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Management for Personal Health Record (PHR)
Implementation

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ABSTRACT

Electronic Personal Health Records (PHRs) are patient-centred health and/or medical records in electronic form. As healthcare authorities move in the direction of empowering consumers to take more responsibility for their own health through self management and education, implementing PHRs in a cost efficient and effective manner is becoming an important issue. Incorporating Health Information Technology (HIT) procurement best practices into a personal health record (PHR) project can be a valuable risk-reducing exercise. Unfortunately, a set of best practices does not yet exist. This paper investigates three important HIT procurement principles including: contract terms (software licensing and service level agreements), vendor relations (influencers, integrators, certification, request for proposals, the vendor evaluation matrix), and privacy. While neither prescriptive nor exhaustive, these three principles, when properly considered and applied may contribute to a best practices model of PHR procurement, significantly reducing the risks inherent in the procurement process.

Keywords: Personal Health Records; Request for Proposals; best practices; procurement; risk mitigation; vendor evaluation matrix

INTRODUCTION

eHealth (often referred to as health informatics) concerns the use of information and communication technologies within healthcare. Initiatives to develop information systems and electronic records to support the information needs and impact the behaviour of potential users, including all the participants in the consumer's circle of care, must actively involve the users in planning, designing, developing, implementing and evaluating such systems (Bath 2008). There is a need for an appropriate evidence base within eHealth to support future developments, and to ensure such systems realize their full potential of improving the health and well-being of consumers and society in general. In Canada and many other industrialized countries, governments take the majority role in financing and implementing healthcare systems. Two major layers of complexity result from this role. The first layer is the complexity of the healthcare system itself, and the second layer is the complexity resulting from the public procurement process.

'Do not underestimate public sector procurement complexity - public sector procurement managers have a very, very tough job to fulfill because everybody is constantly auditing them. They are hemmed in by mandatory regulations, legal restrictions that they have to fulfill and these regulations have been brought in over 100 years of professional administration of the state.' (Bray 2001)

Procurement is the process of acquiring goods, works or services. The process spans the entire lifecycle of a project from identification of needs, through to the end of a services contract or the end of the useful life of an asset (Bray 2001) and, as such, requires quality input at all project phases to inform the vendor contract - the main focus of the procurement process. In this paper we investigate procurement of Health Information Technology (HIT), in particular the procurement of personal health record (PHR) systems. Although technically similar to IT in other sectors, HIT is often not incorporated naturally into the workflow of healthcare providers and it's not integrated with what end users do. Specifically, 'doctors and nurses don't sit in front of workstations to do their jobs.' (Ho 2005). This makes HIT procurement unique and adds significant risk to any HIT project.

In addition to the layers of complexity in the procurement process already mentioned, procuring a distributed PHR system developed from an integrated architecture (Daglish and Archer 2009) and likely to be favoured in the Canadian context, will result in a process that must be examined carefully (Cooper, Grey et al. 2005). Mitigating, as much as possible, the multiple risks inherent in this type of PHR architecture and functionality is essential. The risks involved in HIT procurement are too numerous to list but taking into consideration some of these main issues surrounding risk, increase the potential for project success.

In the public sector, IT procurement typically occurs through an open competitive request for proposal (RFP) process. This process is used when there is a need for solutions to complex problems or when there is a need for which there is no clear or single solution. An RFP is used to articulate these needs and is part of the invitation to IT vendors to submit proposals. Proposals received from the vendor describe how and what they will provide in response to an advertised

solicitation. Selected proposals are reviewed and ranked based on qualitative, technical and pricing considerations, often using a vendor evaluation matrix. The vendor with the highest ranked proposal that meets all the mandatory requirements may be awarded a contract. When creating a contract, it is imperative that the interests of both parties are outlined in a clear and explicit format to avoid any miscommunication. The contents of the contract should address both the requirements of the RFP and the unique qualities of a healthcare environment.

