory

Providing test results to providers.

**Table 2: External stakeholders**

<table>
<thead>
<tr>
<th>Stakeholder</th>
<th>Expectation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Employers</td>
<td>Fewer days lost to disability, sick days and premature mortality.</td>
</tr>
<tr>
<td>Accrediting Agency</td>
<td>Access to medical records for reporting purposes.</td>
</tr>
<tr>
<td>Public Health Agency</td>
<td>Access to patient data.</td>
</tr>
</tbody>
</table>

External stakeholders include employers, accrediting agencies, and public health agencies.

External stakeholders are not directly involved with the care of the patient but are affected by the care the patient receives.

Tables 3 and 4 list the future expectations of our internal and external stakeholders, respectively. The majority of internal stakeholders expect an improvement in the way information is accessed which in turn provides a more streamlined workflow that saves time and is more efficient.

**Table 3: Internal Stakeholders and their Future Expectations**

<table>
<thead>
<tr>
<th>Stakeholder</th>
<th>Future Expectations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stakeholder</td>
<td>Future Expectations</td>
</tr>
<tr>
<td>-------------------------------------</td>
<td>--------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>Employer</strong></td>
<td>Increased productivity due to less sick time taken by employees.</td>
</tr>
</tbody>
</table>

Table 4: External stakeholders and their future expectations.
<table>
<thead>
<tr>
<th>Public Health Agency</th>
<th>Prompt access to accurate data for reporting.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accrediting Agency</td>
<td>Access to data to find out if Healthcare Effectiveness Data and Information Set (HEDIS) requirements are being met.</td>
</tr>
</tbody>
</table>

The future requirements for the external stakeholders varied from less sick time taken by employees, to HEDIS data gathering for Accrediting agencies.

The proposed AHIE will provide the following benefits:

- Quality of care improvement by way of greater access to data and improved diagnostic accuracy. Physicians will be able to gain access to all the data required to effectively treat the patient. Embedded in HIE platforms are prompts, alerts and reminders built around evidence-based guidelines that suggest more thorough ways to query patients and more precise ways to address risk factors, co-morbidities and complex issues that might mitigate an otherwise “simple diagnosis.” Being able to address a host of complex issues and in what order requires synchronous data – accessed through real-time clinical knowledge management tools that are available in HIE’s. This provides the physician with more accurate interventions, especially in medication monitoring (Deloitte Center for Health Solutions, 2007)
• Reduction in costs achieved either through efficiency and productivity gains or avoidance of redundant services. Health providers will be able to check up on tests or procedures that have been performed on the patient and will result in fewer duplicate tests and services.

• Compliance accreditation and standards of care practices. HIE can assist with effects of EHR implementation and data exchange, on the quality of health care delivery.

Massachusetts Health Quality Partners (MAHQ) in collaboration with Massachusetts eHealth Collaborative (MAeHC) and Computer Science Corporation (CSC) have designed, developed, and are implementing an effective clinical quality measurement process using EHR data (see figure 3 below). This process includes selection of appropriate quality measures, identification of necessary data elements, report design, testing and validation and training of participating providers. The end product will be the production and distribution of EHR clinical performance feedback reports to participating providers, which will help them evaluate their performance and identify clinical areas for improvement (Massachusetts Health Quality Partners, 2008)
Figure 3: Clinical Quality Measurement Process

- Provide a reliable and secure connection to the pharmacy, which will generate more accurate medication lists and reduce adverse reactions. This will also assist legitimate prescribers by providing them with data to determine if, or ensure that, consumers are not receiving controlled substances from multiple prescribers, doctor shopping, or over-utilizing controlled substances. The AHIE is capable of allowing providers to access data that verifies consumers have not previously filled a prescription, or are not visiting numerous pharmacies with similar prescriptions from multiple physicians. Appropriately authorized and authenticated providers who use the statewide HIE could have access to data before prescribing or dispensing controlled substance (Maryland Health Care Commission, 2009)

- Better care coordination for the diabetic patient and other patients with chronic conditions. Primary care physicians (PCPs) are viewed by their patients as an influential
health coach, and these physicians consider chronic care management as in the case of diabetes a major focus of their profession. Optimal treatment for a chronic condition usually requires the expertise of specialists, nutritionists and even mental health counselors to change patient lifestyles. An HIE provides a cost-effective mechanism for members of the extended care team to work with the physician and patient to determine the best course of self-care management and to share information to better coordinate care, monitor outcomes and avoid costs associated with complications (Deloitte Center for Health Solutions, 2007).

- It will allow for more timely information about infectious disease and bioterrorism outbreaks, allowing for a more swift response and the potential to save many lives (Aspden, Corrigan, Wolcott, & Erickson, 2004)

**Business Case**

Improving the management of diabetic patients has been called an excellent model for health care reform. This is because:

- Diabetes is one of the three most common, chronic conditions in the U.S.,
- The prevalence of this condition is increasing dramatically, in parallel with the so-called obesity epidemic,
- Treating diabetes, and its complications, is extremely expensive,
- Future health care spending for diabetes is expected to increase, as more patients are diagnosed, and as the technology to manage it becomes more sophisticated,
- Over time, diabetes becomes more difficult and more expensive to manage,
- More medical complications arise over time, resulting in more costly hospitalizations and procedures, and
- Lastly, because the average diabetic patient has 5 co-morbid conditions (Kahn and Anderson, 2009)

The current reality of diabetic care is that patients require multiple office visits to multiple providers. This process demands a well-coordinated, multidisciplinary, and patient-centered approach. This can be accomplished by using the Patient-Centered Medical Home model. Kahn and Anderson recently described the patient-centered medical home “as team based and coordinated, but directed by a single physician. The result being well-orchestrated, continuous, comprehensive, and timely care that, hopefully, will reduce the overuse and misuse of services, and that will lead to better outcomes at reduced cost.” (Kahn and Anderson, 2009)

A fully integrated and interoperable office based electronic health record, that can readily communicate patient information between multiple providers, services, and the patient may offer a viable, integrated solution to the complicated management of the diabetic patient.

Another aspect of the business case relates to the escalating national focus on measuring quality outcomes within healthcare settings. The National Committee for Quality Assurance, or the NCQA, is a private, not-for-profit organization dedicated to improving national healthcare quality. It works with large employers, policymakers, doctors, patients, and health plans. The NCQA aggregates health plan provider outcomes for a variety of health care conditions, and
then publishes health plan report cards for comparative use by stakeholders. NCQA utilizes a standardized tool to measure outcomes, called the Healthcare Effectiveness Data and Information Set (better known as the HEDIS measurements). HEDIS measurements are included in the Quality Compass, which is an interactive, web-based comparison tool. It is the largest database of comparative health plan performance information and is used for competitor analysis, to examine quality improvement initiatives, and for benchmarking plan performance. For the purpose of our business case, we will look at one specific HEDIS performance measurement—the one that relates to comprehensive diabetes care. (NCQA, 2010)

These are the HEDIS measurements that we will be focusing on in this project:

- **HbA1c Management: Testing** Percentage of patients 18-75 years of age with diabetes who had one or more HbA1c test(s) during the measurement year.

- **HbA1c Management: Poor Control**: Percentage of patients 18-75 years of age with diabetes whose most recent HbA1c level during the measurement year is > 9%

- **Eye Examination** Percentage of patients 18-75 years of age with diabetes who had a dilated or retinal eye exam during the measurement year or a negative retinal eye exam during the prior year.

- **Foot Examination** Percentage of patients 18-75 years of age with diabetes who received at least one foot exam during the measurement year.

- **Blood Pressure Management** Percentage of patients 18-75 years of age with diabetes with most recent blood pressure less than 140/90 mm Hg.
- **Urine Protein Screening** Percentage of patients 18-75 years of age with diabetes who had at least one test for microalbumin during the measurement year; or who had evidence of medical attention for existing nephropathy.

- **Lipid Profile** Percentage of patients 18-75 years of age with diabetes who received at least one lipid profile (or ALL component tests).

- **Lipid Management: Control (<100 mg/dL)** Percentage of patients 18-75 years of age with diabetes whose most recent LDL-C level during the measurement year is <100 mg/dL.

You can see that certain laboratory tests must be ordered at certain intervals during the review period, and that certain laboratory outcomes must be achieved in the care of these patients. Furthermore, certain consultations (for eye and foot examinations) must be performed, at certain intervals. The results of blood pressure measurements at patient visits are also monitored. HEDIS measurements must be culled from different information sources and from different caregivers.

Quality outcome measurements are not just being used to measure and compare health plan performance. They are being increasingly used to evaluate how well private providers are managing chronic conditions like diabetes. The Center for Medicare and Medicaid Services has been authorized to offer incentive payments to providers who satisfactorily report quality measurement data. For the reporting year of 2009, physicians who care for eligible patients can earn incentive payments of 1.5% of their total allowed charges, under these Pay-for-Performance Initiatives. For the purpose of this project, it should be noted that the NCQA’s
Diabetes Program has been accepted as a registry for submission of P4P data on behalf of eligible providers (Centers for Medicare and Medicaid Services, 2010).

