

Information Governance in an Academic Medical Center: A Case Study

(Research Paper)

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Abstract: While information governance programs abound in most sectors, they are not widely leveraged in healthcare and vary highly when they exist. We report on a case study of a four-year journey towards information governance at a mid-sized academic medical center. We discuss the factors prompting a more formal approach to information governance, the components of information governance most relevant to our institution, our initial program and lessons learned. We conclude that in our institution, and likely in healthcare in general, information governance and information system governance are essential for enterprise data quality and cannot be treated separately.

Keywords: Information Governance, Data Governance, Information Quality, Healthcare

INTRODUCTION

Robust information governance frameworks, for example the Data Governance Institute (Data Governance Institute, 2017) and the IBM Data Governance Blueprint (IBM, 2007) have been discussed in the IQ community for at least the last decade. However, only recently has information governance entered the discussion in the healthcare sector. Widespread reuse of healthcare information for research, prompted by the Clinical and Translational Science Award program funded by the National Institutes of Health (NIH), was one driver starting in 2006 with the first round of the CTSA program. A second and larger driver is the Electronic Health Record (EHR) adoption curve in healthcare in the United States. Prompted by the Health Information Technology for Economic and Clinical Health (HITECH) Act, enacted as part of the American Recovery and Reinvestment Act of 2009, with rare exception, hospitals in the United States have implemented electronic health records as have office-based medical practices reimbursed by the Centers for Medicare and Medicaid Services (CMS). After an average three-year initial implementation time, healthcare facilities moved from initial implementation to realizing the need to optimize EHRs toward improving the practice of medicine and ultimately patient safety and outcomes. Hitting the optimization phase of the EHR adoption curve ushered in the need to use healthcare information at the point of care, to

guide facility operations and strategic decision-making, for quality improvement, and for research. Thus, the driver for increased and improved information use in healthcare has only recently come upon us and healthcare organizations are just beginning to realize the need for information governance.

A recent literature search of the MEDLINE indexed literature identified seventy-three articles relevant to information governance in healthcare. Ninety-three percent of the relevant articles were published since 2009. Similar to other sectors the scope of described information governance varies widely with some articles and implementations focusing solely on privacy or some other singular aspect of information governance while others cover multiple aspects of information governance. While 78% of the seventy-three relevant articles covered general healthcare information governance, the majority of them (thirty-three of the fifty-seven) were from a Health Information Management (HIM) perspective, which concentrates on record access, security, retention and coding to support the revenue cycle. Twelve (16%) of the articles covering general healthcare focused narrowly on one or two areas of information governance such as security or privacy. An additional twelve (16%) of the articles covered information governance more broadly. The remainder of the articles focused on disciplines within healthcare such as Nursing or Finance, or focused on secondary use of data for research. Compared to other sectors, very little has been published about establishing Information or Data Governance programs in healthcare facilities. While information governance is well established in other sectors, it remains exploratory and unproven in healthcare. Our work augments the understanding of governance in Information Quality (IQ) theory by describing a system of governance *specifically for healthcare*.

HEALTHCARE CONTEXT

Importance of governance in healthcare

While better use of health information is seen as a primary antidote to medical error being the third leading cause of death in the United States, (Makary & Daniel, 2016) (HITECH, 2009) several aspects of healthcare complicate information governance. Healthcare environments must adapt to new demands daily and the Electronic Health Record (EHR) must encode these changes in information and workflow; organizational roles and process must be adapted in kind. Change in this area hasn't been managed well in the past as evidenced by both The Joint Commission's (TJC) Sentinel Event Alert 54 (The Joint Commission, 2015) along with the Office of the Inspector General (OIG) in the OIG Compendium of Unimplemented Recommendations (Office of Inspector General, 2015) (Monegain, 2015). These recognize healthcare clinical systems as a potential sources of adverse events and holds the clinical and operational leadership responsible (Payne, Corley, Cullen, & Gandhi, 2015) (Miller & Gardner, 1997).