When structuring the RFP and vendor contract, applying HIT procurement best practices can be a valuable risk-reducing exercise. Unfortunately, a set of best practices has yet to be formalized. In this paper we investigate a number of key procurement principles for PHRs, a type of HIT that is receiving a great deal of attention since PHRs are supportive of patient centred and self managed healthcare. When properly considered and applied, such a model may contribute to a best practices model of PHR procurement, significantly reducing the inherent risks. These principles, which we consider major procurement risk factors, include: contract terms (including software licensing and service level agreements), vendor relations (including the RFP and Vendor Evaluation Matrix), and privacy (Milrad and Rummell 2007).

Because electronic personal health records are relatively new to healthcare, little evidence exists to inform our investigation of PHR system procurement. However, literature about procurement of electronic health record systems (EHR), electronic medical record systems (EMR) and health information technology does exist (e.g. (Bova 1983; Ho 2005; Milrad and Rummell 2007; Goroll, Simon et al. 2009)). Where possible, we use information extrapolated from this literature as a basis for a suitable PHR procurement model, and we incorporate where necessary additional elements that are specific to the PHR environment. Our intention is to flesh out a best practices model that can be applied to the procurement of a PHR system, using published RFP and contract information as a foundation. The information gathered in this preliminary study of HIT procurement could be used to develop a PHR Project Toolkit.

In the remainder of this document, we will first describe what is meant by Personal Health Record (PHR) systems, the target application under consideration. Then we will discuss the proposed best practices model, the related procurement process, and the Request for Proposal (RFP). The Vendor Evaluation Matrix is developed as a key to organizing the RFP responses for the bidding vendors and for the buyer to evaluate the data. The contracting process is described, and conclusion is made summarizing the identification and mitigation of risk inherent in the PHR procurement process.

PERSONAL HEALTH RECORD SYSTEMS

Personal Health Records, or PHRs, are considered to be patient/consumer-centred health and/or medical records in electronic form. The intent of PHR systems is to help consumers manage their own health. There is no consensus on the information PHRs should contain, but it is generally thought that consumers should be allowed to enter their own data, and at the same time have access to clinical data about themselves, as well as targeted educational information about their conditions. PHR systems tend to be more complex and difficult to implement than other healthcare systems since they bring together a broad and diverse group of stakeholders including

healthcare practitioners, healthcare institutions, payers (governments and insurance agencies) and most importantly – the consumer.

Studies have determined that patients prefer to access and control their own health records (Denton 2001; Adler 2006). Patient access can be important, since records may be missing or incomplete due to the fragmented nature of the healthcare system, as they move from one part of their circle of care to another. Patients can take an active role in validating, verifying, and completing records for the primary care team (Staroselsky, Volk et al. 2006). Studies have shown that active PHR use can be a contributing factor in positive outcomes for the chronically ill (Dorr, Bonner et al. 2007). The PHR can be used by the care team for communication and activity tracking, encouraging active participation in self management with the purpose of achieving good health (Hampshire, Blair et al. 2004). PHRs in emergency environments can help save lives by improving the speed and accuracy of staff response. Individuals may access their own health records under the privacy act, except where it is professionally judged to be harmful, or if it is legally prohibited.

Providing electronic healthcare support that extends to all members of the healthcare community is a complex task. To be successful, projects that develop PHRs must build on and integrate with existing electronic systems such as EMRs (used by family physicians), and EHRs (used by hospitals and other institutions) (Daglish and Archer 2008). Implementing such complex systems requires careful project planning and management. The system architecture of a PHR and how it links to clinical information is of utmost importance (Daglish and Archer 2009). The architectures that might be adopted to support PHRs range from tethered to standalone, resulting in a range of complexity. A tethered PHR is connected in some way to one organization's system (typically the patient's family doctor). A standalone PHR is generally seen to be data stored on some portable media, such as a smartcard. A more complex but possibly more usable and flexible system is an integrated PHR, which gathers and presents data from multiple sources into a single view. This integrated approach implies a central site that stores or gathers the accumulated data with associated access protection and presentation tools.