Another business incentive for providers to integrate the health information of diabetic patients, relates to provider recognition. In partnership with the American Diabetes Association, the NCQA has developed the Diabetes Recognition Program or DRP. Participation by eligible providers is purely voluntary. Eligible providers need to abstract quality data from the charts of 25 diabetic patients and submit that data to the NCQA for review. Data submission through provider software, specifically certified by the NCQA to be in compliance and compatible with their data collection and reporting requirements, is strongly encouraged. The Diabetes Recognition Program publically recognizes physicians who use evidence-based measures and who provide excellent care to their diabetic patients. A free, web-accessed physician directory is published to assist patients in locating doctors with this elite designation.

There are other financial benefits to being designated a "Recognized Diabetes Provider". In New York State, the insurance companies listed in this table offer enhanced reimbursement for diabetes care to recognized diabetes providers (Community Health Care Association of New York State, 2009).
The Bridges to Excellence Program/ Diabetes Care Link is another health quality initiative which offers physicians (recognized for providing excellent diabetes care) up to $200 for each of their diabetic patients covered by a participating health plan and/or employer. Recognized providers are promoted on their HealthGrades Physician Quality Ratings website. There are three paths to achieving Diabetes Care Link recognition. The third option entails electronic submission of quality data directly to IPRO. Data is entered into a standard file format and uploaded to the clinical data portal (Bridges to Excellence, 2010)

In summary, the business case for creating an integrated and interoperable health information system for the domain of caring for patients with diabetes includes:

- Providing an integrated solution for communicating patient information seamlessly across a multidisciplinary team of providers, managing a common, chronic medical illness,

- The ability to easily extract and monitor quality outcome measurements for diabetes care, across multiple providers and information sources,
• Improved individual patient outcomes, because all patient-related data is accessible at all visits,
• Fewer medical complications, due to an integrated, multidisciplinary approach,
• Possible P4P incentives,
• Diabetes Provider recognition, with the possibility of a higher volume of patients to the practice, and
• Greater patient satisfaction with the health care system and practice setting, due to fewer medical errors, less chance of missing information at each visit, and less duplication of tests and procedures.

**COMMON WORKFLOW SCENARIOS**

**CURRENT STATE**
Figure 4: Current state of information flow for a diabetic patient

The current state of workflow that exists today is complicated, and requires a great deal of effort and manual intervention to make it work. Diagram X represents the many different avenues of communication that are required to facilitate the care of one single diabetic patient. The figure specifically identifies the communication pathways that are necessary in addressing the HEDIS requirements for evidence-based medicine.

Diabetes care is especially vulnerable to today’s lack of interoperability, as is evident by the diagram. The need for interoperability amongst diabetes patient records comes mainly from HEDIS, and the guidelines that it has set forth in order to be ranked as a diabetes specialist. Meeting the HEDIS requirements comes with higher reimbursement rates, and higher patient
volume, which is why many physicians are moving towards this recognition (Bridges to Excellence website, Centers for Medicare and Medicaid Services website). However, the requirements that HEDIS have set forth are not typically satisfied by the PCPs records alone; they will need data from other areas to meet the criteria.

The diagram you see here depicts the current state of most diabetic patient’s records. There are seven key indicators that each provider must have in their diabetic patient’s charts if they wish to meet the HEDIS requirements: HbA1c, blood pressure, LDL cholesterol, eye examination, an annual foot examination, assessment for nephropathy, as well as smoking cessation advice and management (NCQA website, 2010). In the diagram there is an asterisk by the provider type that is needed to fulfill these specific requirements, as well a red colored line.

When inspecting this diagram, you will notice that the center image shows the primary care physician’s record of the patient, which is typically paper-based. This is where the PCP will aggregate data from all the ancillary providers that are needed for the HEDIS requirements by hand, through the communication methods identified in the diagram legend.

Looking to the top-left of the PCP file in the diagram, you will notice a standalone lab, like LabCorp, or Quest. The Lab provides us with the HbA1c, LDL, and Urine Protein results. Results such as these, if ordered by the PCP, will receive the results consistently from the lab. However, if the same lab tests are ordered while under the care of another physician, then the PCP would have to call the lab to get these results manually.
In analyzing the diagram, the next section to note is home glucose monitor. Physicians encourage patients to track their own glucose levels in order to keep a close eye on their levels. These machines can then be brought back to the physician, where they can check the device for the patient’s glucose history. However, many patients have a difficult time remembering to do this and that data cannot be counted on.

The Emergency Department is the next notable section on the diagram. Diabetic patients can end up in the ED if they feel light-headed, pass out, or if they have sudden issues with their vision or circulation. A patient’s visit to the ED typically goes unreported to the PCP. While in the ED, a patient can be placed on medication, and can also have several laboratory and radiological images ran while diagnosing the patient. These all need to be brought to the PCPs attention, but typically are not. Often times the patient will not even mention this visit to their PCP, so there is no feed-back mechanism to even let the PCP know to check their for test results or images.

One of the HEDIS requirements is an annual eye-exam, which is represented by the ophthalmologist in the diagram. The ophthalmologist will perform a routine eye exam, as well as check for vascular function in the eye. These results will typically have to be sought out by the PCP, and placed into the patient’s record by hand.

Moving on to the pharmacy, the diagram shows us that the pharmacy can tell the provider whether or not the patient is filling their insulin as directed, and whether or not they are on any other medications that may need to be brought to the attention of the PCP.
Patient hospitalization is next in line on the diagram, and this can occur for either diabetes related issues, or not. The PCP needs to be kept in the loop on labs, meds, and radiology results.

Next on the diagram we have a staff nurse who works for the PCP. The nurse will be entering in data to the chart directly. The nurse provides us with two of our HEDIS required data. Specifically, the nurse enters in the patients’ blood-pressure, as well as the smoking cessation and education requirements.

Diabetes patients need an annual foot exam to look for diabetes related issues, such as vascular function, and the PCP needs these results in their chart. The Podiatrist will not typically send the PCP the results automatically, which will require the PCP to retrieve these results manually.

The radiology box shows a standalone imaging center that the patient may use at the direction of the podiatrist, PCP, or any other provider. Those results could have bearing on the patients care, and should be included in their chart. Specifically though, HEDIS requires a neuropathy and a nephropathy assessment, which is typically done at the direction of the PCP in just such a place.

It is becoming more prevalent these days that patients meet with diabetes counselors, which is the next box. These counselors teach the patients how to avoid activities that can exacerbate their symptoms, or that can lead to more severe problems.
Next, we have the endocrinologist. Many PCPs will refer their patients to an endocrinologist for more advanced diagnostic care, or to take over the care of a patient with a particularly demanding case of diabetes.

Finally, we have the two sections at the bottom of the diagram. These show that both public health and accrediting agencies pull data from the PCPs chart in order to determine if a provider is meeting the HEDIS requirements, and also to aggregate data about the health of a regions population.

**Future State**

The future state of diabetes management in an ambulatory setting will be of a shared single source of information. This shared single source will allow all clinical providers that need access to the information to have access, to the right information, at the right time. It will allow for better managed care, with automated reminders and workflows. Allowing physicians to do what they do best, and treat patients.

We will now present three potential future states, centralized, federated, and hybrid models. The use of any of three models should be fairly transparent to the end user. However there are significant differences in architecture and infrastructure required.

**Centralized**

Below our centralized model is presented.
Figure 5: Centralized Model, 7 key indicators are indicated in red.

All the providers are linked together via a Central Health Information Exchange, each service provider is connected via two-way automated direct data exchange that allows service providers to upload data and query data as needed. As this is an information exchange, each service provider will need to communicate with other service providers in terms of referrals and special requests via manual communications such as email, fax, telephone, etc. However, the HIE can be further supplemented to including messaging and alerts. In this model, the patient will also have one way access to the information stored on the HIE, via a patient web portal. As well as external viewers such as auditors, public health, and insurance companies would be provided only 1 way access.
The centralized model offers many key features. The first is that it offers economies of scale for the technical infrastructure and enhanced security, as the service providers will only need to upload their data on a regular basis, or have the HIE automatically upload as necessary. As well, all contributed data gets stored and duplicated on the HIE Database. Now this model provides the least amount of administrative overhead for the participating providers, and the HIE will also be responsible for privacy and role-based access. Lastly, the model also requires a centralized master patient index which allows the HIE to link the records from the various participants. (Quinn, J. 2009)

Below our federated model is presented.
Figure 6: federated Model, 7 key indicators are indicated in red.