Healthcare is a complicated environment made up of many subcomponents, all of which are adapting daily to pressures from the world outside as well as internal demands (Figure 1). External changes come from the clinical, revenue cycle, compliance and quality areas. New disease management, as well as changes to older disease management, formulary, tests, and procedures are all clinical sources of change. The revenue cycle has undergone changes like Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), the Merit-Based Payment Incentive System (MIPS), Comprehensive Primary Care Plus (CPC+), move from fee-for-service, and the switch to the ICD-10 coding system. State narcotics tracking, 2-midnight rule, and note cosign are some examples of compliance change. Finally, quality change is illustrated by Leapfrog, Sepsis, and PQRS. These changes impact the information and workflow requirements across multiple roles in healthcare and most often require changes in information systems.

Internal sources of change come from the executive level as well as the front line. Often the response in terms of organizational change is accomplished through internal, top-down pressure on facility operational units. While many of the motivators come from the same external forces mentioned before, others are the results of administrative developments like internal reorganization into clinical service lines

versus functional units such as medicine and nursing. On the other hand, the electronic health record (EHR) system users are also a source of internal, bottom-up change. Local quality initiatives are a part of business. Lastly, the EHR itself is in a constant state of change. Every eighteen months major version upgrades are needed to keep current in product functionality; these upgrades bring thousands of changes and enhancements that need to be configured, trained, and adopted.

Healthcare information governance must provide control mechanisms that take into account all of these internal and external factors. Without well-managed data, both administrators and clinicians are working blind or worse, with false information. It is for all of these reasons that information governance in a medical environment is extremely important. Ultimately, the decisions medical data supports affect patient health.

Because of these internal and external sources of change, the modern EHR system is in a continual state of flux. In light of this flux, the importance of governance cannot be overstated. This case study endeavors to examine the complicated process of data management and delivery in one institution. The research question addressed was *“What data governance processes support and encourage the delivery of quality data in a healthcare environment?”*

