Data Standards in Population Health Management

A research analysis on topics pertaining to population health management and the various forms of data that can be collected and healthcare standards to ensure that this data can be utilized and maximized effectively across various systems in an Accountable Care or Coordinated Care Organization.

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# Table of Contents

1. Executive Summary ........................................................................................................... 5

2. Background ........................................................................................................................ 5

   2.1 Project Assumptions ....................................................................................................... 7

       2.1.1 Infrastructure ......................................................................................................... 7

       2.1.2 Implementation Objectives .................................................................................... 8

       2.1.3 Project Goals ......................................................................................................... 8

2.2 Stakeholders (Power, Relationships and Intentions) ....................................................... 9

   2.2.1 Patients ..................................................................................................................... 11

   2.2.2 Physicians, Nurses ................................................................................................... 11

   2.2.3 Healthcare Organizations (HCOs) .......................................................................... 11

   2.2.4 IT, Software Vendors ............................................................................................... 12

   2.2.5 Government Agencies, SDOs .................................................................................. 12

   2.2.6 ACO / CCO Board of Directors ............................................................................ 13

2.3 Business Case .................................................................................................................... 13

2.4 Challenges ......................................................................................................................... 15

2.5 Measuring Success ............................................................................................................ 15

3. Common workflow and Use Cases .................................................................................... 17

   3.1 Use Cases ..................................................................................................................... 17

       3.1.1 System Setup as an HIE “Secure Node” ................................................................. 17

       3.1.2 Registration System Publishes Demographics to EMPI ......................................... 17

       3.1.3 Patient Consent Captured and Conveyed to HIE .................................................... 17

       3.1.4 EMR Publishes a EOB Report (835) to HIE for an Encounter Registry (RLS) .......... 18

       3.1.5 EMR Publishes a CCD to HIE ............................................................................... 18

       3.1.6 Portal Publishes a CCD to HIE ............................................................................. 18

       3.1.7 HIE Publishes data feeds to immunization registry or CDC ................................. 18

       3.1.8 EMR Views Clinical Documents in HIE .................................................................. 18

       3.1.9 EMR Imports Clinical Documents from HIE ......................................................... 18

3.2 Actors, Transactions, & Payloads ..................................................................................... 18

       3.2.1 #A1: HIE Services Patient Identity Manager and EMPI (IHE PIX / PDQ) ............... 18
3.2.2  #A2: HIE Services Audit Trail & Node Authentication (IHE ATNA) ............................................ 18
3.2.3  #A3: HIE Services Registry & Repository (IHE XDS) ................................................................. 18
3.2.4  #A3.1: Record Locator Service (RLS) ............................................................................................ 18
3.2.5  #A4 : HIE Services Patient Consent (IHE BPPC) .......................................................................... 18
3.2.6  #A5 : Wellness portal ...................................................................................................................... 18
3.2.7  #A6 : HITSP DSUB notification ...................................................................................................... 18
3.2.8  #A7 : Reporting ................................................................................................................................. 18
3.2.9  #A8: Payors ....................................................................................................................................... 19

3.3  Transactions........................................................................................................................................ 19
3.3.1  #T1.1 Authenticate Node (ITI-19) VPN between HIE and End Nodes .............................. 19
3.3.2  #T2.1 Demographic Feed - HL7 ADT - Patient Identity Feed (IHE ITI-8) from Registration systems 19
3.3.3  #T3.1 Patient Queries (PIX / PDQ) from EMR or Portal to HIE ................................................. 19
3.3.4  #T4.1: X12 835 remit (EOB) from Payor into various EMR systems ........................................ 19
3.3.5  #T5.1 IHE XDS ITI-41 PnR “Provide and Register Document Set-b” from EMR to HIE ....... 20
3.3.6  #T6.1: IHE XDS ITI-18 RSQ “Registry Stored Query” from EMR and Wellness Portal (#6.2 from ACO/CCO CDT) .......................................................... 20
3.3.7  #T7.1: IHE XDS ITI-43 RDS “Retrieve Document Set Query” from EMR .......................... 20

3.4  Payloads / Documents / Data Elements .......................................................................................... 20
3.4.1  HL7 ADT ....................................................................................................................................... 20
3.4.2  XD*LAB *FUTURE- PHASE 2* ....................................................................................................... 20
3.4.3  XDS-SD *ACHIEVED VIA THE PORTAL* .................................................................................... 20
3.4.4  IHE XDS-SD (HITSP C62) .............................................................................................................. 20
3.4.5  CCD Standard (HITSP C32) ........................................................................................................... 21

3.5  Workflows.......................................................................................................................................... 21
3.5.1  EMR Setup as an HIE “Secure Node” ......................................................................................... 21
3.5.2  Registration System Publishes Demographics to EMPI ............................................................... 22
3.5.3  Patient Consent Captured and Conveyed to HIE .......................................................................... 22
3.5.4  EMR/Portal Publishes a CCD to HIE ............................................................................................. 23
3.5.5  Public Health - HIE publishes data to various entities – ex. CDC or immunization .......... 24
3.5.6  EMR/Portal Views Clinical Documents in HIE .................................................................................. 25
1 Executive Summary

This study focuses on population health management and its relationship in the newly emerging care models within the United States. The current focus in healthcare involves a discussion around Accountable Care Organizations (ACOs), Coordinated Care Organizations (CCO) or Integrated Health Organizations (IHOs). These organizations stem largely from a need to reduce healthcare costs, tie together fragmented health systems, and improve patient outcomes for the health of a defined population. In order to begin to achieve this type of model, significant investment must be made into healthcare IT infrastructure. Funding will come from governmental programs that would offset some of the initial and ongoing costs, however, long term sustainability is still the key to success. The goal is to work towards a phased infrastructure approach that is sensitive to funding needs while also achieving maximum reimbursements of available funding. There will continue to be a need for longer term growth and identification of new sources of revenue in order to fund future infrastructure development.

The perspective of this study is from that of consulting company, Wellness Consulting (WC). The goal and objective will be to explore the necessary steps, use cases, architecture and design needed to implement a wellness portal in a landscape that already benefits from an established hybrid Health Information Exchange (HIE) which draws from federated and co-op models. With the dually focused ACO/CCO and HIE, WC seeks to recommend technology standards, processes and workflows that have the potential to significantly transform the quality and collection of healthcare data within the ACO/CCO model. Specifically, as consultants with expertise in wellness portals, WC has been retained to implement an interoperable solution which can collect and aggregate wellness information to facilitate accessibility of data to care providers, health plans and specialists within the HIE. Additionally, the reporting capabilities shall be extended to outside governmental disease control agencies to foster proactive biosurveillance activities and promote patient safety. In short, the wellness portal is an extended effort of care management transformation that the ACO will need to undertake to manage its patient population more efficiently, as well as to begin the process of creating a single evolving care plan – contributed to and used by multiple sources.

We will outline our approach by underpinning all of our recommendations for data transfer and aggregations with the use of a standards based approach. Standards based approaches allow for easier implementations and a much longer term possibility of success due to factors such as; no vendor ‘lock in’, increased predictability, deeper collaboration and reduced costs.

2 Background

Defined in broad terms, the Institute of Medicine (IOM) defines public health as “what we, as a society, do collectively to assure the conditions for people to be healthy”. (Wagner, Moore, & Aryel, 2006) Government plays a critical role at all levels (federal, state, and local) in ensuring that people stay healthy. There are many governmental agencies that exist for the sole purpose of monitoring disease and chronic conditions that the public suffer with. Where habits can be changed or patients can be
educated, focus on wellness through preventative measures has the most promise. Certain portions of the population are predisposed to chronic disease due to genetic factors and even these can be positively impacted through focused managed care.

Large expenditures accrue annually to manage the resulting disease and conditions that follow from unhealthy behaviors and lifestyles. In an opening introduction that highlighted the problem of the healthcare bill in America, President Barrack Obama has been quoted as saying, “the financial burden has damaged the global competitiveness of American businesses and bankrupted millions of families, even those with insurance. It’s also devouring our government. The greatest threat to America’s fiscal health is not Social Security. It’s not the investments that we’ve made to rescue our economy during this crisis. By a wild margin, the biggest threat to our nation’s balance sheet is the skyrocketing cost of healthcare.” (Gawande, 2009) From the same article, the author sought to understand how this came to be and studied the coordinated care of one small McAllen, Texas town. Through the article, Gawande investigates the issues and determines that population health in comparison with neighboring communities stood essentially equal and ruled that out as a possible cause. In the end it boiled down to lack of continuity of care of patients across healthcare providers. Even though expenditures more than doubled, the neighboring community of similar demographics received no better care than those communities that had spent less on healthcare. From this, we see that through better coordinated care among providers, quality improves and costs decline. Paired with a goal to focus on wellness, the population as a whole could receive better care, while at the same time reducing emergent treatments and focus individuals on being responsible for healthier living and incentivizing them in the process through reduced out of pocket expense.

In order to achieve better coordinated care, providers must band together and form synergies that center around the patients’ needs and seek to foster more effective channels of information flow. In addition, providers, health plans and employers must establish standards for communicating and coordinating benefits and coverage of those they employ or care for. Finally, all of these activities must be measurable, and institutions engaged in the cause, held accountable individually and collectively to the goals established. Because of governments extensive focus on population health, each of the institutions involved in caring for a patient would need to integrate with and report to governmental interfaces that have visibility into population health statistics. Models that are now emerging in an interest to accomplish collective responsibility for patients’ healthcare are Accountable Care Organizations (ACOs) and Coordinated Care Organizations (CCOs). For the purpose of this study, we will consider the ACO/CCO model and the standards, actors, transactions, payloads, use cases, workflows, data sets and system architectures that would foster improved patient outcomes through more effective health information exchanges focused on wellness components within the population health management domain.