Now in the Federated model, you can see that there is no centralized database and that each provider connects to a Record Locator Service (RLS) and Master Patient Index (MPI). The RLS works much the way a search engine such as Google does, and locates patient data for the provider requesting data. Each provider connects to the Record Locator via two-way automated communications. As in our centralized model, each service provider will still need to communicate with other service providers via manual communications such as email, fax, telephone, etc. However, the HIE can be further supplemented to including messaging and alerts. The federated model can be further supplemented to including messaging and alerts.
Some of the key features of the federated model, are that all data resides with the provider, and that data is shared across the HIE. This allows each provider to retain control over its own data, and allow providers to retain their competitive advantage and data ownership. This model, also allows each provider to retain control of security and privacy concerns. However, there are some additional pre-requisites to the federated model. One is a highly reliable network with an advanced security framework in place. The network is connected to every clinical system, in all participating organizations. This model also requires all providers to meet response time Service Level Agreements (SLA). If providers are unable to meet SLA requirements, then critical data may not be shared in time. (Quinn, J. 2009, Just, B. & Durkin, S. 2008)

### Federated vs. Centralized

Now if we compare the Federated and Centralized models, there are very few similarities but in most cases they are on the opposite ends of the spectrum. In the case of control, privacy and security, the federated model allows the provider to retain control, permissions and access, whereas the centralized model provides little or none. In terms of performance, the centralized model offers the best all round performance; the cost of infrastructure is shared, in comparison to the federated model, and each provider must meet performance SLAs. (Quinn, J. 2009)

Some the challenges many HIEs, currently face are that vendor source systems are not designed to support HIEs nor are systems implemented with enough performance capacity to anticipate the needs of an HIE. (Just, B. & Durkin, S. 2008). To complicate things further, the US does not
have universal patient identifiers (Bartschat, W. et al. 2006). A Master Patient Index must be used to augment this deficiency, which can be costly, complex and less reliable. This could lead to False Negative or False Positive results, which would lead to insufficient or too much data being present.

- False Negative matches—this leaves out possibly vital information (e.g., current medicines or allergies) from the patient’s record while indicating that all available data has been retrieved.
- False Positives—this creates an even more undesirable condition where two or more patient’s data is effectively “intermixed” when presented to the HIE using physician.

Hybrid

Now this is our proposed Hybrid Model which is a combination of both the central and the federated model.
The hybrid model, allows the HIE some flexibility as our model places Labs, Medical Imaging and Pharmacy in a centralized model, with all direct care providers in a federated model. This model helps address the issue that many clinical providers would like to retain control of their data, yet allow some data to be shared in a centralized mode. In the hybrid model, patient data privacy protection is a shared responsibility of the HIE, Provider and user. The hybrid model requires the MPI and RLS services as in the Federated Model. However, this model requires a slightly higher amount of maintenance activities than that of a centralized model, but nothing as complex as a true federated. (Quinn, J. 2009, Just, B. & Durkin, S. 2008)
For the purposes of our project, our recommendation is for the hybrid model, as this will allow providers who are most concerned with keeping control to retain their control and yet allow for a centralized model for all results based data. However we ultimately chose this hybrid model, as it would allow us to attract the most number of participants. We are placing a high value on provider participation. Sufficient participation is vital to the success of the project as without it the data stored/accessible is incomplete, and could lead to medical error.

**USE OF STANDARDS**

The role of standards in the health information system environment is paramount. Standards are agreed on conventions for using terms, codes schemes, and processes (Lenz, Mario, & Klaus, 2005)

Healthcare is rapidly changing from isolated treatment episodes and moving towards a continuous treatment that involves multiple health care professionals and various institutions. Diabetes management is no different (Lenz, Mario, & Klaus, 2005). A chronic illness like diabetes requires different providers to adequately manage the patient. The diagram below illustrates the internal stakeholders that require access to the EMR. Internal stakeholders are directly involved with the patient.
Figure 8: Internal stakeholders that need access to clinical patient data.

Healthcare Organizations will also need access to patient information. Below is a diagram depicting the organizations that will need access.
A variety of healthcare communication standards (HCS) have been developed during the last decade. They have improved the interoperability and the connectivity in open hospital information systems to a large extent (Dudek, 1998).

The table below lists the proposed standards to be used in the Diabetes Ambulatory project.
### Table 6: Data elements with standard recommended and type of standard.

<table>
<thead>
<tr>
<th>Data</th>
<th>Standard</th>
<th>Standard Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient demographics</td>
<td>HL7 v3.0</td>
<td>M</td>
</tr>
<tr>
<td></td>
<td>HL7 CCD</td>
<td>DS</td>
</tr>
<tr>
<td>Chief complaint</td>
<td></td>
<td></td>
</tr>
<tr>
<td>History of present illness</td>
<td>HL7 v3.0</td>
<td>M</td>
</tr>
<tr>
<td>Past Medial History</td>
<td>HL7 CCD &amp; CDA</td>
<td>DS</td>
</tr>
<tr>
<td>Family History/Social History</td>
<td>SNOMED-CT</td>
<td>T</td>
</tr>
<tr>
<td></td>
<td>ICD-9</td>
<td>T</td>
</tr>
<tr>
<td>Problem List</td>
<td>SNOMED-CT</td>
<td>M</td>
</tr>
<tr>
<td></td>
<td>HL7 CCD &amp; CDA</td>
<td>T</td>
</tr>
<tr>
<td>Insurance Information</td>
<td>HL7 v3.0</td>
<td>M</td>
</tr>
<tr>
<td></td>
<td>HL7 CCD &amp; CDA</td>
<td>DS</td>
</tr>
<tr>
<td>Procedures (non x-ray)</td>
<td>HL7 v3.0</td>
<td>M</td>
</tr>
<tr>
<td></td>
<td>HL7 CCD</td>
<td>DS</td>
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<tr>
<td>Vital Signs</td>
<td>HL7 v3.0</td>
<td>M</td>
</tr>
<tr>
<td></td>
<td>HL7 CCD</td>
<td>DS</td>
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<tr>
<td>Diagnosis</td>
<td>ICD-9 CM</td>
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<tr>
<td></td>
<td>SNOMED-CT</td>
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<td>Allergies</td>
<td>SNOMED-CT</td>
<td>T</td>
</tr>
<tr>
<td></td>
<td>UNII</td>
<td>T</td>
</tr>
</tbody>
</table>

- **M**: Messaging
- **DS**: Data Structure
- **T**: Terminology
Table 7: Data elements with recommended standard and type of standard.

<table>
<thead>
<tr>
<th>Data</th>
<th>Standard</th>
<th>Standard Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current Medication</td>
<td>RxNorm</td>
<td>T</td>
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<td></td>
<td>NDC</td>
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<td></td>
<td>HL7 v3.0</td>
<td>M</td>
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<tr>
<td>Billing Information</td>
<td>ICD-9 CM</td>
<td>T</td>
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<td></td>
<td>CPT-4</td>
<td>T</td>
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<td></td>
<td>SNOMED-CT</td>
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<td>Radiology Procedures</td>
<td>DICOM PS 3.12</td>
<td>M</td>
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<tr>
<td>Lab Orders and results</td>
<td>LOINC</td>
<td>T</td>
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<td></td>
<td>ELINCS HL7 Release 1</td>
<td>M</td>
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<tr>
<td>E-Prescribe</td>
<td>NCPDP SCRIPT standard version 8.1</td>
<td>M</td>
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<tr>
<td></td>
<td>RxNorm</td>
<td>T</td>
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<tr>
<td>Submission to Public Health Agency (Surveillance, Reports and Labs)</td>
<td>HL7 v3.0</td>
<td>M</td>
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<td></td>
<td>LOINC</td>
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<td>HL7 CCD &amp; CDA</td>
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<td></td>
<td>ASTM CCR</td>
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<tr>
<td>Accrediting Agency (Quality reporting)</td>
<td>HL7 v3.0</td>
<td>M</td>
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<td>HL7 CCD</td>
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<td>HL7 CDA</td>
<td>DS</td>
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<td></td>
<td>ASTM CCR</td>
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The HL7 messaging protocol for electronic data exchange in healthcare is the most widely used medical messaging standard in the US and in more than a dozen other countries, while the HL7 CCD was chosen because the CCHIT certification criteria require all ambulatory and inpatient EHR’s to be CCD compatible, making CCD the preferred standard for clinical document exchange as we move forward into the future. CCD is supported by the following coding systems CPT-4, ICD-9CM, LOINC, NDC, RxNorm and SNOMED CT (Klann & McCoy). CCD was developed as a collaborative effort between ASTM and HL7 combining the benefits of ASTMs.
Continuity of Care Record (CCR) and HL7 Clinical Document Architecture (CDA) specifications. SNOMED-CT was recommended because of its global appeal. SNOMED-CT has been refined and expanded for more than four decades and is now considered the most comprehensive international and multilingual clinical reference terminology in the world (Mervat, Grostick, Hanken, & Jacobs, 2007). UCUM is a code system that covers all units of measures used in international science, engineering, and business with its main focus is on electronic communication, as opposed to communication between humans. RxNorm was chosen over the NDC standard as it covers both prescription and non-prescription medications. LOINC is recommended for lab results. It can also be used for ECG, administrative notes and lab orders. CPT-4 will be used for billing and diagnostic procedures. It is also used to document the justification for a procedure. ICD-9-CM is a classification of diagnosis and disease codes. Version 9 is suggested since that is still what is being used in the United States.

