

Importance of Quality Management in the Implementation of Health Information Exchanges

A FOX White Paper



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Objective

Experience has shown that Health Information Exchange (HIE) efforts face a broad set of challenges in their attempt to link together disparate healthcare organizations and data to improve health outcomes.¹

Although not unique to HIE, the number of challenges grow organically with the number of organizations included in the effort. Historically, the solutions to these challenges have focused on the expanded use of technology. However, these are not simply technology projects; they are also exercises in organizational change. FOX analysis would suggest that the application of fundamental Quality Management (QM) techniques and tools to these challenges can assist in addressing both the technological and organizational components of HIE.

Health Information Exchange Background

The following provides a high-level review of HIE and its current drivers:

*Health Information Exchange (HIE) is defined as the mobilization of healthcare information electronically across organizations within a region or community. HIE provides the capability to electronically move clinical information between disparate healthcare information systems while maintaining the meaning of the information being exchanged. The goal of HIE is to facilitate access to and retrieval of clinical data to provide safer, more timely, efficient, effective, equitable, patient-centered care.*²

With the advent of the Indiana Health Information Exchange (IHIE) in 1994, the healthcare industry has been moving slowly toward a desired end-state of “interoperability,” linking healthcare organizations to their patient-centered data. Other industries, such as financial services, have outpaced the healthcare industry and are able to successfully link client-specific data across organizations on a national and international level. Standardization is a key to success in other industries, and will be in healthcare as well. Current key enablers within the healthcare industry that support HIE include the ongoing development of data and data exchange standards (e.g., EDI for HIPAA and H-7 for clinical messaging).

In 2004, the Federal Government announced its HIE intentions. President Bush’s Executive Order Executive Order 13335 called for:

...the widespread adoption of interoperable electronic health records (EHR) within 10 years and [establishment of] the Office of the National Coordinator of Health Information Technology (ONCHIT) to provide leadership to achieve this goal.

An expectation of Executive Order 13335 is the formation of Regional Health Information Organizations (RHIO) that will serve as repositories of EHR information for all persons in a particular region. RHIO structural success is based upon ongoing “standardization activities” including:

- Widespread adoption of HL-7 version 3
- Acceptance of the ASC X12N 275 Claims Attachment using HL-7 version 3 functionality
- The ASC X12N 275 transactions adoption of LOINC
- Adoption of the standards being developed by HHS, CCHIT, and HL7

¹ Colleen Egan. “Many Lessons To Be Learned from Santa Barbara Data Exchange.” iHealthBeat, Aug., 2007. <<http://www.ihealthbeat.org/articles/2007/8/3/Many-Lessons-To-Be-Learned-From-Santa-Barbara-Data-Exchange.aspx?a=1>>

² “Health Information Exchange.” Wikipedia. 8 Aug. 2007. <http://en.wikipedia.org/wiki/Health_information_exchange_%28HIE%29>

In addition to standardization activities, federal and state support funding (e.g., Agency for Healthcare Research and Quality (AHRQ) Grants Medicaid Transformation Grants) is on the increase. As detailed in the AHRQ funded "Evolution of State Health Information Exchange/A Study of Vision Strategy and Progress,"³ there are over 100 distinct state-based HIE projects in over 35 states that cite Medicaid as a "stakeholder." eHealth initiatives identified 165 HIE initiatives in 49 states. Further is noted in the eHealth Initiative's *Third Annual Survey of Health Information Exchange Activities at the State Regional and Local Levels* published September 25, 2006:

- The level of policy activity and leadership at the state level has increased significantly in the last year. Thirty-six bills were passed in 24 states during 2005 and 2006, calling for the use of Health Information Technology (HIT) to improve health and healthcare, and 10 state governors have passed executive orders related to the same.
- Health information exchange initiatives are continuing to mature. Among the 165 HIE initiatives identified by the 2006 survey, 45 are in the implementation stage (stage four), and 26 have identified themselves as fully operational (stage five or six). This is significantly in line with 2005 results, which indicated that 40 HIE efforts expected to be in implementation within six months, and 25 expected to be fully operational within the same time period.
- Interest in improving quality and safety, inefficiencies experienced by providers, and rising healthcare costs, are the primary drivers for health information exchange efforts. Ninety-two percent of respondents cited "improving quality" as a significant driver of their HIE efforts, while 82 percent cited "improving safety." Additionally, 70 percent cited "inefficiencies experienced by providers who need information to support patient care" as a significant driver, while 56 percent cited "rising healthcare costs."
- Over 20 percent of respondents are exchanging clinical data. At least one-fifth of respondents are now transmitting a broad range of data electronically including claims, dictation, emergency department episodes, enrollment or eligibility data, inpatient and outpatient episodes, laboratory results, and radiology results.