The medical and business communities have been searching for viable business cases when it comes to patient health records. Early attempts at systems failed because they were either too specific or too hard to use with little interaction where it meant the most, which was messaging and billing between patient and provider. We need to look no further than the failures of the Microsoft Health Vault and
Google offering to see the difficulty in tying PHR consumer based medical record inputs into the canon of medical data collection; reporting and quality of care improvement has been slow. (Vineeta Vijayaraghavan & Christensen, 2011) There is however a continued emphasis on patient wellness from an employer perspective. This was born in part due to higher insurance costs per employee as well as the ballooning Medicare costs and reductions in reimbursements. Active patient management has been re-invented in the form of ACO organizations. As part of a patient wellness program – hospital systems would be able to collect health assessments on each enrollee and potentially provide wellness care associated with particular care plans.

The components of wellness could include a form of patient management that would be offered to employers where by providing regular screenings and meetings between a health wellness specialist and enrollee. The enrollment would be voluntary offering incentives. This could be accomplished through wellness portals provided to enable collection, consuming and publishing of data to facilitate a care model that can allow for active patient tracking and monitoring; and publishing of metrics to NCQA for quality reporting.

### 2.1 Project Assumptions

An established ACO/CCO strives to effectively understand its patient population in order to improve better coordinated care and make holistic patient management an attainable reality. A successful implementation will result in improved patient outcomes. The ACO/CCO has approached our consulting agency, Wellness Measures, in order to evaluate the landscape and consider systems, technologies, workflows and other aspects that would foster a successful implementation of a population health management wellness module. Through an initial system analysis and discovery stage, requirements were collected and assumptions noted. Those include all of the following.

#### 2.1.1 Infrastructure

- One Large Hospital Care Organization (HCO)
- One Community Hospital Care Organization located fifteen miles away from large HCO
- Both large and community HCOs have affiliated outpatient Electronic Medical Records (EMRs)
- Five specialty clinics are scattered geographically between the large HCO and Community HCO and are leveraged for referral purposes
- Gateway EDI as the contracted medical claims clearinghouse
- One large health plan provider
- A Health Information Exchange (HIE) is already established and owned by the group ACO/CCO
- HIE was implemented as an initial first stage for Master Patient Indexing (MPI) using PIX and PDQ transactions
- HIE second phase is to implement a wellness portal solution that will enable healthcare wellness information storage, exchange and reporting
2.1.2 Implementation Objectives

- Design the HIE wellness portal solution based from an previous design that was developed for another healthcare organization project
- Module will capture patient consent through the form of opt in/out
- Connected EMRs throughout infrastructure will also be a collection source for opt in/out
- Module will collect patient demographics
- Module will collect patient health statistics
- Module will integrate with and publish to the National Center Committee for Quality Assurance (NCQA) for reporting
- Module will integrate with and publish to the Centers for Disease Control (CDC) BioSense and NEDSS (National Electronic Disease Surveillance System) systems for reporting
- Module will enable future billing functionality for patients
- Module will create Continuity of Care Document (CCD) and transmit, receive and store into HIEs data repository
- Module will be offered to employers as a tool to its employees

2.1.3 Project Goals

- Progressive advancement toward level three integration which embraces full interoperability of CCD within the ACO/CCO for creation, modification, transfer, publication and consumption.
- Enable consumption or view access to care providers affiliated with the ACO/CCO either within or outside of an EMR
- Support HIPAA EDI transactions for medical claims billing and reimbursement through X12 transactions 278 (for Pre-Authorization), 834 (for Benefits Enrollment and Maintenance), 835 (for Healthcare Claim payment/advice) and 837 (for coordination of claim payment and benefits)
- Enable view access by consumers that opt-in
- Identify data elements and data sets within the CCD for publication that qualify and satisfy NCQA and other governmental agencies for quality reporting
- Identify all Actors, Transactions and Payloads associated with creation, publication and storage of CCD documents.
- Provide deidentified minimal data sets (MDS) to leading Biosurveillance systems for public health and safety purposes
- Consider and implement healthcare technology standards in portal solution to embrace reusability and stability through industry approved exchange standards
- Leverage HIPAA standards and ensure for secure transactions throughout the entire integrated solution
- Offer integrated metric reporting that allows for tracking.
2.2 Stakeholders (Power, Relationships and Intentions)

In order to achieve success, an understanding is needed as it pertains to the various stakeholders that are involved and have an interest in being represented. The dynamic that exists between parties and their power of influence plays a key role in being able to bring interests together effectively. Successful execution requires an understanding of the political environment, the interrelationships that exist between stakeholders and motivations and intentions in being involved in the project. Each project participant will have a varied role. Interests will range from the following.

- **Accountable** – Having some level of responsibility to answer for decisions that are made or the resulting outcomes produced by the integrated information flows.
- **Responsible** – Either direct or delegated authority to make decisions for and/or in behalf of an organization, department or institution involved in the integrated model.
- **Consulted** – Interested in being involved for domain expertise as it pertains to the integrated organization and decisions that result or have an effect on their respective areas within the organization, institution or department.
- **Informed** – Interested in staying current on decisions that are made by the collective whole.

Stakeholders should be identified early on in a project and can be augmented as new stakeholders are identified throughout the project life cycle or removed as initially identified parties become disinterested. Establishing a simple matrix known as a RACI (Responsible, Accountable, Consulted and Informed) chart provides an effective visual representation of your stakeholders and levels of interests.

Possible stakeholders that would be involved in managing population health wellness might include all of the following.

- Patients
- General Public
- Physicians
- Nurses
- ACO / CCO Board of Directors
- Steering Committee
- Hospital Administration (C-level executives)
- Upper Management
- Department Managers
- Software Vendors
- Hardware Vendors (of monitoring devices)
- Pharmacies
- Radiology groups
- Health Plans
- Government leadership (Federal, State and Local levels)
- Government agencies (involved in statistical monitoring or reporting, CDC, NEDS, etc.)
- Standard bodies
- Educational bodies (aimed at education materials to educate the public about managing health)
- Business Owners

As demonstrated from the list above, there are many groups and individuals that play a stake in improving population health and their level of interests vary due to their role identified by the RACI matrix. There are however, stakeholders which could be identified as primary. Those would likely include:

- Patients
- Physicians, Nurses
- Healthcare Organizations
- IT, Software Vendors
- Government Agencies
- ACO / CCO Board of Directors

Although all from the list are equally important the five identified as primary frequently interact with one another and play a key role in the path to change. The outcome of improvement directly benefits these groups in the following ways.

Stakeholders are individuals, organizations, or entities who have a direct interest in its success. Broadly, stakeholders are buyers, providers, suppliers, regulators, and owners who cooperate through economic exchanges and shared interests. The success of organizations depends on and is measured by satisfying the needs of the stakeholders.
2.2.1 Patients

Buyers or patients are looking for increased quality of care without the significantly increased associated costs. Patients want to be more involved and empowered in the decision making process of medical care. More patients are using patient electronic portals to view their medical information such as histories, procedures, medications, allergies, alerts, immunizations. Patients may also interested in receiving scheduling alerts, educational materials, physician-patient teleconferencing and emails, employee health management portals, remote monitoring and the use of medical devices. Patients want to be assured that all pertinent medical information will be available for optimal care between different clinical encounters at different medical locations. Patients are realizing that interoperability of information systems regionally and nationally is important for continuity-of-care, faster and more efficient care, and sharing of cost savings. Privacy and security are also important issues for patients. Many patients feel that the HIPPA Privacy Rule does adequately address these issues, although many have privacy concerns about the development national patient identifiers.

2.2.2 Physicians, Nurses

Providers are physicians, nurses, and other healthcare professionals. Providers’ motivation is to provide high quality of care to patients. Many physicians see the benefits, efficiency, cost savings, improved workflow with the use of EMRs. The potential administrative and clinical cost savings and increased quality of care by possible reduction in adverse drug events and medical errors are increasing adoption of EMRs. The ability to provide point-of-care technology and continuity-of-care to increase the quality of medical care are attractive features of HIE to providers. Providers are also looking for accurate, fast, and efficient delivery of medical information, and exchange of administrative information with payers and Medicare/Medicaid. For example, providers want fast and accurate delivery of labs and drug information, and patient payment and claims information. EHRs will also provide nurses with legible, accurate patient data, save time, increase workflow and efficiency, and help contribute to increased quality of care. Providers will provide feedback on user needs to IT with surveys for example, about features and GUI that promote workflow.

2.2.3 Healthcare Organizations (HCOs)

Healthcare organizations want to provide high quality of medical care to patients and the community, support research, values and goals of the organization, and decrease costs and maximize revenue. HCOs realize the implementation of electronic health records will increase the quality of medical care, efficiency, workflow, and provide cost-savings. Features like clinical decision support systems, CPOE have proven to not only in decreasing medical errors but also save significant costs associated with redundancy of test, and adverse drug and medical events. The Meaningful Use incentives for stage 2 and 3 will motivate healthcare organizations to adopt standards and HIE networks for sharing of electronic medical records, and reporting of clinical quality measures to CMS. Integration and interoperability will enable HCOs to provide higher quality of care, support quality and performance measures reporting to NCQA/HEDIS, and public health agencies for biosurveillance. ACOs will help provide better coordinated care and improved communication, creating incentives for healthcare
providers to work together; increasing adoption of EHRs, continuity of care records and PHRs. Medicare Shared Savings Program incentives will help lower costs while meeting performance standards and quality measures. These goals and attractive features may also motivate community employers to partner with ACOs in wellness programs and health management portals to its employees. Executives, CIO, CSO, and steering committees will drive the adoption of EHRs by supporting the goals of integration and interoperability, establishing and addressing user needs, and applying/providing funding to promote these activities. HCOs are also interested in empowering patients for self-care and involving them in the care process by implementing patient care portals. HIE will also enable HCOs to share, cut costs, and streamline the administrative process with Medicare/Medicaid claims.