It appears likely that successful PHRs in the Canadian environment will need to be integrated with existing electronic health record systems. In considering this approach, it is useful to look at the recent history of healthcare system integration projects (eHealth Ontario 2009). Recent history suggests that: Electronic record initiatives must deliver demonstrable value to be successful; Top-down initiatives rarely succeed; Direct beneficiaries of initiatives are often the most effective at executing them, and initiatives leveraging standards and proven technology are often successful; It is important to target early achievable results in an eHealth project; Access to comprehensive and accurate patient information is the principal driver of clinical system adoption; and Widespread adoption of physician EMRs preceding any centralized initiative can lead to fast adoption. These lessons guide the PHR procurement and implementation processes and should be used to inform the RFP, vendor evaluation and vendor contract.

Other healthcare project implementations have been undertaken that have some similarity to the scope and complexity of a PHR project. For example, Goroll et al (Goroll, Simon et al. 2009) describe a project that implemented electronic health records and an associated network

exchange for nearly 500 physicians serving 500,000 patients in the state of Massachusetts. The project involved the development of a suitable business plan that was then presented to over 30 major stakeholders to achieve consensus on working collaboratively towards accelerated EHR implementation. Funding was arranged, working groups for specific functional areas were established, and technical standards were developed. Of 55 eligible communities in the state, 35 submitted applications to join the program. After a rigorous selection process, three were selected as demonstration sites. Technical standards for the systems were developed, and an RFP was designed to facilitate best offering from vendors. Of the 20 responding vendors, 7 were eventually selected and recommended to the demonstration communities. Contracts were drawn up with the participating communities and with the vendors. Privacy and security provisions were developed and agreed upon by each of the communities. Project staff visited each practice and worked with them to assist in converting to electronic records and reorganizing workflows and operations. An important aspect of this project was that, since it was a demonstration project, evaluation was an ongoing activity throughout the project.

A key learning from the Massachusetts project was that the scope of the project must be decided carefully in consultation with all the stakeholders, and consensus is essential in deciding the key areas covered and the associated weighting in the RFP.

BUILDIND A BEST PRACTICES MODEL

IT procurement is usually a document heavy process that relies on ongoing quality input from project team members including the project planners, work flow and change management teams, the implementation team, privacy and security teams, and most of all from the major stakeholders. The main specifications for a PHR system should be defined by all these teams in terms of function, availability, performance, resilience and interoperability (Department of Health 2003). These specifications form the basis of the procurement documentation, including the RFP and the contract, both essential to the relevancy and effectiveness of the "make or buy" decision. The Project Management Body of Knowledge (PMBOK) (PMI 2004) procurement process is regarded as a best practice guideline.

In any procurement there is an element of risk; the vendor may fail to deliver, the products and services may prove unsatisfactory in operation, the vendor's business may fail, or the vendor may abscond; the political environment may alter considerably for reasons outside of our control. Due diligence is essential throughout the procurement process, especially before selecting a vendor, and then monitoring vendor practices and performance after implementation, ensuring that the vendor abides by applicable laws, rules, regulations, and best practices (Becker 2005). In the following sections we discuss the three risk-reducing procurement principles that make up our best practices model: contract terms, vendor relations, and privacy. Neither prescriptive nor exhaustive, this list of principles, when properly considered and applied contributes to a best practices model of PHR procurement. Figure 1 is a graphical illustration of the proposed best practices model.
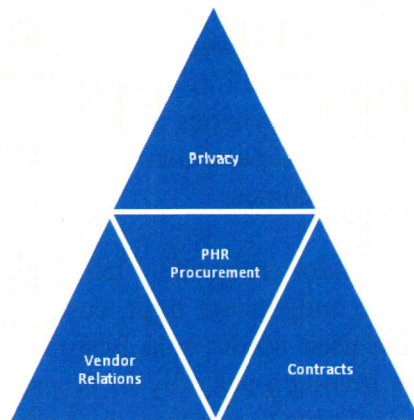
Figure 1 - PHR Procurement Best Practices Model

The Procurement Process

Procurement is a major component of any public project, and is likely to consume the majority of available funding. In the case of a PHR pilot project, the development and implementation of the system would typically be contracted out to a systems integrator. It is therefore essential that the integrator and any vendors working with the integrator be chosen carefully through their responses to an RFP, followed by carefully defining and negotiating a suitable contract. This paper deals primarily with the RFP, vendor evaluation, and contract development (steps 8 through 11 below). However, it is also important to establish context by understanding the process that is followed through the entire project. This is as follows:

