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Mobile eHealth for Self-Management: Procuring the Right Solution

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ABSTRACT

This paper examines the procurement and vendor selection process for a mobile ehealth project for the self management of type 2 diabetes. The method involved literature review, key interviews, research on existing devices for measuring blood glucose, blood pressure and body weight using Bluetooth technology and integration with Personal Health Record systems. The project management context as well as a mobile ehealth solution is discussed. Selecting medical devices and integrated solutions, whether insourced or outsourced, involves specific stakeholders. A clinical procurement team has to be constituted differently from the business model in supply chain management. There are key legal as well as technical requirements such as health department certifications for software and provincially legislated guidelines for Request for Proposals. Industries are making strides in implementing solutions for mobile healthcare but there is a need for continual clinical testing to establish evidence based proof of efficacy and cost effectiveness.

Keywords: vendor selection, electronic medical records, electronic personal health records, diabetes mellitus Type 2, telemedicine, project management

INTRODUCTION

Procurement of Information Technology (IT) for healthcare is a complex project that is much more than the simple signing of contracts and the monitoring of deliverables. It is a process that must engage key stakeholders in all steps of the process of procurement, and there are legal consultations which must be made to better define the Service Level Agreements (SLA) made between the buyers and the sellers. As a business solution, a pilot project for the proof of concept improvement in the lives of diabetics through mobile technology will involve a make or buy decision for the software, hardware, and system integration.

There are a number of medical devices commercially available that hold out promise for improving the quality of life for diabetics by using mobile technologies which lessen interference in their day to day routines. This paper will outline some of these current health care technological solutions. Given that the right solution has to be implemented in Canada, the final choice for a solution must be one that follows Health Canada, and Ontario licensing and privacy regulations. A few best of breed solutions will be examined in more detail than the others. Ultimately, it is hoped that mobile solutions will not only lessen the burden on the healthcare system, but also lessen the burden on individuals who have this condition. As Archer has said, the Return on Investment (ROI) in mobile health applications must not decrease the quality of life or the “return on investment justification becomes meaningless”.¹

Software and IT system projects have a very high failure rate: 80-90 percent for software and 30-45 percent for system.² Electronic Medical Record (EMR) projects used in physician offices have a fifty per cent failure rate.³ When examining the stages of project management in regards to healthcare experimental studies, these facts should be kept in mind. The focus of this paper is on the procurement, vendor selection and contractual obligations for a mobile healthcare project. Procurement is one of the nine major areas outlined in the Project Management Guidelines (PMBOK).⁴ This paper will first outline the burden on the healthcare system of diabetes globally, in Canada, and in Ontario. It will then examine a possible project involving mobile architecture for type 2 diabetics between forty and fifty years of age who live and receive healthcare in a Local Health Integration Network (LHIN) area of Ontario, in so far as the procurement and vendor selection area of an IT project management solution is concerned. The province of Ontario is divided into 14 regional LHINs to administrate and manage health care services.

BACKGROUND

Diabetes is a global health problem and in Canada the rate of diabetes has increased 27% between 1974 and 2000.⁵ It costs the healthcare system in Canada an estimated \$13.2 billion every year in direct and indirect costs, including physician care, medication, long-term disability and early death.⁵ More than two million Canadians have diabetes.⁵ It is the contributing factor in the deaths of more than 40,000 Canadians each year.⁵ “The number of Ontarians with diabetes has increased by 69 per cent over the last 10 years – and is projected to grow from 900,000 to 1.2 million by 2010. Treatment for diabetes and related conditions such as heart disease, stroke, and kidney disease currently cost Ontario over \$5 billion each year”.⁶

Diabetes is a population health problem of epidemic proportions, especially among aboriginal peoples in Canada. First Nations in Ontario, for example, have some of the highest rates of type 2 diabetes in the world.⁷ If there are no intervention programmes and if left unchecked, diabetes mellitus type 2 can lead to chronic complications such as cardiovascular disease, hypertension, retinopathy, nephropathy, neuropathy, extremity amputations, ischemic heart disease, as well as blindness.⁸ The highest prevalence

of diabetes globally is in India, where the yearly percentage increase is also called an epidemic.⁹ The increase is believed to be a result of the growing middle class, change of diet, and an increasingly sedentary lifestyle in urban populations.¹⁰