2.2.4 IT, Software Vendors
The role of IT is to provide information technology services to support more efficient methods for clinical care, administrative and business management, benchmarking, and leveraging the use of technology to help maximize financial revenue for the organization. IT is considered one of the enablers of health information exchange. IT will be the major players in developing and implementing information systems for interoperability. They will provide ongoing support and training, conduct surveys, and application support to physicians, executive, nurses, and other end users. IT will also help to improve administrative functions by implementing business management applications, and analyzing quality and performance indicators. IT will work closely with third party vendors to ensure all functional requirements and RFI are met. Vendors will provide continuous support, updates, and customization of applications based on the needs of the HCO and users. IT will also work with vendors to ensure the use of standards in messaging, vocabulary, and structure to enable enterprise-wide integration and interoperability. IT will also support information systems for quality measures reporting, and reporting data on biosurveillance to public health agencies.

2.2.5 Government Agencies, SDOs
Regulators such as the federal and state governments and Standards Development Organizations (SDOs) play a vital role in promoting health information exchange. Regulators work to address the concerns and needs of stakeholders, such as increasing quality of healthcare and delivery, control of healthcare costs, economics, and public health. Regulators issue and enforce policies, mandates, and guidelines to help stakeholders to increase effective delivery of care, report quality measures to NCQA and biosurveillance for public health, address stakeholder rights, and increase economic competitiveness. One of the goals is to provide a National Wide Health Network (NHIN). Federal programs such as HITECH, HIPPA, Meaningful Use, and organizations such SDOs, HITSP, and HIMMS are working to increase connectivity in networks and HIE. Standards Development Organizations such as ANSI and HL7 play critical roles in bringing together stakeholders to agree upon a set of standards to promote interoperability. States are developing and implementing RHIOs to promote regional interoperability, although about 54% are in the planning stages.
2.2.6 ACO / CCO Board of Directors

The governing board will establish strategic directions for the ACO/CCO, meeting stakeholder needs and addressing issues and concerns. As well as supporting the mission, visions, and values of the ACO/CCO, the governing board must establish the scope and organization of services and set strategic improvement goals. They will set policies based on ACO/CCO best practices to help physicians, nurses, and other providers to improve safety and quality of patient care and control healthcare costs. The goals and plans of the governing board will emphasize communication and coordination of care, and continuity-of-care. Development and implementation of intranets and internets will enable interoperable sharing of patient records in the ACO and other networks. The governing board will oversee the quality of clinical care by approving strategic goals for quality improvement and providing funding for these activities. The goal of patient-centric care in the ACO will promote adoption of Patient Health Records (PHRs) to encourage patients to become more involved in the decision making process. The governing board will also monitor performance against the plans and budgets. The board will review reports of performance, quality measures, and progress of projects. As part of the ongoing efforts to provide patient-centered care and improve the quality of care delivery, quality and performance measures will be submitted to HCQI and data sets submitted to public health agencies and CDC for biosurveillance.

The roles of stakeholders are critical in determining the future of health information exchange. Providers, patients, healthcare organizations, regulators, and federal and state governments, and SDOs all have considerable influence to support, develop, implement, and fund HIE networks. Some of the goals that are shared are to improve overall care quality, decrease medical errors, and cost savings by reducing health care system inefficiencies. Government, providers, IT, and SDOs are working together to build networks between for example, hospitals, physicians, health plans, labs, pharmacies to provide continuity-of-care. Public health agencies realize the potential clinical and economic benefits of health information exchange and are working closely with other stakeholders to achieve this goal. States are bringing together RHIOs and increasing the informational value by connecting with networks and public health data repositories to provide a comprehensive patient electronic health record (EHR).

The roles, needs, motivations, and interactions of stakeholders are necessarily complex. As the NHIN is in the early stages of development, all stakeholders can become involved in for example, apply/lobby for eHealth initiative funding, work with payer stakeholders in implementing PHRs, leveraging administrative information from Medicare/Medicaid to reduce costs and streamline the process, promoting continuity-of-care records, and integrating information systems for quality measures reporting and biosurveillance in public health.

2.3 Business Case

“Since 1995, the percentage of Johnson & Johnson employees who smoke has dropped by more than two-thirds. The number who have high blood pressure or who are physically inactive also has declined—by more than half. That’s great, obviously, but should it matter to managers? Well, it turns out that a
Data Standards in Population Health Management

comprehensive, strategically designed investment in employees’ social, mental, and physical health pays off. J&J’s leaders estimate that wellness programs have cumulatively saved the company $250 million on health care costs over the past decade; from 2002 to 2008, the return was $2.71 for every dollar spent. Wellness programs have often been viewed as a nice extra, not a strategic imperative. Newer evidence tells a different story. With tax incentives and grants available under recent federal health care legislation, U.S. companies can use wellness programs to chip away at their enormous health care costs, which are only rising with an aging workforce.” (Berry, Mirabito, & Baun, 2010)

Employer wellness programs are on the rise and it is big business in the vendor marketplace. Estimates place the wellness market, which is extremely hard to quantify, at $2 trillion in 2010. (Mercola, 2010)

There are significant challenges towards ensuring long term sustainability of an ACO model especially one where maintenance of a large IT infrastructure such as an HIE with direct patient involvement is a shared cost and resource across the healthcare continuum. One of the primary drivers of this approach to delivering on Meaningful Use (MU) initiatives and quality reporting criteria is to create potential new sources of ongoing revenue to replace the reduction and eventual elimination of government funding. In capitalizing on market growth potential that wellness programs offer in the realm of population health management, monetary incentives can be realized and reduce sustainability concerns at the same time. In addition, doing it well will ensure for quality care and create brand recognition for the ACO, and drives patients to hospital owned and operated portals.

This project is attempting to find new sources of revenue while improving the delivery of care, the lack of interoperability between software systems, and improving interaction between providers and patients.

This strategy hopes to ensure a cleaner path to meeting MU criteria as well as providing a needed service to the community in the form of a phased wellness program benefitting employers and patients.

Our strategy will address several goals set out by the ACO board that fits with the missions of both the hospitals and affiliated organizations.

- Patient Satisfaction
- Quality of Care
- Revenue enhancement
- Cost optimization
- Reporting requirements

Healthy employees simply cost less and stay with employers. There are specific pillars to a successful wellness programs. In article in the Harvard Business Review, titled “What’s the hard return on employee wellness programs”, Berry et al list six specific pillars to achieve success. They begin with

1. Multilevel leadership – all employees must care about their health.
2. Alignment with the firms mission
3. Scope Relevance and Quality – in other words the program must work.
4. Accessibility – on site integration is essential for low cost solutions.
5. Partnerships – encourage and leverage partnerships to provide components of the program.
6. Communication – be creative in how to present the message.

We are taking dead aim at being able to fulfill all six pillars with a core competency in patient accessibility and low cost entry to the market. We think that this will result in tangible benefits to participants in the form of lower absenteeism, low costs, reduced visits to the ED, and the beginnings of longer term studies using collected data to provide a community wide commitment to quality healthcare. (Berry, Mirabito, & Baun, 2010)

2.4 Challenges
The challenges to the program will be the following:

1. Capping development costs for the portal
2. Ensuring adequate marketing for the portal to gain 10% enrollment year one
3. Identifying and establishing criteria for MU
4. Providing the resources necessary for the wellness program to be successful
5. Negotiating with payors for premium reductions for wellness participants
6. Engaging the business community and provide incentives to utilize the portal.
7. Ensuring cost containment on ACO/CCO HIE infrastructure that is consistent with rollout strategy.

2.5 Measuring Success
Success will be monitored and measured in a quantifiable manner throughout the duration and all phases of the systems development lifecycle as it pertains to our proposal. Success will be measured specifically through benefits realization and accomplishment of the clearly stated and measurable requirements listed in Section 6 of this document. Each requirement and benefit will be assigned a responsible functional group to oversee the ongoing progress and escalate visibility when necessary to keep the requirement or benefit on track. At the most senior level, each benefit and requirement will have an executive sponsor who has a stake in the achievement of said requirement or benefit. The executive sponsor will also have the clout to remove barriers and influence the necessary people to ensure realization of the benefits and requirements for which they are responsible.

During the planning and design phase of the project, each functional workgroup that is assigned to a requirement or benefit will identify the success criteria and document this in a master benefits realization matrix. The criteria for success will identify the 25%, 50%, 75%, and 100% complete criteria, the expected timeline for reaching each of these milestones, key dependencies and stakeholders, and risks to successful completion. The executive sponsor will ultimately approve and hold ownership for their respective benefits and requirements. During regularly schedule project leadership and sponsor meetings, the benefit and requirement progress will be monitored, providing a forum for the
exploration of risks and issues related to successful completion. The following table depicts specific measures of success for our proposed solution:

<table>
<thead>
<tr>
<th>Topic</th>
<th>25%</th>
<th>50%</th>
<th>75%</th>
<th>100%</th>
</tr>
</thead>
<tbody>
<tr>
<td>EMPI / Demographics</td>
<td>Determine field mapping</td>
<td>Successful query/response</td>
<td>Multi-system query/response &amp; storage</td>
<td>Performing per specification in production environment</td>
</tr>
<tr>
<td>Laboratory Results</td>
<td>Determine field mapping</td>
<td>Successful query/response</td>
<td>Multi-system query/response &amp; storage</td>
<td>Performing per specification in production environment</td>
</tr>
<tr>
<td>Medical Imaging Reports</td>
<td>Determine field mapping</td>
<td>Successful query/response</td>
<td>Multi-system query/response &amp; storage</td>
<td>Performing per specification in production environment</td>
</tr>
<tr>
<td>Medication List</td>
<td>Design architecture / field mapping / codification</td>
<td>Successful abstraction of data from clinical document</td>
<td>Successful abstraction of data from multiple clinical document types &amp; formats</td>
<td>Performing per specification in production environment</td>
</tr>
<tr>
<td>Problem List</td>
<td>Design architecture / field mapping / codification</td>
<td>Successful abstraction of data from clinical document</td>
<td>Successful abstraction of data from multiple clinical document types &amp; formats</td>
<td>Performing per specification in production environment</td>
</tr>
<tr>
<td>Procedure List</td>
<td>Design architecture / field mapping / codification</td>
<td>Successful abstraction of data from clinical document</td>
<td>Successful abstraction of data from multiple clinical document types &amp; formats</td>
<td>Performing per specification in production environment</td>
</tr>
<tr>
<td>Allergy List</td>
<td>Design architecture / field mapping / codification</td>
<td>Successful abstraction of data from clinical document</td>
<td>Successful abstraction of data from multiple clinical document types &amp; formats</td>
<td>Performing per specification in production environment</td>
</tr>
<tr>
<td>Security</td>
<td>Definition of Security Roles, development &amp; documentation of policies</td>
<td>Successful authentication &amp; authorization testing</td>
<td>Successful confidentiality and penetration testing</td>
<td>Performing per specification in production environment</td>
</tr>
<tr>
<td>Record Export</td>
<td>Design format of exported record</td>
<td>Successful population of record from aggregate clinical lists</td>
<td>Successful attachment of approved affiliated clinical documents</td>
<td>Performing per specification in production environment</td>
</tr>
<tr>
<td>Provider Master List</td>
<td>Design architecture / field mapping / codification</td>
<td>Successful abstraction of data from clinical document</td>
<td>Successful abstraction of data from multiple clinical document types &amp; formats</td>
<td>Performing per specification in production environment</td>
</tr>
<tr>
<td>----------------------</td>
<td>---------------------------------------------------</td>
<td>-------------------------------------------------</td>
<td>-----------------------------------------------------------------</td>
<td>--------------------------------------------------</td>
</tr>
<tr>
<td>Meaningful Use</td>
<td>Mandatory &amp; Elective categories determined / approved by organization leadership</td>
<td>Design specifications developed and delivered to build / configuration teams</td>
<td>Non-production demonstration according to attestation criteria for Meaningful Use Stage 1</td>
<td>Performing per specification in production environment; attestation submitted</td>
</tr>
<tr>
<td>Business Continuity</td>
<td>Design &amp; approval of down-time procedures &amp; documentation</td>
<td>Business Continuity computers &amp; printers installed &amp; tested for independent / offline functionality</td>
<td>Successful completion of multi-site failover to downtime procedures</td>
<td>Performing per specification in production environment</td>
</tr>
<tr>
<td>Disaster Recovery</td>
<td>Design &amp; approval of RTO, RPO, and architecture for achievement</td>
<td>All necessary systems installed, configured, and unit tested</td>
<td>Successful completion of integrated disaster recovery drill</td>
<td>Performing per specification in production environment</td>
</tr>
</tbody>
</table>

### 3  Common workflow and Use Cases

Use cases provide a narrative description of how people utilize the exchange and wellness portal in healthcare settings. Use cases summarize the interactions between different people and systems to solve problems. In later sections, these people and systems are further defined as “Actors,” and the interactions between Actors are defined as “Transactions.” When Actors exchange Transactions, the content of the information exchanged in the Transaction is called a “Payload” or “Document.

#### 3.1 Use Cases

**3.1.1 System Setup as an HIE “Secure Node”**

All connections to and from the HIE and to other systems must be secure. This includes the connections to the portal, CDC or other registry and all other systems such as EMRs.

**3.1.2 Registration System Publishes Demographics to EMPI**

Assumptions within the ACO/CCO that all registrations are going to the eMPI for patient AND provider matching and credentialing.

**3.1.3 Patient Consent Captured and Conveyed to HIE**

Basic patient consent on an ‘Opt out’ model is capture at the various end points and stored within the correct systems.
3.1.4  EMR Publishes a EOB Report (835) to HIE for an Encounter Registry (RLS)

3.1.5  EMR Publishes a CCD to HIE
EMR systems publish as complete a CCD as possible to the HIE registry and repository.

3.1.6  Portal Publishes a CCD to HIE
Wellness portal collects and publishes as complete a CCD as possible to the HIE registry and repository.

3.1.7  HIE Publishes data feeds to immunization registry or CDC

3.1.8  EMR Views Clinical Documents in HIE

3.1.9  EMR Imports Clinical Documents from HIE

3.2  Actors, Transactions, & Payloads

3.2.1  #A1: HIE Services Patient Identity Manager and EMPI (IHE PIX / PDQ)
The Patient Identity Cross-Reference (PIX) provides a standard query / response to an Enterprise Master Person Index (EMPI) for patient identity within the HIE.

3.2.2  #A2: HIE Services Audit Trail & Node Authentication (IHE ATNA)
The IHE Audit Trail and Node Authentication (ATNA) provides a model for securely authenticating systems on to the HIE network and providing the necessary Audit trails. In this case, the Node Authentication will leverage a VPN (Virtual Private Network) tunnel and firewall configuration.

3.2.3  #A3: HIE Services Registry & Repository (IHE XDS)
The IHE Cross-Domain Document Sharing (XDS) is a model for sharing clinical data between nodes on the HIE network. The XDS Registry stores "pointers" to clinical documents in the XDS Repository. The XDS Repository is a secure storage database for clinical documents.

3.2.4  #A3.1: Record Locator Service (RLS)

3.2.5  #A4 : HIE Services Patient Consent (IHE BPPC)
The IHE Basic Patient Privacy Consents (IHE BPPC) is a standards-based approach for implementing patient consent and authorization management. The details of the implementation are documented in a later section of the SOW.

3.2.6  #A5 : Wellness portal
Access by patients and providers for the following

3.2.7  #A6 : HITSP DSUB notification
Notification of published documents

3.2.8  #A7 : Reporting
Reporting to various agencies such as the CDC with de identified data.
3.2.9 #A8: Payors
A variety of payors will be participating in the efforts to collect and store payor data.

3.3 Transactions
In general, transactions follow HL7 (HL7.org) specifications and HITSP (hitsp.org) / IHE (ihe.net) constructs. The HITSP constructs largely follow IHE profiles documented in the IHE IT Infrastructure technical framework.

3.3.1 #T1.1 Authenticate Node (ITI-19) VPN between HIE and End Nodes
This transaction is embedded within all network communications activity. IHE does not specify how other protocols that transfer PHI shall perform bi-directional authentication and authorization, but IHE requires that other protocols perform such authentication and authorization. In this implementation the Node Authentication will be accomplished by a VPN between the data center (one data center) and end nodes and firewall rules to allow access to the specific servers running the ACO infrastructure.

3.3.2 #T2.1 Demographic Feed - HL7 ADT - Patient Identity Feed (IHE ITI-8) from Registration systems
This is a typical real time by HL7 ADT transported via MLLP over TCP/IP. The ITI-8 allows a Patient Identity Source Actor to notify a Patient Identifier Cross-Reference Manager Actor of all events related to patient identification. The ADT events types supported include: A04 creation, A08 update, A40 merge (at minimum).

NOTE: During the design phase we will investigate alternatives to ADT.

3.3.3 #T3.1 Patient Queries (PIX / PDQ) from EMR or Portal to HIE
We will follow the IHE / HITSP specifications for patient identity transactions:

HITSP TP22 / IHE PIX ITI-9 allows a Patient Identifier Cross-reference Consumer to find out the identification of a patient in different Patient Identifier Domains by using the services of a Patient Identifier Cross-reference Manager Actor.


HITSP T23 / IHE PDQ ITI-21 “Patient Demographics Query” looks up and returns patient demographic information in a single patient demographics source, based upon matches with full or partial demographic information entered by the user.


3.3.4 #T4.1: X12 835 remit (EOB) from Payor into various EMR systems
These transactions are X12 835 remit (EOB) transactions that are received from multiple payors into the revenue cycle management systems and then are forwarded to the HIE. These transactions are used to
create a Record Locator (RLS) feed for the encounter registry. The data of interest from the remit includes the patient demographics, the location of care, the date of service and any relevant diagnosis or procedure codes. The individual remit transactions will be sent realtime either over MLLP/TCP/IP (Base64 encoded payload) or can be added directly via webservices in the form of XDS registry entries (see XDS Provide&Register transactions).

3.3.5  **#T5.1 IHE XDS ITI-41 PnR "Provide and Register Document Set-b" from EMR to HIE**
Is used by the Document Source to provide a document to the Document Repository, and to request that the Document Repository store these documents and then register them with the Document Registry.

3.3.6  **#T6.1: IHE XDS ITI-18 RSQ “Registry Stored Query” from EMR and Wellness Portal ( #6.2 from ACO/CCO CDT)**
Used by the Document Consumer (wellness portal or EMR) to request a list of documents in the HIE given a patient ID.

3.3.7  **#T7.1: IHE XDS ITI-43 RDS "Retrieve Document Set Query” from EMR**
Used by the Document Consumer (EMR or Portal) to retrieve a set of documents from the Document Repository. The Document Consumer has already obtained the XDSDocumentEntry unique Id from the Document Registry by means of the Registry Stored Query transaction.

3.4  **Payloads / Documents / Data Elements**
This section describes some of the key data elements exchanged within each transaction type as well as the corresponding terminology codes and code sets.

3.4.1  **HL7 ADT**
The main controlled vocabularies are the values in the MSH header and “Assigning Authority” OID (Object Identifier) since these fields are used to determine where the patient was registered.

3.4.2  **XD*LAB *FUTURE- PHASE 2*”**
This is a HL7 ORU lab result transaction which is copied to the HIE so the ACO/CCO can transform it into a XD*LAB document. The purpose is to fulfill the MU lab-reporting requirement.

3.4.3  **XDS-SD *ACHIEVED VIA THE PORTAL*”**
This is a HL7 MDM or ORU transcription transaction which is copied to the HIE so the ACO/CCO can transform it into a XDS*SD document. The purpose is to fulfill the MU reporting requirement for textual documents (i.e. discharge or visit summaries).