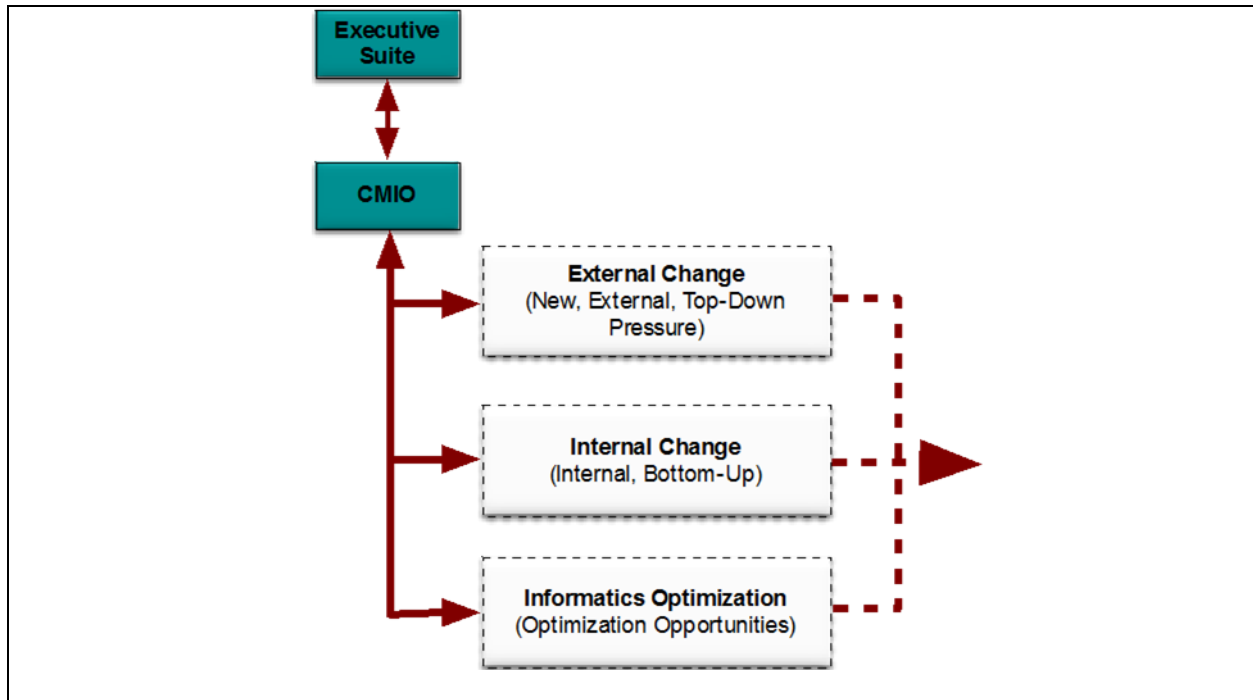


Figure 1: Forces Prompting Change in Healthcare Facilities

INSTITUTIONAL CONTEXT

This case study takes place within a moderate sized academic medical center that also undertakes teaching and research. Narrative data from the perspective of the Chief Medical Information Officer (CMIO) was collected through participant observation in the installation and use of an Epic EHR System over a 4 year time period. Epic is one of a short list of EHR software vendors that is used both nationally and internationally. The governance process evolved over this period and the variables contributing to successes as well as failures make up the following analysis. We are the only tertiary care facility in the state, thus, we routinely see patients who receive the majority of their care elsewhere. Our inpatient facility has 450

beds and 32,000 discharges per year. Our emergency department (ED) sees 60,000 cases per year. Our outpatient facilities include more than 80 clinics servicing 450,000 encounters or patients per year. The health system employs over 5,000 people, most of who regularly enter into or use information from the EHR system.

In 2013, our facility moved to migrate from a hybrid system of paper and multiple EHR (inpatient Sunrise, outpatient GE Centricity) to the Epic EHR unifying inpatient and outpatient record keeping and revenue cycle processes. Prior to this decision, we had never employed a CMIO and all technology decision-making was independently made from within the information technology department, often without important clinical and operational input. This style of IT driven decision making led to a pre-implementation environment of misalignment between operational and clinical best practices and the supporting technology infrastructure. The first CMIO was hired late in the implementation phase after many key design decisions had been made, including the rollout and training strategy. Upon arrival, the CMIO found the implementation at risk. Key operational and clinical leadership expressed a lack of inclusion and input in key decision-making, including key clinical workflows and priorities. There was no active clinical governance and the administrative status reports concentrated only on the overarching timeline and budget impact. In addition, the rollout strategy was constructed around multiple small rollouts that would have left the organization using hybrid systems and workflows for months. The first priority was to establish a system of governance that would assure that key administrative and clinical leadership were included on all design decisions that would impact the business and clinical workflows. The CMIO restructured and began chairing a Project Steering (administrative) Committee, assuring that key stakeholders reviewed and shaped the details of the project plan. A clinical and physician advisory group were staffed and chaired to review and oversee the clinical workflows and training strategy. An Operational Advisory Committee was established, assigning and involving an operational lead in every application group and assuring that these groups were aware of the decisions being made in other application groups. Finally, the CMIO staffed a clinical informatics group to coordinate the day-to-day clinical and operational involvement around application build. The clinical informaticists were able to translate technical requirements to the clinicians, and translate clinical requirements to the technicians. This governance infrastructure successfully improved the involvement, sense of ownership, communication, and alignment of the build decisions with the clinical and business strategy. The Epic go-live was converted to a “big bang”, many of the original assumptions concerning priority, workflow, and design were influenced by this governance process and the institution successfully went live in May of 2014 with Epic inpatient, outpatient, OR, ED, OBGYN, Lab, Radiology, Cancer, and Revenue Cycle.