1. Develop a suitable system proposal and associated business plan
2. Arrange for project funding (in Canada, this would likely include support from Canada Health Infoway (Canada Health Infoway 2009), a federal agency, matched with support from a provincial health agency in the province proposed for the project, plus additional private sector support)
3. Throughout the project, continue to collect data and evaluate every aspect
4. Build a project team with the appropriate expertise and experience needed for the project
5. Solicit applications from Regional Health Authorities interested in participating in the project
6. Select the Regional Health Authority that will serve as the demonstration site
7. Gather information from the principal stakeholders (consumer segments motivated to adopt PHRs, medical practitioners, healthcare institutions, test labs, etc.), and select participating PHR system users and contributors
8. Develop technical standards and other requirements such as a Privacy Impact Analysis (PIA) for the proposed PHR system
9. Develop a Request For Proposal, and distribute to potential interested vendors
10. Select the top vendors, based on proposals submitted
11. Choose the designated vendor and negotiate a contract
12. Negotiate contracts with the participating principal stakeholders
13. Design and develop the project

14. Undertake a PIA for the proposed system design, and rectify any problems
15. Implement the PHR system (through a carefully designed and controlled rollout process)
16. Collect data on usage, satisfaction, and revisions needed for the PHR system.
17. Analyze data collected and evaluate the operational system.
18. Compare current state to expected outcomes

The healthcare sector looks for vendor proposals that show innovation, reliability and accountability. Considering healthcare budgets are tight, cost is an obvious factor in the vendor selection process, but should not be used as the sole basis for selection. There is a need for vendors to understand that they are involved not only in IT projects but in healthcare projects. The more information that is made available to vendors, the better their ability to forecast project requirements and propose sound solutions. Ongoing development and maintenance of vendor relations throughout the entire procurement process is essential to project success. The RFP and vendor evaluation matrix, as discussed below, are communication tools used to enhance vendor relations by reducing uncertainty and thus their risk.

Request for Proposals

An RFP outlines various components of the system and gives a clear and detailed representation of how the system will function when complete. The objective is to find vendors who will meet stakeholder requirements of quality and cost (Porter-Roth 2002). As there is an increase in the number of heterogeneous health information systems that a proposed system will engage, integration increases as a priority. Integration becomes essential to providing consistent patient-centred care and supporting shared care (Cruz-Correira, Vieira-Marques et al. 2007). Combining data from heterogeneous sources involves much effort, as systems tend to differ in software functionality, data standards and representation, system interoperability, technical standards, and adherence to legislative and policy standards. In a major project that involves developing and implementing a large PHR system for a community such as a provincial health region in Canada, it is typical for a consortium of vendors to submit proposals, where lead vendors are system integrators who bring together other vendors of necessary components that will be used to build the PHR system.

After the system requirements have been gathered, an RFP is created and sent out to vendors, inviting their bids for system creation and/or implementation solutions based on stakeholder requirements (Porter-Roth 2002). The PHR system will be complex and it is imperative that the RFP be as detailed as possible to avoid misrepresentation. If the goals of the system are not emphasized, the vendor might focus on non-essential components rather than focusing on the functional requirements (Porter-Roth 2002). In some cases, the RFP is used as a part of the contract, and is therefore legally binding. If the RFP omits key objectives, the vendor might not be liable for implementing those necessary functional requirements. The RFP process is competitive and allows the stakeholder to choose the most cost effective vendor, but cost should not be a sole means for evaluation. On the other hand the procurement authority may be restricted by government laws to select the lowest price proposal.

A well written RFP adds great value to the procurement process:

- It generates a list of potential project risks and gives the vendor the ability to plan for them ahead of time.
- It gives the purchaser the ability to differentiate between vendors in the context of the project; it also gives the purchaser insight into the vendor's corporate culture and structure.
- By specifying the requirements clearly, the vendor can visualize the project and the steps needed for its completion. However, the requirements should not be so rigid that the vendor is prevented from proposing innovative and cost-effective solutions.