3.4.4  **IHE XDS-SD (HITSP C62)**
The IHE XDS-SD profile will be used for the publishing and sending of unstructured clinical documents. The table below summarizes the list of clinical documents for HIE project. Source systems marked as TBD will be determined during the design phase of the implementation.
3.4.5  CCD Standard (HITSP C32)
The Summary Documents Using HL7 Continuity of Care Document (CCD) Component describes the document content summarizing a consumer's medical status for the purpose of information exchange. The content may include administrative (registration, demographics, insurance, etc.) and clinical information (problem list, medication list, allergies, test results, etc.).

The HITSP C32 recommendations are found at [http://www.hitsp.org/Handlers/HitspFileServer.aspx?FileGuid=e1b99525-a1a5-48f6-a958-4b2fc6d7a5c7](http://www.hitsp.org/Handlers/HitspFileServer.aspx?FileGuid=e1b99525-a1a5-48f6-a958-4b2fc6d7a5c7).

3.5  Workflows
3.5.1  EMR Setup as an HIE “Secure Node”

<table>
<thead>
<tr>
<th>Goal</th>
<th>Configure each HIE participant’s system to be capable of secure connectivity with the HIE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Examples</td>
<td>Setup an EMR or Registration system onto HIE network via VPN or PKI Certificate</td>
</tr>
<tr>
<td>Assumptions</td>
<td>Each member has signed a HIE Participation Agreement and/or BAA</td>
</tr>
<tr>
<td>Variants</td>
<td>VPN or PKI Certificates</td>
</tr>
<tr>
<td>Trigger</td>
<td>Signing contract to engage a new member or system into HIE</td>
</tr>
</tbody>
</table>

| Step #1                                   | Receive contract or work order authorizing the new system to be connected to HIE        |
| Step #2                                   | Gather system and network information from new HIE participant                           |
| Step #3                                   | Configure VPN, PKI Certificates, Firewalls to allow secure communications               |
| Step #4                                   | Test systems and once approved move into production                                      |
| Step #5                                   | Exchange key personnel contact information for ongoing support                           |

| End State                                 | A new member is on the HIE network and able to securely communicate with other nodes     |
### 3.5.2 Registration System Publishes Demographics to EMPI

<table>
<thead>
<tr>
<th><strong>Goal</strong></th>
<th>Provide a tool to manage patient identities in multiple electronic systems.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Example</strong></td>
<td>A single patient has different medical record numbers at PCP, Specialist, and Hospital and Portal</td>
</tr>
</tbody>
</table>
| **Assumptions** | • There is not a national personal identifier  
  • The EMPI has a patient-matching algorithm which is tuned for each HIE |
| **Variants** | • Key EMPI use cases: new patient, updated patient, merged patient |
| **Trigger** | Registering (or updating) a patient in an electronic registration system or EMR |

| **Step#1** | Registrar adds a new patient into EMR or Portal system. |
| **Step#2** | EMR sends demographic data to the EMPI in the HIE. |
| **Step#3** | EMPI receives the new demographic record and compares it to existing records. |
| **Step#4** | EMPI calculates a comparison score and compares it to a threshold score. |
| **Step#5** | EMPI adds a new patient into the HIE, if score exceeds the threshold score. |
| **Step#6** | EMPI adds linkage from HIE enterprise identifier to the local medical record. |

**End State** | Patient has an HIE enterprise identifier that links to local medical records. |

### 3.5.3 Patient Consent Captured and Conveyed to HIE

<table>
<thead>
<tr>
<th><strong>Goal</strong></th>
<th>Record patient consent in the HIE. With an Explicit Opt-out model</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Example</strong></td>
<td>The patient is automatically opted-in and the patient’s data is available for viewing for the purpose of treatment of care following the HIPAA compliance</td>
</tr>
</tbody>
</table>
## Assumptions
The HIE has a documented patient privacy policy.

## Variants
- Consent may be Opt-in, Opt-out
- Consent may be captured by a provider or a receptionist

## Trigger
If a patient chooses to opt-out of the HIE then the receptionist will indicate that in the registration system and that will be sent to the HIE via the ADT message

<table>
<thead>
<tr>
<th>Step#1</th>
<th>Patient visits a healthcare organization and is registered.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step#2</td>
<td>Registrar verifies the person’s identity (e.g., driver’s license).</td>
</tr>
<tr>
<td>Step#3</td>
<td>Registrar enters the patient’s demographics into registration system.</td>
</tr>
<tr>
<td>Step#4</td>
<td>Registrar explains to patient the consent policy and the notification of privacy practices.</td>
</tr>
<tr>
<td>Step#5</td>
<td>Patient reviews materials and makes an informed decision to “Opt-in” (or out, etc.)</td>
</tr>
<tr>
<td>Step#6</td>
<td>Registrar records the consent status in registration system and files signed consent.</td>
</tr>
<tr>
<td>Step#7</td>
<td>Registration system sends patient demographics and consent to HIE via an interface (ADT Z-segment).</td>
</tr>
<tr>
<td>Step#8</td>
<td>HIE receives patient consent and optionally transforms format and terminology.</td>
</tr>
<tr>
<td>Step#9</td>
<td>HIE looks up patient and saves patient consent status in the HIE.</td>
</tr>
</tbody>
</table>

**End State**
HIE has recorded the patient’s consent status.

### 3.5.4 EMR/Portal Publishes a CCD to HIE

<table>
<thead>
<tr>
<th>Goal</th>
<th>Provide a mechanism to convey key patient clinical data for transitions of care</th>
</tr>
</thead>
<tbody>
<tr>
<td>Examples</td>
<td>A PCP or Patient using the Wellness portal publishes a Continuity of Care Document (CCD) for a patient referred to a specialist</td>
</tr>
<tr>
<td>Assumptions</td>
<td>• CCD is a generic term for any structured HL7 CDA document</td>
</tr>
</tbody>
</table>
| Variants | • CCDs may be optimized for various use cases (i.e. referral, perinatal, ED, etc)  
• For example, the HITSP C32 is a constrained version of the HL7 CCD intended to summarize a patient’s medical status whereas a C28 is intended as an ED summary. |
| Trigger | • Signing a chart following an ambulatory visit (push model)  
• On demand document requests for a patient (pull model) |

| Step#1 | A patient visits a provider and key clinical data are captured in the provider’s EMR system |
| Step#2 | The provider completes the documentation for the visit and signs the patient’s chart. |
| Step#3 | The EMR publishes a CCD upon signing the chart and sends the CCD to the HIE |
| Step#4 | The HIE saves the CCD to the HIE XDS Repository and registers the CCD in the HIE registry |
| Step#5 | <optional> other data feeds may be sent to the HIE for transformation into a CCD |
| End State | A CCD is sent to the HIE for future access by authorized users |

### 3.5.5 Public Health - HIE publishes data to various entities – ex. CDC or immunization

| Goal | Provide a mechanism to convey key patient clinical data deidentified to governmental agencies |
| Examples | Allergy data is sent to the CDC to aid in drug to drug interactions |
| Assumptions | • CCD is a generic term for any structured HL7 CDA document |
| Variants | • May not be a full CCD or could be transformed to another format |
| Trigger | • Batch model nightly after being deindentified and cleaned (push model) |
### Data Standards in Population Health Management

<table>
<thead>
<tr>
<th>Step#1</th>
<th>A patient visits a provider and key clinical data are captured in the provider’s EMR system</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step#2</td>
<td>The provider completes the documentation for the visit and signs the patient’s chart.</td>
</tr>
<tr>
<td>Step#3</td>
<td>The EMR publishes a CCD upon signing the chart and sends the CCD to the HIE</td>
</tr>
<tr>
<td>Step#4</td>
<td>The HIE saves the CCD to the HIE XDS Repository and registers the CCD in the HIE registry</td>
</tr>
<tr>
<td>Step#5</td>
<td>HIE copies data into separate database where data is deidentified, cleaned and massaged and readied for batch job to send.</td>
</tr>
</tbody>
</table>

**End State**

De-identified data is sent to the CDC for public health studies.

### 3.5.6 EMR/Portal Views Clinical Documents in HIE

<table>
<thead>
<tr>
<th>Goal</th>
<th>Provide access to clinical data to a Provider within the EMR workflow</th>
</tr>
</thead>
<tbody>
<tr>
<td>Examples</td>
<td>A Specialist views clinical data from a PCP for a specific patient</td>
</tr>
<tr>
<td>Assumptions</td>
<td>The EMR and Portal can connect to the HIE, directly in the providers workflow for maximum value</td>
</tr>
<tr>
<td>Variants</td>
<td>The EMR may seamlessly hit a HIE portal preserving patient context (and leveraging SSO)</td>
</tr>
<tr>
<td>Trigger</td>
<td></td>
</tr>
</tbody>
</table>
| • A provider queries the HIE on demand (pull)  
| • A provider is notified of new data in the HIE (push) |

<table>
<thead>
<tr>
<th>Step#1</th>
<th>A provider is seeing a patient and wishes to have historical information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step#2</td>
<td>Provider accesses the HIE from within the EMR workflow</td>
</tr>
<tr>
<td>Step#3</td>
<td>The EMR performs standard HIE queries against the HIE to obtain HIE data</td>
</tr>
<tr>
<td>Step#4</td>
<td>The EMR displays the HIE data in the workflow of the Provider.</td>
</tr>
</tbody>
</table>
### End State

The provider is able to access historical patient data directly from within their EMR or via the Wellness portal system.