The EHR-Lab Interoperability and Connectivity Standards (ELINCS) is a practical, real-world solution to solve the business problem of sending electronic reports between labs and ambulatory care units while the NCPDP SCRIPT Standard V8 is a messaging standard used to transmit prescription data between pharmacies, prescribers, intermediaries and payers. HL7 3.0 and LOINC have been proposed for communication between the Public Health Agencies and the HIE. While the HL7 3.0 and HL7 CCD have been proposed for the HEDIS performance measures data.

CCOW and IHE will be proposed as the Integration standards. Metadata is of high importance to our interoperability project. Metadata is processed by computers and transmitted electronically
across networks such as the Internet. In order for metadata to be used and communicated consistently among different systems (interoperability), its structure must be standardized for different computers and network. Metadata are essential for the data integrity in the database. Controlled vocabularies used for descriptive metadata include the Medical Subject Headings (MeSH), SNOMED, ICD-9.

**DATA STRUCTURE STANDARDS:**

In order to exchange health care data among the many providers within our ambulatory care model, we need to comply with structured document standards set forth by the Healthcare Information Technology Standards Panel. According to HITSP/CAP 119, titled, “HITSP Communicate Structured Document Capability”, released January 31, 2010, the HL7 Clinical Document Architecture (CDA), is an acceptable document standard for our use. CDA is an XML-based, electronic standard that conforms to the HL7 V3 Implementation Technology Specification (ITS), is based on the Reference Information Model (RIM), and uses HL7 V3 data types. (Corepoint Health 2009) “HL7 developed the CDA (R2 in 2005) to provide a common representation for clinical documents through a document markup standard that specifies the structure and semantics of clinical documents. A CDA document is a defined and complete information object that can include text, images, sounds, and other multimedia content. Since CDA derives its content from the HL7 Reference Information Model (RIM) it is specifically designed to integrate with current HL7 technologies.” (Ferranti et al., 2006) The defining characteristics of all CDA documents are persistence, stewardship, wholeness, human readability, and the potential for authentication. The benefits of using CDA in our HIE is that it
is a flexible standard. The body of the document contains a mandatory human readable narrative text, and an optional structured part permits electronic processing. Our health information exchange encompasses many providers and many encounters, and the CDA data structure standard can be used for a number of document types, including hospital admission summaries, outpatient progress notes, emergency room discharge summaries, and radiology reports. “CDA does not specify a transport mechanism and can be utilized within a messaging environment or independently of it. Transport methods can include HL7 v2, HL7 v3, DICOM, MIME-encoded attachments, HTTP, or FTP”. (Corepoint Health 2009)

The ASTM Clinical Continuity of Care Record is another standard we can use for data structure within our proposed health information exchange. CCR-compliant XML documents are compatible with standard HL7 messages and are human readable using a standard Web browser. CCR facilitates the transfer of summary information. While CDA is “document-centric...the CCR was designed to focus on the data elements rather than the documents” (Ferranti et al., 2006) The CCR pools the relevant administrative, demographic, and clinical information from multiple medical documents, from multiple encounters and providers, to create a snapshot of the patient in time, that can then be transmitted to other providers within the HIE. The CCR can be transmitted electronically between providers, or even printed out, so the patient can manually carry it to the next provider. If a patient moves from one geographic location to another and changes primary care physicians, or changes endocrinologists, a summary of that patient’s medical problems can be moved along with the patient, using the CCR. It is crucial then, that all transactions, including open Internet transactions and data on portable digital media, such as USB drives, are secure. (ASTM, 2005) An additional benefit of
using the CCR data structure standard in our model for managing the patient with diabetes is that there are optional extensions that can focus on evidence-based guidelines and quality performance measurements for diabetes.

While CDA and CCR both facilitate electronic exchange of clinical data between physicians, pharmacies, other providers, and EMR systems, they are not compatible with each other. The Clinical Care Document (CCD) harmonizes the two standards by using the CCR within the broader context of CDA. The CCD shares summary information about the patient, but it is also human readable and can incorporate aspects of the patient’s personal health record. “CCD is built on CDA elements, but the data itself is defined by CCR. CCD uses a detailed set of constraints, or templates, for CDA elements (i.e. header, purpose, problems, procedures, family history, social history, payers, advance directives, alerts, medications, immunizations, medical equipment, vital signs, functional stats, results, encounters, and plan of care). The scope of the clinical data itself, within the templates, is set by CCR.” (Corepoint Health 2009) Figure 10 is an example of a continuity of care document, developed by AxSys Health Corp, using their “Excelicare Solution” software. The red arrows in the figure highlight the CDA elements within the document.
Figure 10: The AxSys Health Corp Excelicare Solution supports the exchange of continuity of care documents in multiple formats (www.axsyshealth.com)

The continuity of care document standard is particularly valuable to our proposed health information exchange model, as it can be used to monitor quality measurements and pay for performance indicators for diabetes management. Figure 11 illustrates how the Excelicare Solution application, developed by AxSys Health Corp, specifically monitors performance indicators for diabetes mellitus within their continuity of care document.
Figure 11: The AxSys Health Corp Excelicare Solution Continuity of Care Document can be used to monitor performance measurements for diabetes management (www.axsyshealth.com)

The HL7 CDA RIM-based specifications, that form the base of CCD, are widely compatible with existing applications, browsers, EMRs and legacy systems. “CCD encourages the implementation of XML for clinical document exchange…In June 2008, CCHIT published its final approval criteria which requires all ambulatory and inpatient EHRs to be CCD compatible in order to become CCHIT certified. This means being able to send and receive clinical documents in CCD format.” (Corepoint Health 2009) By using CCD in our health information exchange model for diabetes management, we are on the cutting edge of data structure standard use for moving clinical documents across interoperable healthcare systems. Figure 12 demonstrates how the AxSys Health Corp Excelicare Solution product unifies disparate information.
technology systems, through a shared, patient-centric, information architecture, to create a composite patient CCD. Though we will be using a more complicated information architecture for our proposed health information exchange, the concept of developing a composite CCD from multiple IT systems, is similar.

Figure 12: AxSys Health Corp Excelicare Solution unifies disparate IT systems through a shared information architecture (www.axsyshealth.com)

The actual transfer of clinical information between providers within our proposed HIE, utilizing the CCD data structure standard, can be demonstrated using the example in figure 13. This figure illustrates how data is exchanged with CCD using the Microsoft HealthVault application. (Wagner 2009)
The primary care physician on the left of this diagram sends referral form data from his/her EMR to a specialist within another EMR on the right. That specialist replies to the primary physician with referral data. An encrypted CCD document is then sent from the primary physician to the specialist, which is displayed on the latter’s EMR. While CCR would permit similar exchange of summary healthcare information between these two providers, it would NOT allow narrative text to be communicated. The advantage of CCD, as illustrated here, is that narrative information, important for the continued care of the patient, is not lost in the data exchange. Lastly, a reconciliation process permits the specialist to extract and enter discrete data types from the uploaded document into his/her EMR. This process is represented in figure 14, using the Microsoft HealthVault application. (Wagner 2009)
There are considerable challenges in mapping vocabulary standards within the domain of diabetes management. First, making a diagnosis of diabetes is based on different criteria. “In the United States, diagnosis is typically made on the basis of fasting plasma glucose (FPG) of 126 mg/dl or above or a random blood glucose of 200 mg/dl, with classic symptoms, while in Europe and in clinical trials, a 2 hour plasma glucose of 200 mg/dl or greater on an oral glucose tolerance test (OGTT) is the preferred method. Unfortunately, both tests have rather limited overlap, meaning that most persons diagnosed by an FPG would not be diagnosed by an OGTT, and vice versa. Furthermore, the two tests can produce different results for the same person on different days“. (Nathan 2007) In 2010, the American Diabetes Association (ADA) for the
first time officially endorsed the use of HbA1C as a fourth option for diagnosing diabetes, with a cut-off point of 6.5% or greater. Interestingly, however, in a 2005 survey of 258 internists, 93.4% reported that they routinely screened for diabetes, 49% reported using HbA1C for screening and 58% said they used it for diagnosis of diabetes. Forty-nine percent mistakenly thought HbA1C was already an approved screening test. (Saudek et al 2008)

Furthermore, the various terminologies of diabetes subtypes and the granularity of coding related to medical complications of diabetes add to the mapping challenges. One doctor may use the terminology ‘type 2 diabetes’, while another may use ‘type II diabetes’, and a third doctor may use ‘non-insulin dependent diabetes’, and a last doctor use ‘NIDDM’, all for the same subtype of diabetes. Similarly, some doctors mislabel patients who are ‘type 2 diabetics using insulin only for better glycemic control’ (i.e. insulin-requiring type 2 diabetics), as type 1 diabetics (which means the patient is dependent on insulin to live). This can create serious problems when data is aggregated. Also, there is a prodromal stage of diabetes that has been referred to by various names, including ‘pre-diabetes’, ‘impaired fasting glucose’, or ‘impaired glucose tolerance’, depending upon how the abnormality is detected.