The various risks regarding the PHR system procurement include:

- Creating an RFP is a time consuming task and some vendors might not submit a proposal if they do not believe they have a fair chance at securing the bid (Clarke 2006).
- Since the PHR system is complex, documenting the all requirements can be a difficult task. If this is not done properly within the RFP, it can lead to poor responses due to lack of understanding by the vendor. This can lead to potential misrepresentations in costs and quality.
- In many sections within the RFP, specialized knowledge is needed to understand the vendor's corresponding response (Clarke 2006). Even though a vendor evaluation matrix can be used to judge the vendor's proposal, it is still difficult to create a uniform grading system because of the variance in each vendor's response.

The RFP can be broken down into three general parts (Wheaton 2008): overview; requirements; and organizational structure and responsibilities.

Overview This includes the scope and statement of work with respect to the PHR system. It illustrates the problems around the PHR implementation process and the reasons for creating a PHR system, addresses products and services needed to create the system and, helps potential bidders to see whether or not their products and services align with the interests of the buyer.

Requirements This section outlines a detailed description of the PHR system's functional and non-functional requirements, giving the vendor a clear vision of how the project is intended to operate. By visualizing the final project, the vendor can create an innovative solution based on these requirements. This section also sets the expected level of quality for the vendor by giving requirements such as delivery guidelines, supporting documentation, design specifications, quality metrics, etc.

Organizational structure This defines the buyer's internal structure, culture, current processes and workflows. It may include such documents as internal survey results or performance information. It also illustrates the types of solutions that may be best suited to the buyer.

Vendor Evaluation Matrix

A vendor evaluation matrix is a tool that uses a series of standard questions and ratings to distinguish each vendor's response to the RFP. It is comprised of questions that are based on critical success factors and goals drawn from the requirements of the system. These goals should be developed by a formal committee composed of all stakeholders (Bova 1983), including physicians, nurses, patients/consumers, healthcare educators, and administrative staff.

The committee needs to ensure that the questions created are aligned with the business strategies of clinics/practices, the healthcare regulatory environment, and the needs of consumers. Various tactics, such as surveys, ethnography and/or gap analysis can be used when developing the requirements of the new system. Surveys can be distributed to potential users, asking what is important to them in a PHR system (Sommerville and Koyonya 1998). If the organization has a pre-existing PHR system, ethnography could provide a deeper insight into additional requirements. By observing healthcare providers working with their current systems and detailing their actions, the system's drawbacks are highlighted, documented and turned into requirements (Sommerville and Koyonya 1998). A gap analysis can be performed with existing EMR and/or PHR systems, where the requirements that are already in place are compared to the ones that are lacking (Rockel 2005). By finding what the new system needs and comparing it to what the current system has, a gap analysis can assist in creating new sets of questions and criteria.

After capturing the system requirements, the vendor evaluation matrix can be constructed. The matrix should be designed to include several sections and sub sections, each pertaining to a crucial part of the system. In a PHR system, such sections include: Technical Evaluation, System Characteristics, Security and Privacy, Training and Support, Cost, Requirements Gathering, and Vendor Information. Note that the vendor evaluation matrix is constructed before the RFP is issued.

Technical Evaluation Technical evaluation should be given priority, as the technical aspects of the PHR system are crucial to the overall success of its implementation. The questions developed may reflect functional and non-functional requirements. The technical section can be further broken into sub sections, each ensuring the vendor and stakeholder's expectations are aligned (McGowan, Cusack et al. 2008). Performance measures can be used for benchmarking standards, quantitative outputs, power requirements, process requirements and acceptable throughput times.

Interoperability addresses compatibility issues, which are highly critical for PHR systems. The vendor must address the technical variance in systems, and how to integrate a new PHR system into the existing infrastructure and /or legacy system (McGowan, Cusack et al. 2008). PHR system architecture (e.g. tethered, standalone, or integrated) must be specifically identified considering the characteristics and attributes of each vary significantly (Daglish and Archer 2009). Using the vendor's pre-configured system might require some customization that may have to be negotiated as trade-offs.

A graphical user interface (GUI) will be used by consumers to access their PHRs. A properly designed and usable GUI allows the consumer to navigate through available information.