---

#### 3.5.7 EMR Imports Clinical Documents from HIE

<table>
<thead>
<tr>
<th>Goal</th>
<th>Provide access to clinical data to a Provider within the EMR workflow</th>
</tr>
</thead>
<tbody>
<tr>
<td>Examples</td>
<td>A Specialist views clinical data from a PCP for a specific patient</td>
</tr>
<tr>
<td>Assumptions</td>
<td>The EMR can connect to the HIE, directly in the providers workflow for maximum value</td>
</tr>
<tr>
<td>Variants</td>
<td>The EMR may seamlessly hit a HIE portal preserving patient context (and leveraging SSO)</td>
</tr>
<tr>
<td>Trigger</td>
<td>• A provider queries the HIE on demand (pull)</td>
</tr>
<tr>
<td></td>
<td>• A provider is notified of new data in the HIE (push)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Step #1</th>
<th>A provider is seeing a patient and wishes to have historical information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Step #2</td>
<td>Provider accesses the HIE from within the EMR workflow</td>
</tr>
<tr>
<td>Step #3</td>
<td>The EMR performs standard HIE queries against the HIE to obtain HIE data</td>
</tr>
<tr>
<td>Step #4</td>
<td>The EMR displays the HIE data in the workflow of the Provider.</td>
</tr>
<tr>
<td>Step #5</td>
<td>The EMR is able to save the clinical data from the HIE into the provider’s EMR system</td>
</tr>
</tbody>
</table>

---

### End State

The provider is able to access HIE documents data directly from within their EMR system.
3.6 Sample workflows:

3.6.1 CCD Publish

1. A patient visits a provider and key clinical data are captured in the provider’s EMR system.
2. The provider completes the documentation for the visit and signs the patient’s chart.
3. Upon PCP signing of the patient chart, the EMR/PM performs a PIX query for the patient global ID.
4. The EMR/PM publishes the CCD to the HIE.
5. The HIE stores the CCD in the Repository and registers the document in the Registry.
6. **OPTIONAL**: Other data feeds may be sent to the HIE for transformation into a CCD and subsequent publishing to XDS.

3.6.2 Publish, Consent, Consume

1. The patient logs into the Portal application.
2. The patient keys in any metadata that may be required by the Portal to execute the document publication to the HIE.
3. The patient uploads the clinical document(s) to the Portal.
4. The Portal publishes the clinical documents to the HIE, along with the patient’s consent to do so.
3.6.3 Secure Node

Local Secure Node (EMR)

Remote Secure Node

ITI-19

User

1. Local Secure Node presents identity to Remote Secure Node
2. Remote Secure Node confirms identity of Local Secure Node
3. Remote Secure Node presents identity to Local Secure Node
4. Local Secure Node confirms identity of Remote Secure Node
5. Secure Node authenticates identity of the user requesting access to the node

3.6.4 eMPI

Patient Identity Source (HIS, EMR, PM)

EmPI Identity Manager

Registrar

Portal

1. Registrar adds a new patient into EMR or PM system.
2. EMR/Portal sends demographic data to the EMPI in the HIE.
3. EmPI receives the new demographic record and compares it to existing records.
4. EmPI calculates a comparison score and compares it to a threshold score based on MPI algorithm determined during the tuning process.
5. EmPI adds a new patient into the HIE, if score exceeds the threshold score. Otherwise, flag as potential duplicate or no match.
6. EmPI adds linkage from HIE enterprise identifier to the local medical record.
7. EmPI sends patient EMPI to the Document Registry via an ITI-8 message.
4 Identification of the Origin of Individual Data Elements

A data set is a collection of data that is produced from a data source such as a database or information system. It will contain data elements which are units of data that are clearly defined by a controlled vocabulary. The data elements captured by the EHR and clinical information systems will be mapped to the CCD. It will contain a header and a body. The CCD body will contain the core patient data sections corresponding to the CCR sections.

CCD will contain relevant administrative, demographic, and clinical information about a patient's health in one or more clinical encounters. It will allow providers and healthcare organizations to aggregate pertinent patient information and forward it for continuity of care. CCD uses standards in terminology, messaging, and data structure for data exchange of diverse clinical information for patient care, public health, and quality reporting. One of the motivations was to enable aggregation of patient data from multiple disparate systems into one format, and enable PHRs to provide effective delivery of care across multiple providers.

CCD maps the CCR functionality into HL7 V3 CDA format. CCD puts a set of constraints on CDA by using templates. CCD was originally intended to provide clinical summaries, and is increasingly being used for
other types of entries such as labs. CCD can be looked as a set of templates which can be added or taken out depending on the needs of its users. The CCD is semantically equivalent to the CCR, both using XML and ANSI-based specifications.

In the header, each CCD document will be identified by a universal unique identifier (UUID), and will ensure the uniqueness of the document. A human readable document ID will also be provided. The patient, date, time will be identified at document creation. The document type or title will be provided such as admission, follow-up transfer, referral, or discharge, or progress notes. The CCD will also contain information about electronic processing and retrieval for example, language, conformance (identifies specific version of document), and ACK (acknowledgement of receipt).

The CCD body will contain the core patient data sections corresponding to the CCR sections. The problems section will contain the current and past problems list. The procedures section will include the patient’s therapeutic, diagnostic, and surgical procedures. Family history section will contain familial diseases and risks. Social history will include demographic information as well as occupation, social, lifestyle, and health risks. Payer section will contain information to collect payment. Advance directives section will contain living wills and DNR status. Alerts sections will provide allergies and adverse drug reactions. The medications section will contain the current and past medications list. Immunizations section will list the current and history of immunization status. Medical equipment section will include durable and implanted medical devices. Vital signs section will contain the recent vital signs and trends. Labs section will contain current and recent labs results. Functional status section will contain the patient’s normal functioning status at time the record was created. The results section will contain results from radiology and other procedures. Encounters section will list other clinical encounters of the patient. The plan of care will contain orders, referrals, appointments, procedures, or other pending services, and also include the goals of the clinical encounter.

**Continuity of Care Document (CCD)**

<table>
<thead>
<tr>
<th>Header</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Document ID</td>
</tr>
<tr>
<td>• Date/Time</td>
</tr>
<tr>
<td>• Document Type</td>
</tr>
<tr>
<td>• Subject</td>
</tr>
<tr>
<td>• Source: Author, Organization</td>
</tr>
<tr>
<td>• Intended recipients</td>
</tr>
<tr>
<td>• Purpose</td>
</tr>
<tr>
<td>• Metadata: Language, Processing status, Conformance ID, ACK acknowledgement</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Body</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Problems</td>
</tr>
<tr>
<td>• Procedures</td>
</tr>
<tr>
<td>• Family History</td>
</tr>
<tr>
<td>• Social History</td>
</tr>
<tr>
<td>• Payers</td>
</tr>
</tbody>
</table>
• Advance directives
• Alerts
• Medications
• Immunizations
• Medical equipment
• Vital signs
• Functional status
• Labs
• Results
• Encounters
• Plan of care

Data Elements captured by Information System

<table>
<thead>
<tr>
<th>Information Systems</th>
<th>Data Elements (DEs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>EHR</td>
<td>Document ID</td>
</tr>
<tr>
<td>EHR</td>
<td>Date/Time</td>
</tr>
<tr>
<td>EHR</td>
<td>Document Type</td>
</tr>
<tr>
<td>AIS</td>
<td>Subject, demographics</td>
</tr>
<tr>
<td>EHR</td>
<td>Source: Author, Organization</td>
</tr>
<tr>
<td>EHR</td>
<td>Intended recipients</td>
</tr>
<tr>
<td>EHR</td>
<td>Purpose</td>
</tr>
<tr>
<td>EHR</td>
<td>Metadata: Language, Processing status, Conformance ID, ACK acknowledgement</td>
</tr>
<tr>
<td>EHR</td>
<td>Problems list</td>
</tr>
<tr>
<td>EHR</td>
<td>Procedures</td>
</tr>
<tr>
<td>EHR</td>
<td>Family History</td>
</tr>
<tr>
<td>EHR</td>
<td>Social History</td>
</tr>
<tr>
<td>AIS</td>
<td>Payers</td>
</tr>
<tr>
<td>AIS</td>
<td>Advance directives</td>
</tr>
<tr>
<td>EHR (CPOE)</td>
<td>Alerts</td>
</tr>
<tr>
<td>PIS, EHR</td>
<td>Medications</td>
</tr>
<tr>
<td>EHR</td>
<td>Immunizations</td>
</tr>
<tr>
<td>EHR</td>
<td>Medical equipment</td>
</tr>
<tr>
<td>EHR</td>
<td>Vital signs</td>
</tr>
<tr>
<td>EHR</td>
<td>Functional status</td>
</tr>
<tr>
<td>LIS</td>
<td>Labs</td>
</tr>
<tr>
<td>EHR</td>
<td>Results</td>
</tr>
</tbody>
</table>

Metadata’s which will provide both structured and unstructured entries for these data elements in the CCD, will include the following.

(HITSP, 2009)
## Problems Metadata
- Problem Date
- Problem Type
- Problem Name
- Problem Code
- Treating Provider
- Age (at Onset)
- Cause of Death
- Age (at Death)

## Procedures Metadata
- Procedure ID
- Procedure Type
- Procedure Free Text Type
- Procedure Date / Time
- Procedure Provider

## Family History Metadata
- Pedigree
- Family Member Information
- Family Member Demographics
- Family Member Relationship
- Family Member Relationship Free Text
- Family Member Identifier
- Family Member Name
- Family Member Date of Birth
- Family Member Administrative Gender
- Family Member Ethnicity
- Family Member Medical History
- Family Member Condition
- Family Member Age
- Family Member Age (at Onset)
- Family Member Cause of Death
- Family Member Age (at Death)
- Family Member Biological Sex
- Family Member Multiple Birth Status
- Family Member Genetic Test Information
- Family Member Genetic Test Code
- Family Member Genetic Test Name
- Family Member Genetic Test Result
- Family Member Genetic Test Date

## Social History Metadata
- Social History Date
- Social History Type
- Social History Free Text
- Social History Observed Value

## Medications Metadata
- Free Text Sig
- Indicate Medication Stopped
- Administration Timing
- Frequency
- Interval
- Duration
- Site
- Dose Restriction
- Product Form
- Delivery Method Coded
- Product Name Free Text
- Product Name
- Free Text Brand Name
- Drug Manufacturer
- Product Concentration
- Type of Medication
- Status of Medication
- Indication
- Patient Instructions
- Reaction
- Vehicle
- Dose Indicator
- Order Number
- Fills
- Quantity Ordered
- Order Expiration Date/Time
- Order Date/Time
- Ordering Provider
- Fulfillment Instructions
- Fulfillment History
- Prescription Number
- Provider
- Location
- Dispense Date
- Quantity Dispensed
- Fill number
- Fill Status
These data elements captured by the EHR and clinical information systems will be mapped to the CCD, providing a PHR for continuity of care, supporting patient wellness portals, and providing employee health management to employers. The CCD will be used in reporting to public health agencies for biosurveillance, by collecting and analyzing data elements such as chief complaints, microbial labs results, radiology results, and medications both prescription and over-the-counter. Data elements such as asthma medication use, high blood pressure control, diabetes care, immunization status, cancer screening, weight/BMI assessments, and beta-blockers after a heart attack can be used in the Healthcare Effectiveness Data and Information Set (HEDIS) as a tool to measure quality, performance, and trending to NCQA.