Diabetics have been managing their condition for many decades, taking their own blood glucose readings, given themselves insulin injections, keeping written journals and trying to follow diet and exercise programmes. Technologies have been developed over the years to assist. In fact, technologies for home use seem to be quite adaptable to this condition. The industry that produces medical devices is a billion dollar a year industry involving some of the leading names in healthcare, like Johnson and Johnson, Bayer, Roche Diagnostics and Lilly. In terms of industry growth, a recent MarketResearch.com report said: "The U.S. market for new technologies in patient monitoring of diabetes totaled \$410 million in 2007, but is expected to grow at a compound annual rate of 20.5%, reaching \$1.2 billion in 2013".¹¹ The next generation of devices like no pin prick, or non-invasive blood glucose testing, and Bluetooth wireless communication to Smartphone devices, are in a rapid state of development and testing. There are now even proposed "medical nanorobotics for diabetes control".¹² Any project should involve only medical devices approved for use by the US Federal Drug Administration (FDA) and Health Canada, and nanorobotics are still a few years in advance of approval.

Wensing et al referred to a Cochrane Library systematic review showing that interventions like electronic medical record systems improve the management of diabetes mellitus in primary care and out-patient settings.¹³ According to the Canadian Diabetes Association Guidelines, diabetes is a chronic disease that responds extremely well to self-management, be it monitoring blood sugar levels, or following standard guidelines for healthy lifestyle.¹⁴

An advance in an ehealth approach in self-management for the treatment of diabetes is using mobile devices and Electronic Personal Health Records (ePHR). As Holbrook et al maintain, there should be more Randomized Clinical Trials (RCTs) on self-management of diabetes using clinical decision support and electronic medical records.¹⁵ A literature review has indicated that there are few RCTs or evidence-based studies on ePHR for self-management of diabetes.^{15,16,17} A recent Ontario Health Technology Assessment (OHTA) series article by the Medical Advisory Secretariat on "Home Telemonitoring for Type 2 Diabetes" recommended more studies be done in Ontario, as there was low quality evidence, but significant statistical improvements using telemonitoring compared to usual care.¹⁸ The hypothesis of this OHTA study is that outcomes for diabetic patients will improve because of better continuity and integration of evidence-based guidelines for the control of risk factors such as HbA1c, hypertension and hyperlipidemia. This improvement in quality of life can be enhanced with the Bluetooth telecommunication of medical device readings transmitted through a Smartphone to the ePHR, and/or EMR.

RCTs involving computerized interventions showed improvements in outcomes to HbA1C and blood pressure in the intervention group.^{15,19} These studies showed improvements in Low Density Lipoprotein (LDL) cholesterol and even weight loss. Several studies showed improvements in readjustment to medicines and adherence to guidelines.^{15,16,17} User satisfaction of the computerized systems was strong in most studies,¹⁵ even though participants might not have used computers before.¹⁷ Studies considered to be "web-based" are often integrated into shared medical records, but are not ePHRs, such as the Ralston study²⁰ which showed improvements to lower blood glucose levels. Several studies mentioned the need for cost-effectiveness studies of web-based systems.^{15,19,21} The "digital divide" or socio-economic status was mentioned as a confounding variable, and attempts were made to adjust for it in some studies.²² Most studies had small samples or were pilot studies of feasibility, so it is difficult to

generalize to wider populations. Therefore, the Ontario Medical Advisory Secretariat is right and there should be more studies in this area.

METHODS

This paper involved extensive internet searching on devices used by diabetics that can be configured for mobile ehealth applications. There was not a lot of literature uncovered in the clinical area of vendor selection during searches on engines like Pubmed. One of the authors attended the HealthAchieve 2009 conference in Toronto to meet vendors and collect business pamphlets and other sources of information. Samples of Requests for Proposal to study for key features were obtained through informal networks and searches on the internet. Key interviews were conducted with representatives from healthcare companies.