ICD9 coding for diabetes is equally complex, since it captures whether the patient is type 1 or type 2, whether glycemic control is controlled or uncontrolled, whether there are vascular complications, if there are acute metabolic complications, and if end-organ complications exist. Note the granularity of coding in the ICD 9 coding listed below. Implementation of ICD10 codes will be even more specific.
**Note: for 249-259, the following fifth digit can be added:**

- (250.0) **Diabetes mellitus type 2**
- (250.1) **Diabetes mellitus type 1**
- (250.2) **Diabetes mellitus type 2, uncontrolled**
- (250.3) **Diabetes mellitus type 1, uncontrolled**

**Secondary diabetes mellitus**

- (249.0) Secondary **diabetes mellitus** without mention of complication
- (249.1) Secondary **diabetes mellitus with ketoacidosis**
- (249.2) Secondary **diabetes mellitus with hyposmolarity**
- (249.3) Secondary **diabetes mellitus with other coma**
- (249.4) Secondary **diabetes mellitus with renal manifestations**
- (249.5) Secondary **diabetes mellitus with ophthalmic manifestations**
- (249.6) Secondary **diabetes mellitus with neurological manifestations**
- (249.7) Secondary **diabetes mellitus with peripheral circulatory disorders**
- (249.8) Secondary **diabetes mellitus with other specified manifestations**
- (249.9) Secondary **diabetes mellitus with unspecified complications**

**Diabetes mellitus**

- (250.0) **Diabetes mellitus** without mention of complication
- (250.1) **Diabetes with ketoacidosis**
- (250.2) **Diabetes with hyposmolarity**
- (250.3) **Diabetes with other coma**
- (250.4) **Diabetes with renal manifestations**
- (250.5) **Diabetes with ophthalmic manifestations**
- (250.6) **Diabetes with neurological manifestations**
- (250.7) **Diabetes with peripheral circulatory disorders**
- (250.8) **Diabetes with other specified manifestations**
- (250.9) **Diabetes with unspecified complication**

*Figure 15: ICD-9 Classification for Diabetes Mellitus*

In addition, comparison of laboratory results can be challenging within the domain of diabetes. Most clinical laboratory systems in the United States report glucose results in mg/dl units, while many research laboratories report the results in mmol/L. Plasma glucose levels, moreover, may not be exactly equivalent to the capillary glucose levels derived from finger stick testing. Assays for glycosylated hemoglobin levels also contribute to vocabulary mapping challenges. ‘Glycosylated hemoglobin’, ‘HbA1C’, and ‘A1C’ levels may all refer to the same laboratory test,
but older laboratory systems were not standardized for direct comparison between different assay methods.

Lastly, some specialty-related terminology, particularly, within narrative ophthalmology documents, is difficult for other physicians to interpret and for mappers to standardize. Hwang et al. assessed intercoder agreement for ophthalmology concepts by three physician coders using five controlled terminologies (ICD9-CM, CPT-4, LOINC, SNOMED-CT, and Medical Entities Dictionary). “The proportion of complete intercoder agreement ranged from 12% (LOINC) to 44% (SNOMED-CT), and the difference in intercoder agreement between LOINC and all other terminologies was statistically significant (P<0.004)” (Hwang et al 2006)

DATA CONSISTENCY AND INTEGRITY

Ensuring data consistency and integrity across the information exchange model is imperative for direct patient care, quality and performance measurements, patient safety initiatives, research, public health reporting, and other administrative uses. The American Health Information Management Association’s (AHIMA) November 2008 Statement on Data Stewardship recommends creating a partnership of stakeholders within the health information exchange to set uniform rules and requirements to ensure uniformity and consistency of data. We will implement the following of their recommendations, to assure data consistency and integrity across our health information exchange.

• Ensuring that information is collected once and repurposed many times
- Defining the data exchange model and the specific data to be exchanged, based on our RHIO’s mission, vision, purpose, and goals

- Developing standards for acceptable data quality and data quality measurement, that will be required of our participants,

- Assessing the process to capture patient identity, as well as its consistency across each of the RHIO’s participating organizations,

- Auditing the accuracy of the electronic linking of records within the RHIO and providing evidence of the accuracy rate,

- Auditing the accuracy of the clinical documentation within the RHIO’s participants’ EMRs and reporting the results to the governing board,

- Enabling an effective method for standardizing release of data to approved agencies and organizations.

- Developing privacy and security policies, regarding methods for accessing the RHIO system, provisioning, authorizing, and authenticating users, and auditing access. (AHIM 2008)

STANDARDS IMPLEMENTATION RISKS:

While there are many benefits to implementing standards, there are also inherent business, financial, technological, and organizational risks. For instance, there are (re)training costs, new business rules, lost productivity, coding backlogs, and reduced cash flow to consider in any
implementation and/or upgrade of standards. Also, systems, interfaces, and storage space in databases need to accommodate coding changes (for instance, an upgrade from ICD9 to ICD10). Participants in the RHIO need to review, amend, and/or replace vendor, clearinghouse, and health plan contracts to accommodate new data standard requirements. Mapping strategies, billing forms, and practice workflow need to all be revised with the evolution of HIE industry standards.

There are also multiple standards to choose from that do the same thing or similar tasks such as RxNorm & NDC. While some standards overlap like SNOMED and ICD-9. Lastly, there is always a risk of having to replace or update software systems to permit new electronic standards in the future. (Ingenix 2008)

**Information System Requirements**

The objective of our Information Systems Requirements is not to simply digitize clinical data/workflows from paper to digital media, but to reap the benefits by moving clinical workflows to the digital workflows. By having a focus on digital workflows allows for timely access of patient information, in addition to standardized formats and standardized workflows across the entire continuum of care. Use can include quality monitoring, reporting, health management, and decision support. (Bernstein, W. 2009) We divided the requirements in to 6 categories.

- Interoperability
- Functional
- Technical
Interoperability is the ability of two entities, whether those are human or machine, to exchange and predictably use data or information while retaining the original meaning of that data. Not to be confused with interface engines which routes information from one system to another but stops short of enabling the second system to understand and use that information. There are two types of interoperability: syntactic and semantic. Syntactic is the ability to exchange the structure of the data, but not necessarily the meaning of the data. This is also referred to as the ‘functional’ interoperability. I.e., web pages built with HTML. Semantic guarantees that the meaning of the exchanged data remains the same at both ends of the transaction. I.e., Standards such as HL7 relies on XML markup language for the storage and movement of clinical documents between systems.

As a result two general requirements were developed for interoperability. The first is Multi Vendor Interoperability. Having multiple vendors being able to complete for business is vital to encourage new product development and fair pricing. Each system must work within the parameters of the standards established by the not only at the regional level, but at the state and national level as well. (HealthUnity, 2007)
The second is Extension to other Parties. Since a new system is being built, the new system must be designed to allow for the growth of the HIE only in size but in the services it provides as well as the types of service providers that will connect. Having new services such as blood banks, or services that do not currently exist, is an important consideration. This will allow for a diverse and complete network to be building with access to all possible health information.

(HealthUnity, 2007)

**FUNCTIONAL**

For Functional Requirements, a slightly different approach was used, and made our requirements results based, as well as features based. Functional Requirements were divided in to eight sub-categories. Taking a results based approach was important as it allows for the focus to be on the end results, not just the features of the system. The features are ultimately what are needed to meet the end results, but focusing on just the features can be short sited. The goal of the HIE is to benefit our end patients as testified by W. Bernstein in 2009.

Requirements must also be created to ensure that participants in HIEs use information to improve care coordination, reduce medical errors, promote wellness, advance public health, and pursue any other number of laudable health improvement objectives. Additionally EHR incentive payments must be tied to a recipients’ participation in clinically-driven programs that are proven to improve the quality of health care, while at the same time reducing unnecessary health care expenditures. Furthermore, data must allow advanced clinical decision support and clinical intelligence to identify gaps in care
from evidence-based standards and to communicate with doctors and patients about issues that need to be addressed. (Bernstein, W. 2009).