5 Use of standards
The proposed solution will rely entirely on established and relatively mature emerging standards for healthcare IT. Standards applicable to the collection, storage, transport and exchange of clinical and demographic patient information will be leveraged to the extent that they do not subject the organization to undue and uncomfortable levels of risk from a legal, regulatory, compliance and IT strategy standpoint.
5.1 Illustrated Example

5.2 Base Standards

EDI (X12): the ASC X12 organizations is the officially designated standards body for development of electronic data interchange (EDI) standards. “ASC X12 has sponsored more than 315 X12-based EDI standards and a growing collection of X12 XML schemas for health care, insurance, government, transportation, finance, and many other industries. ASC X12's membership includes 3,000+ standards experts representing over 350 companies from multiple business domains.” (Wikipedia)

Integration Profiles: describe an integration solution to a particular problem by documenting roles, actors, standards and design details to ensure the systems will operate in cooperation with each other. There are numerous standard established integration profiles available and our solution will leverage the applicable ones. (IHE)

HL7 CDA R2: “...Health Level Seven International (HL7) is a not-for-profit, ANSI-accredited standards developing organization dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information that supports clinical practice and the management, delivery and evaluation of health services.” (Health Level Seven International)

DICOM: is the industry standard for transferring radiologic images between healthcare and radiology information systems, and is patterned on the open system interconnection model of the Industry Standards Organization. (Radiology Society of North America)
ASTM: “ASTM International, formerly known as the American Society for Testing and Materials (ASTM), is a globally recognized leader in the development and delivery of international voluntary consensus standards.” (ASTM International) While ASTM has developed and manages hundreds of standards across many industries, we will leverage only those applicable to our proposed solution.

NCPDP: creates and promotes pharmacy focused electronic data interchange standards. The standards are continually revised, with changes identified through the version number of the standard. NCPDP is accredited by ANSI. (NCPDP)

5.3 Composite Standards
In some cases, no one single standard can be leveraged and in these cases, standards are forged together to build composite standards. In the case of Health Level Seven (HL7) Version 3.0 Continuity of Care Document (CCD), the below make up the composite standard. (Committee, TN 901 - Technical Note for Clinical Documents, 2008)

- IHE Content Profiles specified by the Integrating the Healthcare Enterprise (IHE) Patient Care Coordination (PCC) Technical Framework Revision 4.0
- Health Level Seven (HL7) Implementation Guide for CDA Release 2.0: History and Physical (H&P) Notes
- Health Level Seven (HL7) Implementation Guide for CDA Release 2.0: Consultation Note

Additionally, in a way, the CDA content modules suggested make up a composite standard in that no one standard stands alone on its own, but together, they make up and constrain the content that can be used. Those content modules that make up HITSP/C83 include all of the following. (Committee, TN 901 - Technical Note for Clinical Documents, 2008)

<table>
<thead>
<tr>
<th>Construct</th>
<th>Interoperability Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>HITSP/C28 - Emergency Care Summary Document Using IHE Emergency Department Encounter Summary (EDES)</td>
<td>HITSP/IS04 - Emergency Responder Electronic Health Record</td>
</tr>
<tr>
<td>HITSP/C32 - Summary Documents Using HL7 Continuity of Care Document (CCD)</td>
<td>HITSP/IS03 - Consumer Empowerment and Access to Clinical Information via Networks HITSP/IS04 - Emergency Responder Electronic Health Record HITSP/IS05 - Consumer Empowerment and Access to Clinical Information via Media HITSP/IS07 - Medication Management HITSP/IS08 - Personalized Healthcare HITSP/IS09 – Consultations and Transfers of Care</td>
</tr>
<tr>
<td>HITSP/C37 - Lab Report Document</td>
<td>HITSP/IS01 - Electronic Health Records Laboratory Results Reporting HITSP/IS03 - Consumer Empowerment and Access to Clinical Information via Networks HITSP/IS05 - Consumer Empowerment and Access to Clinical Information via Media HITSP/IS08 - Personalized Healthcare HITSP/IS09 – Consultations and Transfers of Care</td>
</tr>
<tr>
<td>HITSP/C38 - Patient Level Quality Data Document Using IHE Medical Summary (XDS-MS)</td>
<td>HITSP/IS06 – Quality</td>
</tr>
</tbody>
</table>
### 6 Information system requirements

#### 6.1 Operational Requirements

A system with a financial and operational impact as significant as our proposed undertaking requires the appropriate focus on defining operational requirements. Operational requirements generally focus on how, when, why, and where the system will be used. What follows is the list of operational requirements that are defined for our proposed solution:

**Business Continuity Plan:** An effective business continuity plan will be developed, tested and operationalized prior to any component of the system integration going live.

**Disaster Recovery Plan:** The system will have a Restore Point Objective (RPO) of 1 hour, and a Restore Time Objective (RTO) of 2 hours. In layperson terms this means the system will be configured with backups in such a manner that a catastrophic failure would lose at most 1 hour’s worth of data, and the system would not be unavailable for more than 2 hours.

| HITSP/C48 - Encounter Document Using IHE Medical Summary (XDS-MS) | HITSP/IS02 - Biosurveillance |
| HITSP/IS04 - Emergency Responder Electronic Health Record |
| HITSP/IS08 - Personalized Healthcare |
| HITSP/IS09 – Consultations and Transfer of Care |
| HITSP/C74 - Remote Monitoring Observation | HITSP/IS77 - Remote Monitoring |
| HITSP/C75 - Drug Adverse Event Report | HITSP/IS11 - Public Health Case Reporting |
| HITSP/C76 - Case Report Pre-Populate | HITSP/IS11 - Public Health Case Reporting |
| HITSP/C78 - Immunization Content | HITSP/IS10 - Immunizations and Response Management |
| HITSP/C84 - Consult and History & Physical Note | HITSP/IS08 - Personalized Healthcare |
| HITSP/IS09 – Consultations and Transfers of Care |
| HITSP/C35 - Lab Result Terminology | HITSP/IS01 - Electronic Health Records Laboratory Results Reporting |
| HITSP/IS05 - Consumer Empowerment and Access to Clinical Information via Media |
| HITSP/C80 - Clinical Document and Message Terminology | HITSP/IS08 - Personalized Healthcare |
| HITSP/IS09 - Consultations and Transfers of Care |
| HITSP/IS10 - Immunizations and Response Management |
| HITSP/IS11 - Public Health Case Reporting |
| HITSP/IS77 - Remote Monitoring |
| HITSP/C83 - CDA Content Modules | HITSP/IS08 - Personalized Healthcare |
| HITSP/IS09 - Consultations and Transfers of Care |
| HITSP/IS10 - Immunizations and Response Management |
| HITSP/IS11 - Public Health Case Reporting |
| HITSP/IS77 - Remote Monitoring |

Table Source: (Committee, TN 901 - Technical Note for Clinical Documents, 2008)
Transition & Go-Live Plan: The HIE solution will be on-lined in a phased approach, with the core infrastructure going live initially, and then each additional system going live one at a time with an elaborate testing and change freeze window around the go-live date.

Meaningful Use: While the ARRA Meaningful Use Stage 1 requirements are not specifically depended upon HIE due to the relative scarcity of functioning HIE’s in the US, there is a requirement of successful exchange of clinical information. (HIMSS 2010 - 2011 Health Information Exchange Committee, 2010) Our proposed solution will leverage the HIE technology to achieve the clinical information exchange requirement of Meaningful Use Stage 1 and position the organization for what is almost certain to be a required robust adoption of HIE in the future stages of Meaningful Use.

6.2 Functional Requirements
When designing a complex integration / interoperability platform for health information it is critical that functional requirements be identified and adhered to throughout the system development lifecycle. Functional requirements are the fundamental inputs, tasks, and outputs the system must utilize to perform the desired work. It is imperative that the functional requirements be designed in collaboration with, and largely driven by, the end user – the person / people for whom the system is being designed and built for. Failure to accurately identify functional requirements prior to building the system, or failure to adhere to them throughout the build result in a product that doesn’t meet the needs of the end user and will likely be costly to remediate.