Working with Key Stakeholders

In the EMR selection research by Holbrook, the “first” COMPETE project, a literature search on “medical record systems, computerized” and “selection” in leading medical databases resulted in zero hits.³⁷ Studying procurement in IT business resources will uncover a lot more sources of information, but is often more of the “grey literature” type. Selection and procurement of IT systems or materials management is the staple diet of a Chief Information Officer, an IT division, or a purchasing department in a Healthcare Institution. It is an area of business associated with supply chain management. However, in the clinical healthcare setting, the difference in a contract in industry for IT procurement is that it is a contract between business entities, whereas in healthcare, the contract boils down essentially to a bond of trust between patient and clinician. Software used in primary care (patient management) is currently being construed as a medical device subject to regulation and classification, and IT errors in healthcare can be more than just costly.³⁸ Holbrook recommends the following best practices for systematically selecting an EMR solution, which should be kept in mind when choosing an ePHR system, and mobile accessory medical devices for diabetes self-management:

1. survey of interest, barriers, desired functionality, willingness to pay;
2. development of detailed EMR evaluation form;
3. broad search for available EMR systems;
4. brief review of features of EMRs;
5. detailed vendor demonstration of EMR features in person;
6. site visits to EMR system user practice and vendor headquarters;
7. user evaluation of working copy of EMR using typical case scenarios;
8. finalist evaluations and negotiations³⁷

The key decision maker in a project procurement of wireless mobile healthcare devices for the self-management of diabetes, besides the patient, is the primary care physician. Engagement of the physician in any healthcare IT procurement is essential.³⁹ In the Holbrook research, there are the many ways physicians were involved in assessing, evaluating, testing and procuring the clinical EMR systems. Among these were: attending information sessions and conferences, rigorous EMR software assessment, surveys, individual interviews and focus groups, feedback for an EMR evaluation form, detailed quantitative review of features, recruitment to act as pilot sites, demonstrations of EMR for “peer influentials”, observations by clinical and technical research team members, and an evaluation of the final 4 EMRs by 12 family physicians.³⁷ But that research was for physicians selecting EMRs. Any project of this nature might also require similar input from patients, who will be the main users of the medical devices. Probably though, the clinical research team would compose a vendor selection

committee who would be the main assessors, while patients would be involved in usability assessment and feedback after extensive testing and test piloting.

Specialists are other key stakeholders in a study of type 2 diabetes who need to be involved in the evaluation and selection of systems. For diabetes, specialists include nephrologists, neurologists, endocrinologists, dieticians, cardiologists, and podiatrists. Dieticians, for example, need to be consulted on any online surveys of patient adherence to following food guidelines. In a research trial involving wireless medical devices, depending on the number of patients and the number of outcome measures being studied, a biostatistician is also needed to analyze clinical data. Certainly if a project were to be designed in the manner of a RCT, a biostatistician would be essential. Any one of the specialists could be added to a vendor selection committee. Forming the right selection team is just one of the key steps in a successful hardware and software procurement as Krouse recommended. The eight key steps he recommends are: understand the need, capitalize the project, understand the market, structure the right team, gather vendor information, apply drivers and values, integrate process and system, and negotiate wisely.⁴⁰ Taylor recommends adding a different kind of specialist called the systems engineer to a procurement team for projects that involve multiple devices.² The main reason for this is to evaluate technical compatibility between different vendors, but especially to test for electromagnetic interference between devices, as Garcia-Saez mentioned.²⁶

The selection of the medical devices, and the procurement of systems does depend on the requirements and preferences of the patient group, but Holbrook's study of EMR selection recommended a rigorous multidisciplinary process for selection because there are potential multi-users of the system, and not just patients.³⁷ Patients might be able to choose their own medical devices like glucose monitors and smart phones, which will enhance their own comfort level with usability and the prospects of a successful project. A key factor in a project is first determining the number of participants needed. This will set criteria for procurement expenses, training, and other resources needed. The MyBP study, which was a pilot for a larger clinical trial, recruited from only one family care team, and had one nurse research assistant who acted as recruiter, coordinator, and nurse triage. It might even help if this person had technical skills in order to field questions on medical devices, since this role is a first line of contact one. They contacted 119 people who met the inclusion criteria, and who were searched on the family practice EMR (an OSCAR system) before being contacted.⁴¹ The MyBP study had a research team with a close connection to a family practice, so there were a number of shared resource options, thus cutting costs, for example, for the procurement of some computer services.