Questions must be specific enough to vividly represent how the GUI will be constructed, ensuring ease of navigation. (McGowan, Cusack et al. 2008).

System Characteristics System characteristics will explain whether or not the vendor can implement key components of the PHR. These characteristics might be core or non-core functions of the system, and may add some resource requirements for the consumer. Some examples include whether or not mobile access is available, or if reminders of upcoming appointments can be sent in the form of an email to the consumer.

Security and Privacy Security is an important section within the matrix, especially when dealing with personal health information. Due to the sensitive nature of medical records, the stakeholder must ensure the vendor is familiar with privacy and security standards in the jurisdiction where the PHR will be implemented, whether and how unique patient identifiers are created and protected, where the data will be backed up (on-site or off-site), whether the vendor will have access to the system after the implementation and what types of measures the vendor will take in case of a security breach (Rockel 2005). Also of concern is whether the vendor intends to outsource any part of its PHR system (e.g. data storage or customer service operations) to other organizations. It is important to determine whether or not these external entities comply with privacy and security standards, especially if the outsourced activities cross international borders. Incorporating questions relating to the vendor's privacy policy is essential.

Training and Support Training and support questions focus on whether or not the vendor provides any form of training and accompanying materials, and if change management processes will be supported (McGowan, Cusack et al. 2008). In addition, these questions should evaluate the type of technical support, if any, the vendor will provide once the system is implemented.

Cost Cost is key to determining whether or not the PHR project has a good return on investment (ROI), and provides the financial impact of the project (McGowan, Cusack et al. 2008) estimated in the business plan. The cost of the project is the greatest risk to its success. Related questions should cover costs of: the actual system, telecommunication infrastructure, physical renovations, maintenance, staff time, and training. Cost overruns resulting from a delayed project, or hidden costs (such as support for emergency system recovery) should be addressed to avoid unnecessary risk (McGowan, Cusack et al. 2008). Cost is also a significant factor when comparing competing vendors; knowing these cost factors in detail helps to select the best vendor.

Requirements Gathering The questions in this section help characterize how much of the stakeholders' resources will be tied up during requirements gathering, and what special conditions this will impose on the stakeholders. It also includes questions regarding any difficulties the vendor might have. This might give some insight into the vendor's competence.

Vendor Information Specific vendor information provides an intimate understanding of the vendor's management, experience, and technical expertise. Questions regarding the status of the vendor and references from past implementation projects will provide a standard of reference to generate performance benchmarks (Porter-Roth 2002). Checking the vendor's references provides insight into its strengths and weaknesses, how it has managed past customer

relationships and how it has managed to meet past stakeholder's requirements during the design and development process (Porter-Roth 2002).

After all the questions are generated, metrics need to be developed in order to measure the vendor's responses. The sections/questions should be ranked in priority sequence and given a weight, the higher the priority the higher the weight. By making the total score higher (e.g. out of 100), a more detailed difference among the responses is provided. It is not advisable to make any section worth more than 25%, as this skews final results (Porter-Roth 2002).

Based on the vendors' responses, each section is rated using a scale appropriate to the RFP (Bova 1983). These ratings are tabulated and ranked in priority sequence. Comparisons between vendors can then be made. Depending on the nature of the project, the matrix can be sent with the RFP to the vendor to complete, or it can be completed by the organization after a shortlist of vendors has been generated.

The vendor evaluation matrix is an integral part of the overall RFP process. It provides a checklist of key questions that need to be addressed, and gives a uniform basis for measuring each vendor's ability to meet the requirements of system creation and implementation (McGowan, Cusack et al. 2008). With a better understanding of the varying attributes of competing vendors, the stakeholders have clearer picture as to which vendor will meet the requirements of the PHR project. This in turn helps manage the risks inherent in such a complex project.

Contracts

'One of the most often cited reasons for the spectacular failure in Australia and elsewhere was that most public-sector organizations failed to monitor and evaluate their IS/IT outsourcing contracts properly, especially the performance of contractors' (Chad, Graham et al. 2007).