Enterprise Master Patient Index (EMPI): The solution will provide a single master unique identifier for each patient as well as an index to easily cross reference the identifiers from integrated systems with the identifier in the HIE. Intrinsic to the HIE, it will accumulate and / or index data for patients from disparate systems and sources, most of which are using proprietary patient identification schemes. It is critical to the success of an integrated / interoperable system that patients are uniquely identified, and all appropriate and associated documents are linked to the correct patient regardless of their source. It is an imperative requirement in achieving both semantic and syntactic interoperability. The HIE must be able to accept information from connected systems and identify the appropriate patient in two different ways: EMPI number; demographics matching. In the former, the downstream systems adopt the EMPI scheme used by the HIE and send clinical information that is positively identified and connected to a specific patient based on the EMPI identifier. The latter is more complex, less precise, but essential. Rules are configured for the matching algorithm and demographic information from the incoming clinical record is matched against the demographic information stored in the EMPI. Examples of demographic data commonly used in the matching algorithm include date of birth, social security number, name, gender, address, phone number, etc. (HIMSS HIE Guide Work Group, 2009)

Record Disambiguation: The system will provide a platform for manually evaluating and associating clinical records with EMPI records. Based on the complexity, and configurability of matching rules as a component of the EMPI functionality, incoming records are classified in one of three ways: matched, unmatched, and undetermined. For records that are classified as matched, no further action is required as the clinical documentation is automatically associated with the appropriate EMPI record. Records
that are classified as unmatched often generate and associate a new EMPI record (although this behavior is configurable). For the records that are classified as undetermined, essentially they kind of match an existing record, manual review is required. The undetermined records are generally put into a work list, which requires a human to review and determine if an association with an existing EMPI record should be associated or a new one generated.. (HIMSS HIE Guide Work Group, 2009)

**Insurance Eligibility:** The system shall perform real-time eligibility verification considering the patient’s insurance provider and benefit level, diagnosis, proposed treatment or procedure, and medical necessity. ASC X12 transaction 278 shall be used for preauthorization request. Depending on the outcome of the eligibility verification, the system shall provide confirmation of eligibility, allow a pre-authorization request to be sent, or prompt the medical provider to initiate an Advanced Beneficiary Notice (ABN) for a non-covered treatment or procedure.

**Medication List:** The system will aggregate and store a codified list of medications based on the National Drug Code (NDC) and transmit payloads using NCPDP. By storing the summarized clinical lists in a codified manner we are continuing to adopt established and emerging industry standards for healthcare information portability and furthering the basis for statistical analysis of the clinical data.

**Problem List:** The system will aggregate and store a codified list of problems based on the International Classification of Disease (ICD) diagnosis code. By storing the summarized clinical lists in a codified manner we are continuing to adopt established and emerging industry standards for healthcare information portability and furthering the basis for statistical analysis of the clinical data.

**Allergy List:** The system will aggregate and store a single list of known patient allergies. By storing the summarized clinical lists in a codified manner we are continuing to adopt established and emerging industry standards for healthcare information portability and furthering the basis for statistical analysis of the clinical data.

**Immunization List:** The system will aggregate and store a single list of immunizations. By storing the summarized clinical lists in a codified manner we are continuing to adopt established and emerging industry standards for healthcare information portability and furthering the basis for statistical analysis of the clinical data.

**Procedure List:** The system will aggregate and store a codified list of historical procedures based on the Current Procedural Terminology (CPT) and HCPCS Level I codes. By storing the summarized clinical lists in a codified manner we are continuing to adopt established and emerging industry standards for healthcare information portability and furthering the basis for statistical analysis of the clinical data.

**Laboratory Results:** The system will provide an aggregated longitudinal view of all lab tests and results in customizable views to include flow sheet and trending options.

**Record Locator Service (RLS):** The system will identify the source system and current “source of truth”, as well as current location for each piece of clinical information indexed and presented through the HIE.
This HIE model will be a hybrid of the central repository and federated models. A key to increasing subscribership to HIE’s is allowing the member organization’s to maintain local ownership and control of their records, but providing organized and controlled access to them based role. This model aggregates and stores some information, such as the clinical lists (meds, problems, allergies, etc.), but simply links to connected systems and pulls records on demand. (HIMSS HIE Guide Work Group, 2009)

**Provider Index:** The system will provide an aggregated codified index of healthcare providers based on the National Provider Identifier (NPI). Each provider in the index will be uniquely identified by their NPI and associated with the patients and clinical documentation for which they’ve provided treatment.

**Patient Record Export:** The system will provide a method to export the aggregated longitudinal medical record in a standard Clinical Document Architecture (CDA) format to meet patient medical record portability guidelines.

### 6.3 Security

The system will store and communicate all information using industry standard encryption and security methodologies in compliance with the appropriate regulatory requirements.

### 7 Information System Architecture Diagram

As demonstrated from the above information systems architecture diagram, the network topology will be comprised of a multi-layered network that embrace a foundational security model to ensure
restricted access to information within the ACO/CCO HIE network. The physical network is brought together on the backbone of the internet that connects private healthcare provider networks together through encrypted channeled networks that then sustain an intranet layer network which facilitates information exchange across connected network subnets. Composite security standards shall be employed, combining VPN, PKI certificates and firewalls marshal the access to information. All communications, once connected, on the HIE network is protected through encrypted pipelines that encapsulates packets that are transmitted and received between end points. Public cipher keys are used to encrypt message packets as they are sent and private keys applied to decipher the payload. If either part of the keys is tampered with, checksums are violated and the message is invalidated. The encryption routines employed will ensure that integrity is preserved. All transactions that occur and payloads within are then protected.

Shared data dictionaries will be adopted to define definition of terms and nomenclatures to map data across the compatible fields across the disparate systems and data repositories that are shared across the ACO/CCO.

The public facing wellness portal is populated with information from the aggregated wellness data sets sent in CCD payloads from the HIE data warehouse. Access to the wellness portal is done through the internet. Any connected consumer or contributor will be required to authenticate with credentials that are predetermined. Sessions will be established and protected with the same composite security standards that are used by care providers within the HIE. Future enhancements will enable patients to share information from their PHR with specified providers. Using service oriented architecture (SOA), web services shall allow disease control agencies such as the Center for Disease Control and Prevention (CDC) to call methods to subscribe to information data changes. The wellness portal will serve as the publisher of information and changes occur the subscribing system(s) are alerted and can consume it for processing into the interested systems. Following a subscription model, timely updates can be received in real time and connected decision support systems can act and alert proactively when action is needed. The wellness portal will be located within a demilitarized zone (DMZ) which requires authentication and authorization in order to access and is segregated within its own segmented network for greater protection to the downstream connected networks. Future uses of the portal may include provider credentialing, user registration, community registrations, email campaigns, etc.

8 Description of the flow of data sets between systems

With the data elements identified that are available in CCD, the decision next is how to bring the elements together in a minimum data set (MDS) that can be used while satisfying the business needs. To do this HITSP interoperability specifications (IS) were researched. There are a number of IS related to HL7 CCD but through HITSP a select few have been chosen and combined together to form a composite set of standards to effectively transmit HL7 CCD across systems and facilitate exchange of wellness information.
A base IS that will be leveraged is HITSP/C32 Summary Documents Using HL7 Continuity of Care Document (CCD). Independent IS are referred to as “Components” or “Constructs” in HITSP documents. The summary documents “describes the document content summarizing a consumer’s medical status for the purpose of information exchange. The content may include administrative (e.g., registration, demographics, insurance, etc.) and clinical (problem list, medication list, allergies, test results, etc) information. Any specific use of this Component by another HITSP specification may constrain the content further based upon the requirements and context of the document exchange. This specification defines content in order to promote interoperability between participating systems. Any given system creating or consuming the document may contain much more information than conveyed by this specification. Such systems may include Personal Health Record Systems, Electronic Health Record Systems (EHRs), Practice Management Applications and other persons and systems as identified and permitted.” (Committee, HITSP Summary Documents Using HL7 Continuity of Care Document (CCD) Component, 2006)

In addition to HITSP/C32, HITSP/C83 is used for defining content modules and includes modules such as “HL7 CCD, IHE PCC Technical Framework, HL7 Consult Note, etc.” (Committee, TN 901 - Technical Note for Clinical Documents, 2008) HITSP/C80 supplements the combined Constructs to add Clinical Document and Messaging Terminology.

The below diagram shows the suggested integration specifications that will be used for information exchange within the IHE. The items in blue represent implementation guides containing data sets within a composite standard and those in grey the base standards. We can see that all of the data sets are brought together by the combined standards and through accepted industry standards, the solution achieves interoperability with other systems that implement the same. The diagram also shows how each of the various data sets map or relate to one another together as combined transactions. In relation to the ACO/CCO, all of these transactions occur from different systems and at different times as users of the systems interact with patients in coordination of their care. HL7 CCD allows for a reliable means of exchange of this information. As it is exchanged and destined for the HIE data store where this information is aggregated and finally sent to the wellness portal where biosurveillance systems and patients can consume and in some cases manage information which then feeds back into the HIE.
Diagram reference: (Committee, TN 901 - Technical Note for Clinical Documents, 2008)
9 Recommendations and Conclusions

In reflection again on the IOMs definition of population health, it is Wellness Consulting’s belief that through employing the recommended wellness portal, the ACO/CCO will be collectively assuring “the conditions for people to be healthy” (Wagner, Moore, & Aryel, 2006). The ACO/CCO will be contributing to society by proactively engaging individuals under our care to take ownership of their own health and enable care providers to better coordinate that care.

All stakeholders identified shall be involved at their identified level of interest and shall champion adoption by socializing the project within their respective channels of influence. Responsible and accountable stakeholders shall receive regular project updates through the ACO/CCO Project Management Office. Steering committees will be created to involved key business leaders in order to make critical project decisions.

To implement, we recommend a phased standards based approach to begin the exchange of clinical data, encapsulated by a CCD, at the HIE and community levels. In parallel, we recommend the development of a wellness portal to capture patient specific information. This portal will consume, publish and send data to governmental and downstream systems within the ACO/CCO model. As the portal launches it will be marketed directly to the general patient population as well as towards local employers looking to provide benefits to their employees with the added benefits of cost reductions in healthcare insurance premiums.

Success will be evaluated at predetermined intervals and measured according to the metrics identified in the study. Expectations are that the proposed solution will establish a balance and mitigate forseen risks. When executed correctly, the population health management capabilities through the added ACO/CCO wellness portal will ensure the sustainability and funding needed to continue to develop the IT infrastructure necessary for long terms savings estimated by converting towards an ACO/CCO type model. It also offers appealing secondary revenue and patient loyalty retention opportunities that the market have shown exists.

The standards based architecture that has been proposed will open possibilities for future integrations for future projects that can help establish the ACOs/CCOs leadership position in the market further.
Works Cited


http://www.ncpdp.org/standards.aspx