Following go-live, there was a substantive period of stabilization required. During this phase, unanticipated breaks in process and build were repaired to return the organization to full function. All elements of the established governance was required to vet the changes being made to the system. Once stabilized, our organization made a common, yet critical underestimation of the ongoing operational workforce required to govern and advise the ongoing change. Many of our administrative and clinical subject matter experts were reabsorbed into their clinical and operational roles. Attendance and participation in governance waned. This paper addresses the tough decisions that every organization needs to consider when they take on these transformative EHR projects - clinical/operational staffing and processes around change. Epic had numerous resources and experience to advise the IT department on the number and types of technical resources required for the maintenance of the system, but offered little organizational guidance around the ongoing clinical and operational workforce needs and processes. Our institution is now in the optimization phase of EHR use. Optimization, requires using the clinical and revenue cycle data to drive improvements in the triple aim of our organization (patient care safety/quality, cost containment, and patient satisfaction). Data becomes a key organizational resource which demands an entire governance framework, inclusive of the change governance surrounding the clinical systems. Data governance includes the strategic philosophy around data use, access by the organization members, transmittal to external entities, identification of stewards and methodologies to assure adequate data quality, and even technologic questions concerning privacy, security, and archiving methods. One of the key lessons learned is that since our migration to our

EHR, the need for Governance has grown to assure that data, a key institutional resource, has the appropriate quality to serve in reliable institutional transformation. Ongoing data and change management governance needs to accompany the ongoing need for build and workflow change brought by the ever changing clinical, regulatory, financial, and user landscape.

EARLY ATTEMPT AT INFORMATION GOVERNANCE

As is common, the initial institutional state of governance around information systems was none at all, this is level-1 maturity in the IBM Data Governance Council Maturity Model (IBM, 2007). The IT department decided whose build and data requests to fulfill, developed the project plan, and determined the priority. This led to many common idiosyncrasies of non-governed systems:

1. Inappropriate Access to Change and Information – in a complex academic institution, there are many employees who vary in their authority to command work effort and system change. Often, the IT department is not equipped to arbitrate on this demand management.
2. Workload Issues – in our organization, there were numerous pathways and sources for build and data demands to enter the system. This project load overwhelmed our resources.
3. Lack of Appropriate Priority – in our organization, clinical quality, regulatory compliance, and financial stability are key priorities. IT departments are rarely equipped to gauge the priority of business and clinical projects. Critical projects were often delayed by projects of lower priority to the business.
4. Lack of synchrony – it was not uncommon for people to request overlapping or opposing changes to the system. This lead to redundant work effort and incompatible demands.

It was clear that the non-governed state was unsustainable. A governance process was needed to assure that the system change and data access assured that decisions were being made by the business, at the correct level, and with the correct priority.

INFORMATION GOVERNANCE GROWING PAINS

The challenges to instituting governance we faced fell into two distinct categories, operational resistance and IT resistance.

1. Operational Resistance/Reluctance – many of our institutional issues with information systems came from a historic lack of participation by the business in technical decisional making and prioritization. Early on, this was exacerbated by an operational and clinical workforce that was naïve to information technology impact and lacked dedicated time and interest in information technology systems. But, over time, the growing informatics workforce and education as well as growing societal exposure to information technology had created an operational workforce capable of providing deep insight onto technologic needs and workflows. In addition, IT governance grew in importance to the institutional financial viability, as the IT budget consumed above 3% of gross revenue. The CMIO emphasized that governance needed to be in place to assure that the IT systems and data supported to the key pillars of the organization (patient care quality and safety, patient satisfaction, and cost containment). Now, leadership desires to participate in product selection, design, project planning, and workflow.
2. IT Resistance/Reluctance – in our institution, another source of challenge was from our information technology colleagues. The historic vacuum created by the lack of business participation had created a paternalistic IT style. The assumption was that the end user knew nothing about

technology or their requirements, so IT would make these determinations. Most technical projects created large user dissatisfaction, because individuals who did not understand the business requirements and workflows made the decisions. Concurrently, the national shortage in health information technology personnel created an IT workforce with minimal technical experience. The customer satisfaction surveys during this phase were so poor that the need for change became clear. The institution went through an independent, external audit of IT processes. The results showed significant institutional impact and dissatisfaction around 4 key areas:

- a. Lack of inclusion of the clinical and operational owners early in the process of selecting and configuring the product.
- b. A lack of involvement of the clinical and operational owners in the project planning and build decisions.
- c. A lack of involvement of the clinical and operational owners in the testing and signoff of the delivered product.
- d. A lack of communication and training to the clinical and operational owners prior to release of change.