The first is Extensibility or Future Growth. The business environment will always be changing, as we learn more about HIEs, and with this comes changes to technology, laws, standards and practices, and the system must be adaptable to these changes. The system must be able to accommodate new version of standards such as new HIPAA regulations, as well as HL7 and new services. (HealthUnity, 2007)

The second is Rich Client Support. This is important since not all providers currently use an EMR, and with no vendor currently providing HIE support, the new system must provide an rich client support with a non-EMR support. It may be unrealistic to require all service providers to have an EMR in place to join the HIE, as this will place a significant barrier in preventing service providers from joining and using the HIE. The rich client application must allow for high level of interaction as well as be user friendly and support basic clinical features such as search, data entry and review. The client must allow providers to download information and have a collaborative feature that allows clinicians to team up and provide better service. (HealthUnity, 2007)

The third is Manageability. HIE can potentially connect to thousands of nodes which process, collect and disseminate data. This network, could potentially service a few thousand to millions of nodes depending on the scale of the HIE. Providing service to all these nodes is a non-trivial task, and the management of all the pieces involved as to be distributed between the HIE and
service providers. The system must be designed so that local administrators can be effectively and manage their portions of the system. Incorporating this in to the design is a key feature to reduce the IT skills needed at each service node. (HealthUnity, 2007)

The forth is Compliance. Having a system that is compliant to key standards such as HL7, as well as legal in HIPAA is an obvious requirement for the system. However a key item is that the system be designed in way that it be adaptable to new and changes in standards as they occur. Examples of standards the system should comply with are: HIPAA, HL7, XML, SOAP/Web Services, CCR etc. (HealthUnity, 2007)

The fifth is Standards Support. Standards support is key feature, as without being able to support these various vertical and horizontal healthcare and industry standards will severely impact the HIEs ability to attract new providers and its ability to function. The following standards are worth considering as indicated by HealthUnity in 2007: (HealthUnity, 2007)

- HL7: Standard HL7 messages must be used when communicating with backend systems, as well as with network services such as Labs. This enhances the interoperability of the solution and makes it easier to integrate with other systems.
- Secure Web Services and SOAP: All inter-node communications as well as client-server communications must be performed through standard transport and communication layers. SOAP and XML web services are the emerging standards for this type of communication, and is supported on all major platforms today
- WS-I (Web Services Interoperability): The system must comply with the WS-I basic profile for web service communications.

- WS-Security: for secure communications between nodes in the system

- XML: The system must be capable of exchanging information with other parties using XML versions of HL7 documents. This enhances interoperability.

The sixth is Patient Involvement. As clinical practice becomes more focused on the patients, as well as patients become more informed about their own care, patients are requiring more access to their own health information. As a result, the HIE must be allow patients to access their data, yet still maintain privacy and security. (HealthUnity, 2007)

The seventh is Customer Focus. Although the clinical mode is moving toward a patient focused approach, the primary consumer for the HIE still remains the physicians and clinicians. By having the system include patients, the system benefits the ability of physicians and clinicians to provide better service. (HealthUnity, 2007)

The eighth is Use Cases. To provide complete return on investment, the system must focused on digitizing workflows. Having the system be able to accommodate key use cases, the ROI can be significantly improved. Listed here are 7 minimum use cases that must be met.

(HealthUnity, 2007)

- Patient demographics information sharing and updates
- Emergency data propagation and retrieval
- Electronic Referrals
• Patient online check-in to practice
• Electronic Lab Ordering and Results delivery
• Electronic Prescription filling
• Inter-Physician secure messaging

TECHNICAL

Technical requirements were broken down into two main categories, Scalability and Cost Effectiveness, with the focus on the benefit our end patients as testified by W. Bernstein in 2009.

The HIEs must be designed and built in ways that take maximum advantage of Internet-based architecture and common HIE protocols. The system must be Technology agnostic and vendor neutral, to achieve inherent scalability, as well as an over-reliance on proprietary systems results in one-off custom integrations, ends up being expensive and brittle. Furthermore, proprietary systems are limited in use and scalability.

Technical requirements were divided into two subcategories. (Bernstein, W. 2009).

The first is Scalability. Since this a Health Information Exchange, the size of the exchange cannot be limited. Potentially, the system must be able to accommodate exchanging information with the entire nation, and this is of key requirement. Each HIE will be focused on providing information for a specific region, but must be scalable with all the other HIEs in the nation. (HealthUnity, 2007)
The second is Cost Effectiveness. The majority of physician and clinical practices have limited budgets, and in order to convince them to join a HIE is not a simple task. In order for this group to consider joining the HIE, must be able to show that the system will show them immediate benefit, and be able to provide this benefit almost immediately. The system must also have a low barrier of entry, with no IT staff requirement and this should result in reaching underserved communities. Another aspect to this is the HIE’s ability to serve underserved communities. This means that HIEs must somehow be able to service communities with limited internet access and limited funding. (HealthUnity, 2007)

**Performance**

Considering that our HIE partly employs the federated model, performance is a concern that cannot be marginalized. As discussed earlier, we plan to encrypt the data in both our centralized database, as well as within each of the federated data sources. Decrypting that data add time to the overall process, as will using a secure connection, such as SSL, which we plan to use to ensure our network traffic is secure from prying eyes.

Since everything but our laboratory and radiology data is retrieved with a distributed call to the remote data sources, latency and corruption become an issue. To address the latency issue, we propose that a time limit be placed on how long the record locator service will wait for responses before it returns results to the user. Something on the order of 3 seconds would suffice. This time is simply how long it takes the remote systems to send us an acknowledgement that it has data or not. The timer does not include sending the actual data...
itself, which may take longer depending on the type being returned; radiology data takes longer to retrieve than does simple laboratory results.

Since a time limit is being imposed for performance reasons, there will need to be a way to let the user know that there is more data in the HIE that they are not seeing. It is also possible that data that takes too long to get back to the user could be spun off on a new thread on the RLS, and its data can make its way to the user when it can.

Although it is possible to call the HIE for data every time, there is expense that comes in doing so. Instead, it could be possible to gather the data from the HIE, and then download it to the users local EMR. Once the data is stored locally, subsequent calls to the HIE may not become necessary. This may cause staleness issues if the patient has had several new results after the data has been cached locally.

One final performance concern for our HIE, any HIE really, is simply the type and amount of searches being done on the system. Running just a few resource intensive reports can bring the system to a crawl if not put in check. It is recommended that a separate reporting database, or data warehouse be created, and that reports and analytics be performed against that, rather than against the production database.

**Privacy and Security**

Privacy is of the utmost importance for many users and patient rights groups, and there is a plethora of data available on this topic. Many of these groups have come up with some well
thought out ideas on how to best ensure patients privacy when their information leaves the confines of the single physician’s domain. Our proposed hybrid model exposed pieces of the patients profile to anyone with access to the data. However, that does not mean that every provider should be able to see every aspect of the patient’s record, which is central theme to patient privacy concerns.

Access to the data within the HIE should be as granular as possible. Granularity of data access should be reinforced by levels of access to the system; a billing clerk would need only a procedure code, whereas a surgeon might need a complete medical history. Ideally, the system would not be used for administrative purposes to begin with, so a billing clerk would not have access to the patient data anyway.

Another central theme to patient privacy is that chart access needs to be logged, and patients be given the right to review those logs. The patient should be given this control, and should be able to be certain that their dentist does not have access to their mental health records, or that like-kind infractions are not occurring. Patients also need the right to view their electronic medical record in its entirety, and be allowed to report or protest any anomalies. HIPAA already gives patients the right to view their paper based medical records on demand, and presumably that same right will transfer to its electronic counterpart.

Several patient rights advocate groups have also expressed a desire to receive disclosure of how their records are used, and for what purpose. There is an expectation of doctor-patient confidentiality under normal circumstances. However, there are questions about how that
confidentiality will hold up in a system such as an HIE where people other than their doctor can view their data. Patients have been known to withhold critical information about their medical problems; for fear of someone other than their doctor would view it, and possibly be embarrassed by it. This of course hampers diagnosis and treatment, and is of growing concern.

Many organizations de-identify their patient data and send it to other organizations for research, or to public health agencies for reporting. Patients have asked for the ability to know who else will get their data in this manner, and be given the opportunity to decline participation in such activities. Studies have found that many organizations don't have a way to handle this opting out by patients, even if they express their desire to do so.

Several other interesting ideas that have come from patient rights groups are that they feel healthcare organizations should collect the minimum amount of information needed for their specific purpose, and nothing more. There should also be and established processes to ensure data are only used for purposes agreed to by the patient, and which has been disclosed to them.

Even if patients are given access to review their chart access, patient advocate groups have asked that the healthcare organizations themselves proactively monitor electronic chart access, and look for potential breaches, from either employee abuse, or external access from unauthorized personnel, such as dentists to view mental health data, break-glass, or even hackers. In the event that a breach does occur, there should also be an established mechanism
for handling complaints, as well as remedies for affected parties to compensate them for any harm caused by breach.

Patient rights groups have advocated that the federated HIE model be used over the centralized model. These groups feel that having all the constituent pieces of a record in several different places would make it much less likely that a single attack or breach will give anyone unlimited access to the entire record. Along those same lines, advocate groups also wish that all data stores, either centralized or federated will store data as encrypted text, rather than as plain text.

Outsourcing transcription and radiology to other companies or even other countries poses a special security consideration. There was a case reported where an employee in Asia who received medical records for medical billing transcription had threatened to post the records online, if the hospital did not pay back wages (Lazarus, 2003). There are several legal issues raised when a patient record crosses international and domestic borders.