In short, there is a convergence of elements that will bring increasing "interoperability" to healthcare and support a nationwide HIE structure. This inexorable march is not without obstacles.

HIE Known Barriers

The nationwide Health Information Network (NHIN) that we create will almost certainly consist of a "network of networks," a collection of interconnected, interoperable health information exchange (HIE) networks that are, in turn, a collection of interconnected, interoperable health information systems. To interconnect these HIEs, we need to establish consistency in the interfaces that transport data between the various subsystems. This consistency is required for both technology (*What message formats will we use?*) and policy (*Is it appropriate to make data available to this type of user in this specific setting?*).⁴

The concept of "nested" networks highlights the complexity of the HIE cross-organizational endeavor. The industry has noted three major areas of concern that have surfaced in almost every HIE initiative. They are:

³ AHRQ, Avalere Health, LLC.

⁴ Marc Overhage. "Health Information Exchange: 'Lex Parsimoniae.'" Health Affairs. Aug., 2007

- **Organizational Alignment** — These issues manifest as the lack of commonality in stakeholder interest, a lack of clarity regarding the state-level HIE and the federal NHIN roles, and the absence of demonstrated strategies for success.
- **Privacy and Security** — The overall level of “trust” must be increased in order to share this highly sensitive data across the many organizational entities. Data sharing among competitors in the healthcare arena is a prerequisite for HIE success and must be effectively addressed. A long-term data “custodianship” structure has not been identified.
- **Funding and Long-term Sustainability** — The lack of a “standard” for business case development and the perceived “high cost of entry” are two of the aspects of funding that have surfaced in HIE efforts nationwide.⁵

These problems, although challenging, are not entirely unique to HIE projects and our analysis would suggest that in applying Quality Management (QM) principles, some of the challenges and inherent risks could be mitigated successfully.

This kind of cross-boundary collaboration has been evaluated by the National Association of State Chief Information Officers (NASCIO), which suggests 10 structured steps that can make a difference in successfully engaging in HIE cross-boundary collaboration. They are:

- | | |
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| 1. Define Goals | 6. Examine Statutory Limits |
| 2. Make a Business Case | 7. Establish Fiscal Responsibility |
| 3. Gain Executive Buy-In and Support | 8. Build Trust |
| 4. Understand the Environmental Landscape | 9. Communicate the Benefits |
| 5. Determine Governance | 10. Evolve to a Networked Community of Practice (CoP) |

HIEs are distributed systems that are dependent upon the ability to link multiple disparate systems and independent data sources owned by multiple stakeholders. This underscores the importance of utilizing sound QM structures exemplified by Capability Maturity Model Integration (CMMI).

Quality Management

“In God we trust all others bring data.”
—*W. Edwards Deming*

The use of QM tools and techniques is widely accepted in the Information Technology (IT) arena. Carnegie Mellon University, in conjunction with the United States Department of Defense, has developed a model for assessing quality in IT. Their model is referred to as the Capability Maturity Model Integration (CMMI).

A basic premise drawn from the model that could be applied to all IT projects (including HIE projects) is presented in the following statement:

⁵ Cal RHIO Summit Report. “Barriers and Solutions to Health Information Exchange.”

The quality of a system is highly influenced by the quality of the process used to acquire, develop, and maintain it. This premise implies a focus on processes as well as on products. This is a long-established premise in manufacturing (and is based on TQM principles as taught by Shewhart, Juran, Deming, and Humphrey). Belief in this premise is visible worldwide in quality movements in manufacturing and service industries (e.g., ISO standards).

“Quality Management is a subset of project management that includes the processes required to ensure that the project will satisfy the needs for which it was undertaken.” – *Project Management Body of Knowledge (PMBOK)*⁶

FOX has been using QM tools and techniques in its consulting engagements for the past 20 years and has developed Quality Principles for use internally, as well as QM structures for use by our state and federal clients.