These are especially important to the institution and physicians given that the workflow and decision support provided through the EHR impacts the practice of medicine and the precedent and prevailing philosophy of the learned intermediary, where liability for care accrues to the physician and institution. Briefly, based on legal precedent set in the therapeutic development industry regarding product warnings provided to physicians, the physician is viewed as a learned intermediary and final decision-maker regardless of the underlying information system or information provided. Leveraging the clinical informatics teams ability to translate technical and operational requirements, the CMIO devised a governance system to address these four areas of concern.

CURRENT STATE

In our institution, the data governance framework shown in the in figure 2 is intended to function similarly to the DGI framework and our institution has moved to a level-3 in data governance maturity. The clinical informatics change cycle requires the roles and processes to provide the control mechanisms that establish a process for governing how data is generated / delivered and by whom (Data Governance Institute, 2017). There are four job roles which together process the flow of change: clinical informaticist, subject matter expert, project manager and the builder/programmer. An information-based approach to healthcare delivery requires clinical informatics, the science of information technology as applied to healthcare (American Medical Informatics Association, 2017). Clinical informaticians are the clinical and operational workforce that assures systems are optimized to meet the requirements of patient care. The subject matter expert, a medical professional, is the end-user end user who will use the tools being developed or modified, can speak to the clinical/operational process as an expert, serves as spokesman for all end-users. Project managers are trained project management professionals (PMP). They develop and manage the project plan, timeline, and duty roster for each project and can hold enterprise resources accountable. Informatics and information technology (IT) builders make up a build team. Informatics builders are typically certified by Epic and work to optimization of operational information whereas IT builders maintain the technical aspects of the information processing.

Change Cycle

A clinical informatics change cycle for managing EHR changes will help to ensure a smooth process flow. The stages of this cycle begin with a planned governance process and complete a cycle with the evaluation of the resulting informatics output (Figure 2). The first step, governance, is about oversight and priority of change in an effort to align work effort with need and timeline (Lorenzi & Riley, 2000). In this stage, the clinical informaticist and subject matter expert decide which projects are worth doing and in what order should they be addressed. Stage two is informatics strategy, which is designed to align build strategy with need. All four roles participate in this stage, taking a systematic approach to determining what the need is, what changes should be made and what the scope should be based on cost. The build is the third stage, where the objective of the builders is to build according to the plan in order to align build quality with need (Payne, Corley, Cullen, & Gandhi, 2015) (The National Learning Consortium, 2013). The fourth stage is test and signoff. To assure build quality and alignment with need, all four roles participate in assuring the build strategy and build is correct and usable. In stage five communicating the change and training are the focus, assuring use aligns with build (Lorenzi & Riley, 2000) (The National Learning Consortium, 2013). Informaticians, subject matter experts and project managers are involved along with instructional designers. Training resources are created and a training environment is built. This stage prepares end-users for the change to their environment. The final stage is informatics evaluation where the system is monitored and evaluated for optimization opportunities (The National Learning Consortium, 2013). Here informaticians make sure that build functionality and usability is at an optimum.