There is a legal framework that exists for use in cases such as these, which is known as DURSA. DURSA is a legal framework for maintaining security across multiple data sources, and pertains mainly to the protection of PHI (personal health information). Key components of the DURSA include the extension of HIPAA to all participants on the NHIN. HIPAA is the baseline for all activities related to NHIN, but local and state laws that go beyond HIPAA are not preempted. DURSA also provisions for limited permitted uses of data (e.g., neither use for research or legal/enforcement is allowed). The framework goes on to state that all participants must
respond to a data request from an NHIN member. One is not required to share data, but must at a minimum acknowledge request for data. Finally, DURSA states that once data is transferred to a recipient, that the data is now owned by the recipient and they can share/exchange data anyway they see fit that is in conformance to their policies (DURSA reference).

**Usability**

Many of the decisions that have been made when setting up privacy and security for our HIE could potentially affect its overall usability. For example, if data is so locked down that it is hard to get at the data we need, such as with frequent authentication, then the system becomes less useable. There is a balance to strike though. Entering in your credentials one time should be sufficient. One should not have to enter them in for each type of data they wish to view.

Process and workflow affect usability perhaps the most visibly. If it is cumbersome to perform simple or repetitive tasks, then the system has also lost usability. However, when compared to paper based equivalents, usability is seen in a different light. More users can see the same record at a single time. Auditing, security, and backups can be leveraged to all provide a better usability experience than was previously possible. Perhaps most important however, is that any workflow changes should above all else, not increase barriers for physician use.
The speed of the HIE is also affected by our security and privacy policies set forth. A federated model already has inherently slower access, due to its distributed architecture. Add to that time for encrypting and decrypting data from the database, plus the use of SSL for our data transmissions and the time to receive data goes up, which ultimately affects our systems usability. Usability can also be affected by the staleness of data. In some HIE models, rather than querying for data constantly, some choose to store it locally, and only refresh it every 24 hours or so. That works in most cases, but its possible that you are not seeing all the most current data. Once a physician sees inaccurate information in the system even one time, the overall usefulness of the system in their mind has gone down significantly.

**Information Architecture**

As stated earlier, the Hybrid Model was chosen for our Information Architecture, which is a combination of both the central and the federated model.

*Figure 16: Information Architecture - Hybrid*
The federated portion of our architecture has no centralized server, and all data is stored on each provider’s systems. Data is queried and provided in real time. The system incorporates a Record Locator and Master Patient Index to allow records to be searched and retrieved quickly. The architecture also includes a messaging & alerts server that allows each node of the system to message other nodes with information and requests. As well, clinical reminders are kept tracked by this server, with alerts sent out when necessary. The main benefit to this architecture is that it allows clinical providers to retain control of their data.

This hybrid model, allows the Labs, Medical Imaging and Pharmacy to be in a Centralized model, which is supported by a health information exchange. This architecture offloads all
responsibility of storage, distribution and privacy to the HIE, and allows these providers to focus on providing care.

A decision support system could also be implemented in our model, specifically designed to alert the physicians when to order yearly eye exams, foot exams, HbA1C, LDL cholesterol, and urine protein testing. We can also take the decision support to a more active model, and based upon previous results and/or existing complications, the testing intervals will be modified. For instance, if the patient has well controlled diabetes, a HbA1c may be ordered twice a year. However, if the diabetes is poorly controlled, the next HbA1C should be ordered in 3 months.

Ultimately, this hybrid model allows the HIE to be flexible with our providers. However, this model requires a slightly higher amount of maintenance activities than that of a centralized model, but nothing as complex as a true federated, and the resulting benefit is that the added flexibility would allow more providers to join the network.

**Identification of the Origin of Individual Data Elements**

HEDIS measures apply to both preventive care and condition-specific care e.g. depression, diabetes, asthma to name a few. For the purpose of our project we will be focusing on the HEDIS measures that apply to diabetes.

For 2010 these are the HEDIS measurements for diabetes recommended by The National Committee for Quality Assurance (NCQA)
<table>
<thead>
<tr>
<th>HEDIS Measurements</th>
<th>Screening needed</th>
<th>How often</th>
</tr>
</thead>
<tbody>
<tr>
<td>HbA1c</td>
<td>HbA1c test</td>
<td>Quarterly</td>
</tr>
<tr>
<td>Eye examination</td>
<td>Retinal eye exam</td>
<td>Yearly</td>
</tr>
<tr>
<td>Foot examination</td>
<td>Foot exam</td>
<td>Yearly</td>
</tr>
<tr>
<td>Blood pressure</td>
<td>Blood pressure testing</td>
<td>Every visit</td>
</tr>
<tr>
<td>Nephropathy</td>
<td>Urine protein screening</td>
<td>Yearly</td>
</tr>
<tr>
<td>Lipid Profile</td>
<td>Fasting</td>
<td>Yearly</td>
</tr>
<tr>
<td>Smoking cessation</td>
<td>Counseling</td>
<td>Quarterly</td>
</tr>
</tbody>
</table>

The Decision Support System (DSS) will include reminders so that the physician can be reminded about when these need to be done. This will be particularly useful for physicians using the web portal to access information from the HIE.

Even the NCQA requests these tests to be done yearly, the professional standards for the care of the diabetic patient mandate more frequent measurements, based upon individual patient characteristics, complications, and response to treatment.
Different providers and organizations provide care to the diabetic patient and a lot of information is gathered. The Laboratory provides the HbA1c test information. The Lab also provides the Lipid profile and nephropathy test results. The nurse at the physicians’ office takes blood pressure readings. This is a test that may also be provided by the patient when they use a home blood pressure monitor and upload results to the web portal. Foot examinations are done by the Podiatrist at the request of the PCP and the results of the exam stored on the podiatrist’s system. The retinal eye exam is performed by the Ophthalmologist and stored on the local system of the ophthalmologist. The PCP or Nurse provides smoking cessation counseling to the patient. This can involve setting goals to help stop smoking and recommending resources to help them quit.

Once tests have been performed the results of the lab work are sent to the HIE. The blood pressure readings and smoking cessation information are stored on the PCP’s EMR. The DSS will include alerts to inform PCP when the requested information from the specialist or lab is received and also a notification if it is not received within a certain period of time. Below is a diagram detailing the different clinical personnel and organizations and the data they provide and where the information is provided.

Table 9: Clinical data elements with origin and location of data element.

<table>
<thead>
<tr>
<th>HEDIS Measurements</th>
<th>Provider of Information</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>HbA1c</td>
<td>Laboratory/</td>
<td>HIE</td>
</tr>
</tbody>
</table>
### Description of the Flow of the Data Sets Between Systems

Within our proposed health information system, certain data elements related to diabetes management must be freely exchanged between defined entities. For instance, it is imperative that patient self-monitoring results be available to the primary care provider and/or endocrinologist. Patients can download finger stick glucose results directly from their glucometers, and data regarding basal insulin rates, insulin boluses, and insulin sensitivity ratios directly from their insulin pumps onto software programs. These programs can graph trends in

<table>
<thead>
<tr>
<th>Test</th>
<th>Provider</th>
<th>System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient’s Nephropathy</td>
<td>Laboratory</td>
<td>HIE</td>
</tr>
<tr>
<td>Patient’s Lipid Profile</td>
<td>Laboratory</td>
<td>HIE</td>
</tr>
<tr>
<td>Patient’s Blood Pressure Testing</td>
<td>Nurse</td>
<td>PCP’s EMR</td>
</tr>
<tr>
<td>Patient’s Foot Examination</td>
<td>Podiatrist</td>
<td>Podiatrist’s system</td>
</tr>
<tr>
<td>Patient’s Eye Examination</td>
<td>Ophthalmologist</td>
<td>Ophthalmologist’s system</td>
</tr>
<tr>
<td>Patient’s Smoking Cessation</td>
<td>Primary Care Physician/Nurse</td>
<td>PCP’s EMR</td>
</tr>
</tbody>
</table>
glycemic control and insulin requirements at different times of the day, with different levels of activity, and during intercurrent illnesses. Home blood pressure measurements, patient weights, and meal diaries can also be directly communicated to the physician via a HIE patient web portal, via an email messaging server, via tele-monitoring technology, or by telephone.

It is equally important that the primary care physician and/or endocrinologist communicate recommendations back to the patient. These instructions may include addition or deletion of medications, changes in doses, or dose frequency, change in insulin sensitivity ratio, or insulin:carbohydrate ratio. The physician may also need to report the results of tests or procedures to the patient and suggest referrals. These processes may be accomplished via the email messaging server or by telephone.