FOX has embraced the PMBOK definitions of the three components of Quality Management:

- **Quality Planning:** Involves identifying which quality standards are relevant to the project and determining how to satisfy them.
- **Quality Assurance:** Is all the planned and systematic activities implemented within the quality plan or system to provide confidence that the project will satisfy the relevant quality standards.
- **Quality Control/Independent Verification & Validation (IV&V):** Involve monitoring specific project results to determine if they comply with relevant quality standards, and identifying ways to eliminate causes of unsatisfactory results.

Quality Management Consists of:

Quality Planning
Inputs
Quality Policy
Scope Statement
Product Description
Standards & Regulations
Tools & Techniques
Cost/Benefit Analysis
Benchmarking
Flow-charting
Cost of Quality
Outputs
Quality Management Plan
Operational Definitions
Checklists

Quality Assurance
Inputs
Quality Management Plan
Results of Quality Control
Measurements
Operational Definitions
Tools & Techniques
Quality Assessments
Quality Audits
Outputs
QA Status Reports
Quality Improvement

Quality Control
Inputs
Work Results
Quality Management Plan
Operational Definitions
Checklists
Tools & Techniques
Inspection/Reviews
IV&V
Trend Analysis
Outputs
Quality Improvement
Acceptance Decisions
Rework/Adjustment
Completed Checklists

⁶ The Project Management Institute (PMI). *Project Management Body of Knowledge Guide (PMBOK® Guide)*, 1987.

The HIE/QM Connection

Our analysis suggests that HIE projects would benefit from the use of QM in both the technology and organizational dimensions. As we noted earlier, the major barriers faced by HIE initiatives are Organizational Alignment, Privacy/Security/Trust, and Funding/Long-term Sustainability. In each of these areas, the benefits of QM techniques appear clear:

Organizational Alignment

Task and Deliverable Definition — Clear task and deliverable definition is particularly important when dealing across organizational boundaries.

Structure, Processes, Procedures, and Schedule — The cross-boundary collaboration brings unique factors into play, and a well-documented plan with project processes, procedures, and schedule/milestones helps the many disparate parties keep moving in the same direction.

Resources, Roles, and Responsibilities — Perhaps the key element in a QM plan that helps promote organizational alignment is a clear definition of the collaborators' specific resource commitments, roles, and responsibilities.

Privacy/Security/Trust

Periodic Measurement against Quality Standards — The HIE initiatives are relying upon published Privacy and Security standards established by the HIPAA Privacy and Security Rule. Using periodic compliance reviews of the HIE project plan and software components should begin to build a level of trust.

Measurable Quality Specifications and Requirements — Applying measurable standards for Privacy and Security along with Memorandums of Understanding (MOUs) between the collaborating partners to clearly define data use and ownership boundaries would assist HIE partners with establishing "trust."

Funding/Long-term Sustainability

Quality Management Plan — The metrics developed in creating a QM plan should assist the HIE collaborators in developing and maintaining a strong business case. The business case should contain "measurable" success criterion (e.g., financial, clinical and operational). These metrics can serve dual purposes (e.g., budget projections for long-term sustainability and outcome measurement).

Capability Maturity Model Integration (CMMI) — The potential use of a model like CMMI within the HIE effort to provide prospective funding sources with widely expected metrics should assist in retaining existing funding and obtaining new funding sources.

Summary and FOX QM

In summary, FOX believes that the "fledgling" state of most HIE initiatives offers the opportunity to apply QM tools and techniques to help ensure their success. The key barriers would appear to be at least partially mitigated through sound structure and measurement afforded by Quality Management. FOX metrics for successful application of Quality Management is presented below.

Quality Management Is Effective When:

- It is aligned with the organizational philosophy
- It is valued within the organization
- It is proactively planned into projects
- QM activities are regularly communicated
- It is based on industry standards

About Fox Systems, Inc.

Fox Systems, Inc. (FOX) is a nationally recognized consulting practice that provides information systems and operations consulting services to public and private sector health care clients. FOX specializes in consulting services related to large-scale information systems that support state Medicaid programs, Managed Care Organizations (MCOs), Pharmacy Benefit Managers (PBMs), and Clearinghouses. Incorporated in California in 1987 by Susan J. Fox, Ph.D., FOX is a privately held corporation, with woman-owned certification in several states. FOX maintains corporate headquarters in Scottsdale, Arizona, and has numerous field offices throughout the United States to facilitate the completion of major health information technology contracts.

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