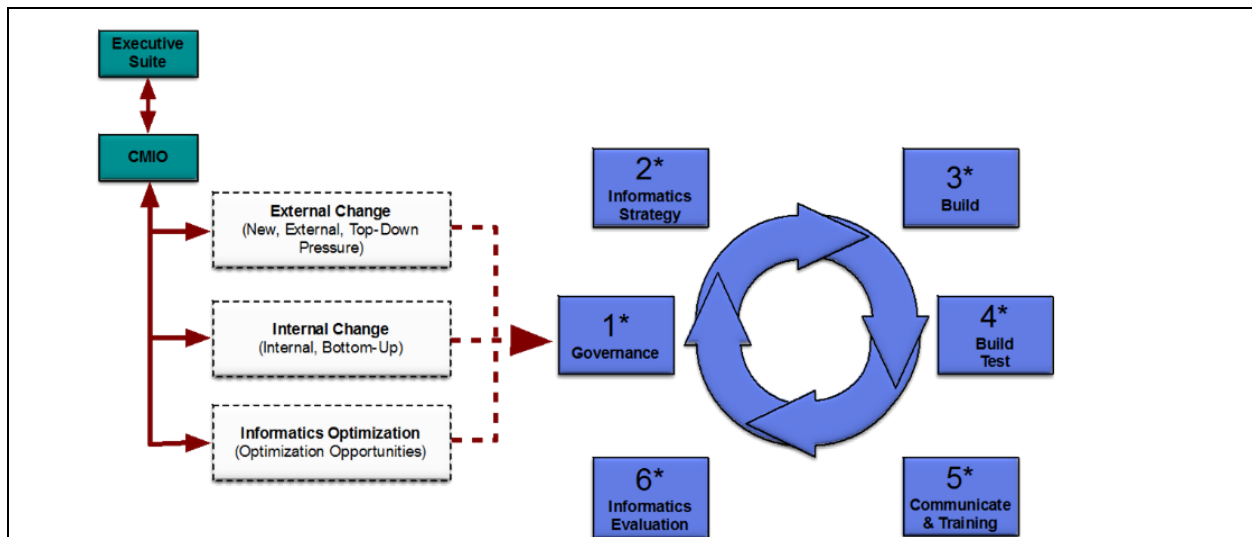


Figure 2: Clinical Informatics Change Cycle

Role clarity

Informatics and IT are differing roles. A clinical informaticist is an operational role on an operational optimization team. They are trained in informatics science, have clinical experience, a technical skillset and they are trained in the EHR technical schema. Clinical informaticists also have experience in the local clinical administrative environment and build choices as well as membership in the optimization team administratively coordinated from the office of the CMIO for alignment. The optimization team designs, implements, and adapts tools and workflows to extract full benefit from human and technology interaction. They work through complex operational, clinical projects which are challenging to iterate without constant interaction. This role requires operational and clinical knowledge, relationships, and credibility to succeed. The job of optimization is that of adapting tool build including Clinical Decision Support (CDS), Computerized Physician Order Entry (CPOE), clinical documents, the clinical interface, and workflow for optimal performance. Managing change in clinical quality, revenue cycle, compliance and usability/efficiency are all aspects of optimization. The role of clinical informaticist is also vertical and

spans from problem characterization, to solution conceptualization and specification, build, implementation and evaluation. The practice of informatics by necessity encompasses the entire vertical span and the aforementioned cross-training in clinical and technical knowledge is required to achieve it (Friedman, 2013) (Friedman, 2009).

IT roles are focused on the hardware, software and its functionality. The build analyst is a technical role on a service-based technical team that requires training in the EHR technical schema and experienced in local IT administrative environment but not clinical experience. The application team is administratively coordinated from the office of the CIO. The application team is responsible for the constant and ongoing support for day-to-day system needs such as incident support, maintaining the product, organizing the technology triad and environment upkeep as well as build migration.