In order for the primary care physician and/or endocrinologist to provide comprehensive diabetic patient management, he/she requires the following specific data elements from other entities within the HIE:

Table 10: Clinical Data Elements Required by the Primary Care Physician/ Endocrinologist in order to Provide Comprehensive Diabetes Management

<table>
<thead>
<tr>
<th>SOURCE OF INFORMATION</th>
<th>DATA ELEMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nurse</td>
<td>Blood Pressure Results</td>
</tr>
<tr>
<td>Laboratory</td>
<td>LDL cholesterol, HbA1C, Urine protein</td>
</tr>
<tr>
<td>Certified Diabetes Educator</td>
<td>Nutrition advice, exercise instruction, sick day instructions, compliance issues</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>--------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Pharmacy</td>
<td>Prescriptions/ supplies required by patient</td>
</tr>
<tr>
<td></td>
<td>Updated medication list</td>
</tr>
<tr>
<td>Ophthalmologist</td>
<td>Results of last formal eye exam, instructions supplied to patient, further studies, follow-up interval</td>
</tr>
<tr>
<td>Podiatrist</td>
<td>Results of last formal foot exam, instructions supplied to patient, further studies, follow-up interval</td>
</tr>
<tr>
<td>Hospitals</td>
<td>Clinical records from interim hospitalizations, including procedures, discharge summary and medications</td>
</tr>
<tr>
<td>Emergency Rooms</td>
<td>Clinical records from interim ER visits, including medications</td>
</tr>
</tbody>
</table>

The certified diabetes educator is an equally central figure in the management of the patient with diabetes. In some instances, the patient has more frequent physical and telephone visits with the CDE than with the physician. As such, the CDE must have access to a full, and current, clinical history from the PCP/Endocrinologist and from the patient.
Table 11: Clinical Data Elements Required by the Certified Diabetes Educator, in order to Provide Comprehensive Diabetes Management

<table>
<thead>
<tr>
<th>DATA REQUIRED FROM PCP/ENDOCRINOLOGIST</th>
<th>DATA REQUIRED FROM PATIENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type of diabetes- type and duration</td>
<td>Fingerstick glucose results</td>
</tr>
<tr>
<td>Diabetes complications- eye, renal, neurologic</td>
<td>Glucose/ insulin trends from software programs</td>
</tr>
<tr>
<td>History of hypoglycemia</td>
<td>Insulin sensitivity ratio/ insulin : CHO ratio</td>
</tr>
<tr>
<td>History of diabetic ketoacidosis or hyperosmolar state</td>
<td>Total daily dose of insulin- doses/ frequencies</td>
</tr>
<tr>
<td>Other past medical and surgical history</td>
<td>Oral hypoglycemic- doses/ frequencies</td>
</tr>
<tr>
<td>Physician goals for management</td>
<td>Patient sick day management</td>
</tr>
<tr>
<td>Recent LDL cholesterol, HbA1C, urine protein</td>
<td>Meal diary</td>
</tr>
<tr>
<td>Recent BP results</td>
<td>Weight history</td>
</tr>
<tr>
<td>Recent BMI; weight history</td>
<td>Compliance issues (including economic factors)</td>
</tr>
<tr>
<td>Results from ophthalmologist and podiatrist</td>
<td>Symptoms of hypo-/hyper-glycemia</td>
</tr>
<tr>
<td>Current medications and supplies</td>
<td></td>
</tr>
<tr>
<td>Current type of glucose meter, insulin pump</td>
<td></td>
</tr>
<tr>
<td>Contact numbers for pharmacy, diabetic supply company, insulin pump company</td>
<td></td>
</tr>
</tbody>
</table>
In order for the ophthalmologist and podiatrist to perform focused evaluations, these specialists require the following diabetes-related information from the PCP/endocrinologist:

Table 12: Clinical Data Elements Required by the Subspecialist(s) to Provide Diabetes Management

<table>
<thead>
<tr>
<th>OPHTHALMOLOGIST</th>
<th>PODIATRIST</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient’s diabetes history</td>
<td>Patient’s diabetes history</td>
</tr>
<tr>
<td>Current medications and allergies</td>
<td>Current medications and allergies</td>
</tr>
<tr>
<td>History of diabetic complications</td>
<td>History of diabetic or other neuropathy</td>
</tr>
<tr>
<td>Surgical history</td>
<td>History of foot infections</td>
</tr>
<tr>
<td>Vascular history</td>
<td>Surgical history</td>
</tr>
<tr>
<td>Recent HbA1C, LDL cholesterol, BP</td>
<td>Vascular history</td>
</tr>
<tr>
<td></td>
<td>Recent HbA1C, LDL cholesterol BP</td>
</tr>
</tbody>
</table>

Public health agencies require de-identified diabetic patient data to measure and compare quality outcomes, for disease surveillance, for research purposes, for allocation of services, and for policy development. Accrediting organizations, like the Joint Commission and the National Committee on Quality Assurance, will require that physicians within our HIE submit core measurements and HEDIS results for their diabetic patients, to assure consumers and employers that a high quality of diabetes care is being provided, and perhaps to determine levels of reimbursement.
Lastly, insurance companies will need access to administrative information (including patient demographic information, patient financial information, provider information, encounter dates, encounter reasons, and charges for services) to process claims, and access to complete clinical information (including diabetes type, duration, complications, medications, other past medical history, surgical history, physical exam findings, previous test and procedure results, and clinical notes) to make determinations on those claims.

Real-World Example

Up until now, our system has been described in a series of complicated abstractions. A walkthrough of the proposed system using a real-world example will provide clarity and understanding. Recalling an earlier section labeled “description of the flow of the data sets between systems”, the data needs of an ophthalmologist were identified. Specifically, the ophthalmologist needs to know the patient’s diabetes history, current medications, current allergies, history of diabetic complications, surgical history, vascular history, and recent diabetes control such as last HbA1C, LDL, and blood pressure. Specifically, we will examine the retrieval of vascular images, and current allergies from the HIE.

For our walkthrough, assume that a patient has had a recent retinal vascular image done on their eyes just a few months ago at the request of their PCP under the care of a different ophthalmologist. Now our patient goes to this ophthalmologist for a yearly check-up. Before the doctor sees the patient, he decides to do a scan for the patient in the HIE to see what their history is, and if there is any data they can refer to.
In order to perform the search the doctor opens up his EMR and opens the patient search screen. He enters in a few bits of the patients demographics, and is returned with a few possible matches. The match results are able to be returned simply by taking that demographic data and translating it into a set of search filters, and then passing them on to the MPI.

The doctor checks a few other bits of data, and narrows the list of results down to the one specific patient he are looking for. The doctor clicks the patient, and is brought into that full patient chart. The doctor clicks on the radiology tab in the EMR, and is presented with a list of the type of images that they might be interested in. Our physician clicks on vascular imaging, and it is at this point that the HIE kicks into gear. Since our radiology is stored in a centralized database in our HIE the amount of work that occurs here is not too complex.

First, the patient identifier that was stored as a result of us bringing a patients chart into focus is used, and is sent to the record locator service, along with the noted interest for vascular images. The RLS brokers the request, and relays the request to the centralized database, and returns a list of possible matches for the vascular images of that patient.

The doctor looks over the list, and notices that there is a new image that he has not yet seen, and clicks that item to view the entire image. Once clicked, that data, which is just the document id, is sent to the RLS, which then goes back to the centralized database, and begins streaming the image back to the EMR for the physician to view. However, it is also likely that all the database knows about the document is simply a URL to a PACS viewer, which knows how to render that image in a more meaningful way than the EMR does. The physician can view this
image, and use it as a reference point for the imaging he plans to do in today’s visit, and can compare the two for any sort of degradation, or improvement.

Moving on, the physician is now interested in identifying any allergies that the patient has, to see if there are any possible issues that may arise with the use of the dye that he wishes to use in today’s visit. Since the doctor is already in the EMR, and the system still knows what patient is in context, the physician simply has to click on the tab in his EMR labeled allergies. Recalling the diagram for our architecture, you will remember that this specific type of data is not in a single centralized location, and will require the record locator service to flex its muscle.

First, the patient identifier, as well as the type of data we are looking for, allergies in this case, and are sent to the RLS. The RLS takes these bits of data, and broadcasts a request to all the registered data sources in the HIE to see if any of them have data similar what is being requested. Remember that the data sources in our case are simple physicians’ offices, hospitals, and laboratory offices. Immediately, results begin coming back to the RLS either affirming or denying the existence of data that is being sought.

The RLS will wait for as long as possible, perhaps 3 seconds, at which time it will aggregate the results, and return the list back to the physicians EMR. Alternatively, this can be done in an asynchronous manner if configured to do so, but a time limit will still need to be set so long running queries can be aborted to save system performance.

Now the physician can click through the possible allergy results returned to him one by one, or he can use his EMR to merge these like kind records into one consolidated view. Since allergies
vary with time, both in sensitivity, as well as in the allergies themselves. The data can be all over the place on a merge, so the physician decides to go with the latest and most complete one, and then just to confirm the information with the patient once he arrives.

Now that the doctor was able to use all the information that was given to him from the entire HIE, he is able to better care for his patient.

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