Many patients in the MyBP study, besides having hypertension, were also diabetics, but the most relevant element of this clinical trial for procurement considerations is the fact that MyBP was based on the open source MyOSCAR ePHR system. Open source means it is free to download, install and modify the code. MyOSCAR though, is fairly proprietary, in that you more or less need to be a patient of a clinical practice that uses OSCAR or some other EMR, in order to use it. Costs associated with using open source software need to be evaluated against other commercially available products. Adapting MyOSCAR into something like "MyBG" however, would require an insourcing strategy. Google Health and Microsoft Healthvault are also free, even though they might not be open source, and they already provide the convenience of being fully developed and compatible with many medical devices. Google Health and Microsoft Healthvault are American, but Telus has contracted with Microsoft for a ePHR for Canadians called Telus Health Space.⁴² Telus also recently procured an experimental personal health record system from Sunnybrook Health Sciences, the MyChart system, indicating the seriousness of their intent to either provide a service or test a market for ePHRs management.⁴³ So Canadian options exist for ePHRs, but it remains to be seen what Telus Health Space will cost consumers when it unrolls in 2010.

Financing, Contracts and Ownership

Recent news stories on audits of Canada Health Infoway and eHealth Ontario exposed irregularities in the RFP and written contracts. There are more than several sources of information on this. The federal auditor, Shelia Fraser found: "a \$144,000 competitive contract that was amended five times, raising the total value to \$726,000 -- with no competition for the amended amounts. This practice is not conducive to the fair and transparent awarding of contracts and it raises questions about the appropriateness of *Infoway's* contracting policy."⁴⁴ The report also found that in a sample of 35 contracts, 13 were signed only after the work had begun. Consulting the Auditor General of Ontario's special report is worth an examination, especially in regards to the sections on procurement and use of consultants.⁴⁵ The special report states that in their estimation two thirds of the value of all eHealth Ontario contracts was sole-sourced. Procurement policies were not being followed and instead "urgent" competitions were justified for the sole-sourcing, a practice the auditors found unwarranted. Recommendations by the auditor hark back to the beginning of this paper that states a large percentage of software and IT systems fail, and the main reason at eHealth Ontario, thought the Auditor General, was the lack of a "Strategic Plan".⁴⁵ When there were ten times as many consultants at eHealth Ontario than full time employees at one point, consultants who were hired to manage other consultants, who hired from within their own companies, it seems evident that project management had gone off the rails somewhere.

At eHealth Ontario, a recent alliance with OntarioMD showed irregularities in the vendor selection process: "The deal, which is being brokered by the Ontario Medical Association's subsidiary OntarioMD, lets doctors apply for a grant of nearly \$30,000 to purchase either a local electronic medical records system or a system that ties into eHealth Ontario's server. Family doctors or specialists choose one of 11 vendors to buy their system from, which has other computer firms saying they are being shut out of the Ontario market."⁴⁶

As this paper has shown, choosing a mobile healthcare solution involves evaluating not only medical devices, but ePHRs, the architecture that integrates them, and perhaps even an evaluation of the EMR systems some physicians might use to access a patients' personal data. OntarioMD has tried to evaluate and approve, according to its own evaluation criteria, qualified EMR systems for it's' profession. A key objective is to make sure the systems are well certified and acceptable in the medical community. There doesn't appear to be an OntarioMD list of certified ePHR systems for recommendation as vendors, probably because this is not under the purview of the Ontario Medical Association since it is a consumer choice decision? That being said, the Canadian Medical Association has unrolled the MyDoctor.ca ePHR for members.⁴⁷