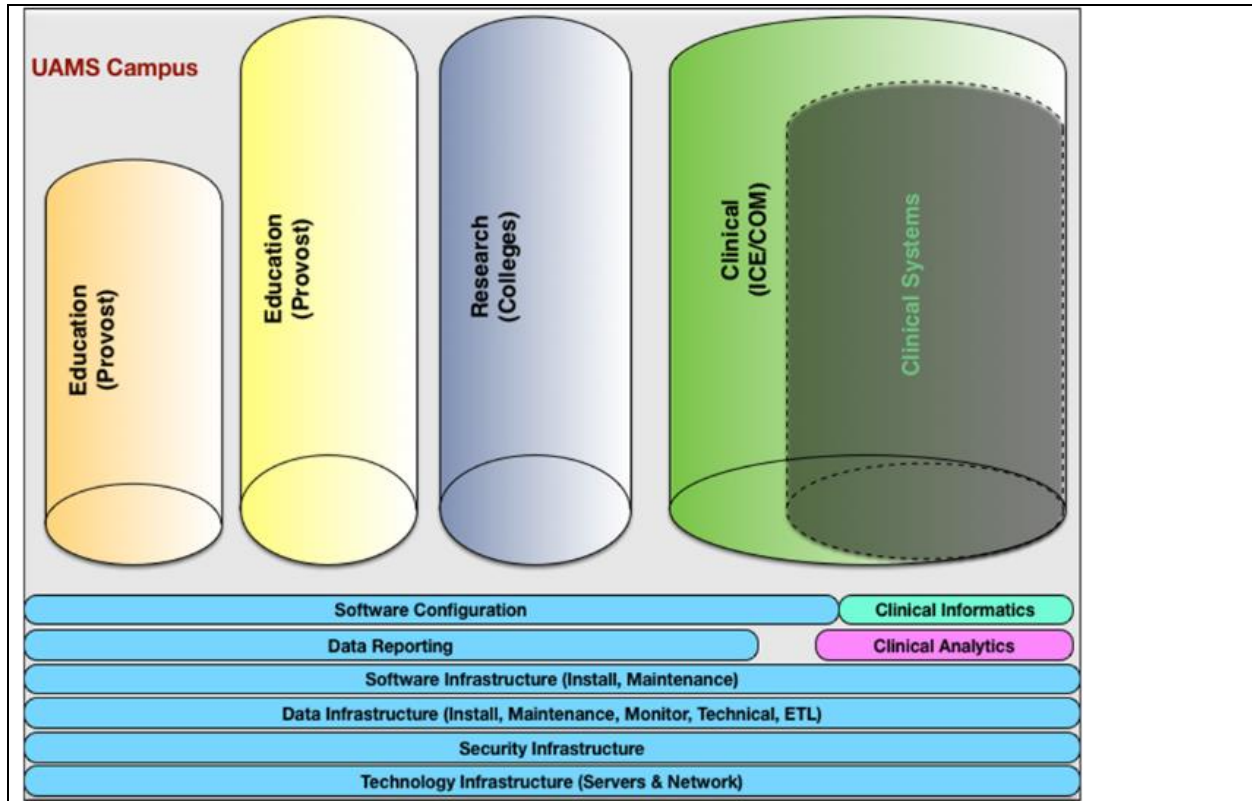


Figure 3: IT Service Level Agreement

Process Management

This institution has an IT Service Level Agreement. A service level agreement (SLA) is a contract between a service provider and the end user that defines the level of service expected from the service provider. The metrics that define levels of service for an ISP should guarantee A clear description of the service (role) being provided, reliability, responsiveness, procedures for reporting problems, monitoring and reporting service level, consequences for not meeting service obligations and escape clauses or constraints.

The Integrated Clinical Enterprise currently funds in lump sum to the central IT department. Our institution is working to increase transparency regarding what that money purchases and what constitutes new expense. Additionally we are working toward predictable schedules of maintenance, update and upgrade. At the time of original purchase, these should be predicted and budgeted in advance. IT should be providing a clear service and product in a clear budget and as part of the SLA.

CONCLUSION

Healthcare environments are constantly changing to fit the current needs of society and the healthcare environment is complex (The National Learning Consortium, 2013). It is critical that proper business and IT alignment exists and this alignment results from good governance practices. EHR systems must change in response to changes in the healthcare environment but to avoid institutional frailty personnel and processes have to function harmoniously as they adapt. The EHR change process is especially important and following a change process, which does not put clinical concerns, first is risky for the patients and institution (Payne, Corley, Cullen, & Gandhi, 2015) (Miller & Gardner, 1997). EHR changes are not IT projects, they are clinical projects with safety and financial risk (Payne, Corley, Cullen, & Gandhi, 2015) (Miller & Gardner, 1997). Therefore, governance plan is needed that takes these clinical concerns into consideration and to move toward a higher level of data governance maturity as an organization. This paper contributes to IQ theory by describing a system of governance in healthcare and following the governance plan described here will promote a smooth reliable change process.

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