Within the RFP procurement process, two interrelated yet sequentially distinct events occur: vendor selection and contract negotiation. Interestingly, (Guth 2008) suggests that contract negotiations are compromised when a vendor is notified that it has been selected prior to the beginning of negotiations. When this happens the purchaser loses leverage, and the door is left open for the vendor to control negotiations, mainly due to the fact that the competition has been eliminated. A number of contract related best practices are mentioned briefly below, including software licensing, service level agreements, and software escrow. If requirements and expectations for each of these items are well-defined and articulated during contract negotiations, vendor relations will be enhanced and procurement risks will be reduced.

Contract Process A contract is a "mutually binding legal agreement that obligates the seller to provide the specified products, services or results and obligates the buyer to pay the seller" (PMI 2004), p. 355. In a project where a third party vendor is used for any reason, a contract must be created and signed by both the vendor and stakeholder to ensure that each party understands their roles and responsibilities. The contract process should encompass the entire life cycle of the

project, including post-implementation to ensure that the vendor takes responsibility for the system after it has been created. The management of the contract should explicitly cover all activities (even post implementation activities), some of which include: the statement of work, the time-frame/schedules, period of performance (where performance evaluations are conducted to measure the contractual competency of the vendor), roles and responsibilities of both parties, pricing and payment, and inflation and adjustments (Halvey 2005).

The framework of a contract needs to deal with all aspects within the life cycle of the PHR project. It must address all present concerns, as well as any potential problems which may arise during or after the process. By being aware of the potential risks, the contract can be constructed to have contingency plans in the unfortunate event of a vendor-stakeholder disagreement. A PHR system's contract framework would consist of the following categories that can be examined if more detail is required (PMI 2004): contract management plan, contract change control system, software licensing, stakeholder conducted performance review, payment system, claims administration, records management system, information technology (IT), and contract closure.

Software License Agreements Software is generally a set of computer instructions stored in a computer's memory, on a hard drive, or on a CD or DVD - its intangible. Software is provided by a vendor under limiting conditions, usually described in writing in a document called a "license." The organization that purchases software does not usually acquire ownership of the software, but only the right to install and use it on a machine or network in accordance with a software vendor's licensing agreement (Milrad and Rummell 2007). Software licensing legally protects the copyright and distribution rights of the vendor's software (Halvey 2005). The license agreement defines how many licenses the stakeholder is allowed to have and the period of validity for each (Halvey 2005). Typically, PHR software purchased will include: the primary PHR application (may be comprised of multiple modules), operating systems, an interface engine and identity and security management. It is important to understand who owns each of these components and document ownership in a software license agreement.

Service Level Agreements During the life cycle of most HIT implementation projects, outsourcing certain components, possibly even the management of the entire project by a system integrator, has become a common practice (Keller and Ludwig 2003). Despite the numerous benefits, using a third party for implementation services can be risky if the objectives of both the stakeholder and the vendor are not clear. For both parties to maintain a strong relationship, a service level agreement (SLA) must be created to outline each party's responsibilities. An SLA is a contract that is negotiated by both the stakeholder and the vendor. It outlines each party's responsibilities with respect to: services, priorities, objectives and goals. It also gives specifics as to how the stakeholder supports the vendor during the implementation process and what the vendor needs to do to meet the stakeholder's requirements (Keller and Ludwig 2003).

Software Escrow When dealing with a third party vendor who owns the rights to the source code, it is imperative that the party licensing the software ("licensee") is protected in case the vendor ("licensor") does not maintain the software within the terms of its contract (Anonymous 2008). To avoid the licensee from loosing access to the source code in case the vendor breaches the contract or goes bankrupt, the source code is put into escrow account. This software escrow uses

a neutral third party, possibly an agent, to hold the source code for safe keeping; the agent will be responsible for releasing the source code to the licensee in case of any contractual breaches. The escrow agreement itself must be made in addition to the software license agreement, as this agreement has an additional party involved.

Contract Summary When it comes to contracts, nothing is unreasonable or not worth questioning. Engaging a lawyer is imperative. Contracts generally tend to be rigid and inflexible, unable to readily support changes such as changing strategy, policy and technology that naturally occur within a dynamic HIT environment. Good contract management and well-defined and articulated software licensing, service, and escrow agreements, together with re-sequencing traditional vendor selection and contract negotiation events, are considered important parts of a HIT procurement best practices model, leading to improved vendor relations and risk mitigation.