The results of the improprieties of the eHealth Ontario procurement practices lead to some rewriting of the rules for procurement in government, and some important lessons learned. Changes to the rules came out not just as a result of the 2009 Audit Report of eHealth Ontario and Cancer Care Ontario.⁴⁵ A release called the Supply Chain Guideline 1.0 (April, 2009) by the Ontario Ministry of Finance will apply to hospitals, community care access centres, LHINs, and share service organizations.⁴⁸ There is also an Ontario Management Board of Cabinet Procurement Directive (July, 2009) which focuses on "policies for procurement, planning, addressing procurement value and procurement value increases, establishing vendors of record (VORs), non-competitive procurements, the conduct of the evaluation process, and the conduct of vendor debriefings."⁴⁸ Generally these guidelines and ethical considerations apply to larger projects, contracts greater than one hundred thousand dollars. The common law of procurement and the duty of fairness generally recognizes that e-health projects are often complex involving more than one IT group and there is a lot of negotiation on "pricing, specifications, and implementation time lines".⁴⁸ Bidders aren't usually held for account on firm RFP contract wordings in such cases.

Table 1 summarizes the lessons learned from the RFP process, based on a survey of 50 public healthcare institutions on best vendor selection and evaluation practices.⁴⁸ Many of these are key risk management triggers or alerts that should be incorporated into any project management guideline or schedule. Never negotiate without a lawyer of course. Any contractual obligations between vendors and clients should be vetted by legal advice, such as Borden Ladner Gervais LLP Health Informatics Practice, co-authors of this HIROC-BLG report.⁴⁸ There are many other law firms that specialize in this area. Universities that are research intensive are also interested in potential commercial applications from research and have offices that specialize in intellectual property.

HIROC-BLG REPORT – DOS AND DON'TS OF VENDOR / SOLUTION EVALUATION BEST PRACTICES	
DO	DON'T
Conduct full due diligence on vendors, including financial assessment	Be inconsistent with vendor evaluation
Insist that vendors provide a complete list of sites where the solution has been installed and call them all. Follow up with site visits or detailed site calls to other organizations within the industry that have used the vendor's product.	Share any information that could breach privacy or confidentiality.
Where possible, evaluate solutions from established market leaders and companies that have local, national or international reputations	Be seduced by features or buy on impulse.
Ensure there is extensive questioning of all proposal language to get 100% clarity, including a breakdown of every cost.	Accept verbal reassurances without a corresponding written document
Involve IT and functional experts in the selection process.	Make any verbal agreements with the vendor.
Get everything in writing before moving forward. Designate one person to handle written documentation throughout the process and to monitor outstanding items.	Place too much importance on prices as a selection criterion.

Table 1: HIROC-BLG-Report

Keshavjee reminds procurement specialists to follow implementation through to post-implementation activities, for it is there that many vendor contractual agreements continue and must be in place. For example, technical support should be clearly articulated, perhaps as early as in an RFP or at least in the service level agreement.³ Backup systems have to in place in case of disasters or outages, and these critical systems need to be quickly implemented.³ Perhaps post-implementation detailing could be the work of an outsourcer, but it should be clear whether or not they are training the trainers, of if they will be available by help desk or on site if a system experiences fire or flood. These two latter should be covered in the risk management plan, possibly through liability insurance.

Project Management of Mobile eHealth Procurement

The HIROC-BLG report also had a table of best practices for Procurement and Implementation of IT Material Transactions, and one on negotiation Dos and Donts.⁴⁸ Many of the procurement of IT best practices are key risk management triggers or alerts that should be incorporated in any project management guideline or timeline. A project management team would be wise to pay attention to these best practices. Among suggestions for successful RFP writing and issuing is the advice to never “underestimate the importance of project management, organizational commitment, or the time and diligence required for project and program delivery.”⁴⁸ Project management is of such importance that many RFPs ask that a Project Management Gantt chart be submitted as well. The legal aspect has been

touched upon, but risk management needs to be monitored by all the different project teams at all times, and Gantt charts are a good way to visually see the project.