PRIVACY

The protection of personal health information (PHI) is imperative, yet spectacular privacy breaches continue to make headline news (Lazarus 2003). Outsourcing is a procurement strategy in which IT functionality is contracted out to a third-party service provider. Even though outsourcing is considered a means of transferring certain risks to contractors (Chad, Graham et al. 2007) and is an attractive business model for a PHR project, it can also introduce new risks to the contracting organizations and is often cited as the reason for these privacy breaches.

Vendors can do a great deal to alleviate privacy risks and it is the job of the procurement team to make sure they do so. In a study of thirty PHR vendor privacy policies, the Altarum Institute (Lecker, Armijo et al. 2007) found many serious breaches:

- Existing privacy policies are incomplete;
- Consensus requirements for the contents of a PHR privacy policy do not yet exist, and many vendors appear to have focused instead on security procedures and Internet privacy descriptions;
- Transparency of secondary use of data could be greatly improved;
- The majority of vendors reviewed did not reference compliance with a privacy governing body;
- Data disposal rules and regulations are ill-defined, especially for closed accounts and vendors that go out of business; and
- Many specific terms including "personal health information" are not defined in the privacy policy or related documentation.

A Privacy Impact Assessment (PIA) is another formal risk management tool used to identify ways in which privacy risks can be mitigated. The end result of the PIA process is to provide documented assurance that all privacy issues have either been adequately addressed or, in the case of outstanding privacy issues, brought forward for further direction. For example, the Ontario Information and Privacy Commissioner (Cavoukian 2005) has published specific

instructions or guidelines to assist organizations in conducting a PIA. Ideally a PIA should be incorporated into the early phases of the project and system development life cycles.

The risks of losing consumer confidence and trust resulting in PHR project failure are high. These risks, however, can be mitigated by incorporating privacy best practices into the procurement process by way of proper wording in the RFP and contract, asking probing questions in the security section of the vendor evaluation matrix, and assigning high priority to reviewing the vendor's privacy polices. Assistance and guidelines are available in both Canada (Strasbourg 2008) and the U.S. (CCHIT 2008) for certifying PHRs, which ensures privacy best practices are followed.

CONCLUSION

'According to recent studies, 20 to 25 percent of large information technology acquisition projects fail within two years and 50 percent fail within five years. Mismanagement, the inability to articulate customer needs, poor requirements definition, inadequate supplier selection and contracting processes, insufficient technology selection procedures, and uncontrolled requirements changes are factors that contribute to project failure. Responsibility is shared by both the supplier and the acquirer. The majority of project failures could be avoided if the acquirer learned how to properly prepare for, engage with, and manage suppliers.'(Coplan 2008)

Proper risk assessment and management are critical to minimizing the problems of 'embedded contract mentality.' Risk assessment should be carried out before signing the contract to ensure all future risks are addressed and documented. Risk management is a continuous process that should be conducted throughout the life cycle of the project, guiding the project on a path that avoids risk. If done correctly, both risk assessment and management can significantly reduce the project's exposure to risk, granted procurement best practices are used throughout the project. In addition, the project team must keep in mind that implementing a PHR system is not an IT project, but a healthcare project; therefore the project must tackle the unique barriers of a healthcare system. The procurement process should reflect an understanding of the changing roles and requirements of vendors in the healthcare sector and include questions about systems integration and software product certifications. Applying proper controls to the development of these documents ensures clear communication to the vendor, enhances relations, reduces risk and becomes an integral part of the HIT procurement best practices model. Vendor relations should be approached in a manner consistent with the goals and objectives of the project, taking into consideration the changing roles of HIT vendors and the influences of major stakeholders like Canada Health Infoway in the Canadian context. Protection of personal health information, in the form of vendor privacy policies and Privacy Impact Assessments cannot be emphasized enough. Three main procurement principles, contractual terms, vendor relations and privacy, and related practices, contribute to an HIT procurement best practices model that will help to substantially reduce the risks that are inherent in the procurement process.

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