In fact, planning, communication, and implementation teams, all need to be able to communicate and recognize alerts setup for various risks that occur in the timeline of the project, not just among themselves, but to each other. The role of the Project Manager is vital in keeping all the players working together, which is why it is said that the skills needed by a good Project Manager are 90 per cent interpersonal skills and only ten percent technical.² Risk management is a key factor for overall project success. It is not just the responsibility of the Project Manager, but for everyone on the project team. There are nine areas recommended by the Project Management Body of Knowledge Guidelines and Procurement and Risk Management are areas of that. The others are Integration, Scope, Time Management, Quality Management, Human Resource Management, Communication Management and Cost Management.⁴ Risk Management in the form of a matrix, can be tabulated for each of these areas. It can describe triggers, impacts, who is responsible, and whether the risk is positive or negative.

The operation of a project for mobile healthcare can be run like a Project Management team. Even if it is a RCT to prove the efficacy of the patient monitoring software used to help type 2 diabetics by employing wireless medical devices and Smartphones, it can still follow project management principles. The PI can be thought of as the Project Manager, the Research Assistants are the Implementation Team, the project lawyer could be the Risk Manager, and other similarities could be drawn in comparison. A procurement team could be a coming together of leads from each team section, plus a few outside experts like IT specialists, patient advocates, and the university lawyer. A Gantt chart of the key activities for each resource area can be devised for the RCT. An article by Whitehead comparing Project Management to Action Research was very insightful because it offered the possibility of applying project management techniques or tools to different forms of research methodology.⁴⁹ An RCT is certainly but a form of research methodology. Or, would Action Research methodology be best applied to procurement practices?

Proposed Solution & System Architecture

Given the fact that self management of diabetes helps improve quality of life, reduces healthcare costs, prevents morbidity and mortality from chronic conditions, the purpose of a future research project should be to:

- Advance the efficacy of self management of diabetes through technological interventions like integrated eHealth solutions.
- Explore the feasibility of mobile Homecare interventions using a pilot study with patients aged 40 – 50 who have type 2 diabetes.
- Examine the trend towards patient centered care and improving quality of life for patients via remote self- monitoring.

Criteria for self management of diabetes may include:

- Measuring Blood Glucose
- Measuring Blood Pressure
- Measuring Weight
- Monitoring Diet
- Monitoring Exercise
- Using ePHR and wireless communications

A proposed solution for a project would be an open source integrated platform of mobile medical devices – see Figure 1 for system architecture. These devices communicate through secure, wireless protocols and standards. Participants could be recruited from a local family care practice that uses EMRs. The devices will monitor Blood glucose, Blood pressure and Body weight and the data will be uploaded to the ePHR System either using serial cable (USB) or Bluetooth technology. All medical devices would have to be Health Canada certified and the overall patient monitoring system would have to be certified as a Class II medical device.

If the patient’s vital sign fall below or goes above the normal level, the ePHR system will trigger alerts in the form of voice/text messages or emails. There will be a nurses’ triage where nurses would either respond themselves to the alerts or email messages sent by the ePHR systems by calling the patients or by sending messages or emails through the ePHR system. In a critical situation, they may call the family physician for consultation. The family physician will then either call the patient or would call a specialist and discuss the concerns and then would call the patients. It is assumed that the nurses’ triage, family physicians and the specialist should have access to the ePHR system. Although, data from ePHR will not be uploaded into the EMR system, some information could be downloaded into the ePHR system. ePHR is typically an electronic health record of an individual that conforms to nationally recognized interoperability standards and can be drawn from multiple sources while being managed, shared, maintained and controlled by the individual and hence is not considered legal health records and, therefore, is not protected by any health-specific privacy legislation like Personal Health Information Protection Act (PHIPA) in Ontario. On the other hand, EMRs are medical records that contain information about health compiled and maintained by healthcare providers and hence are considered legal records and are protected by PHIPA in Ontario.

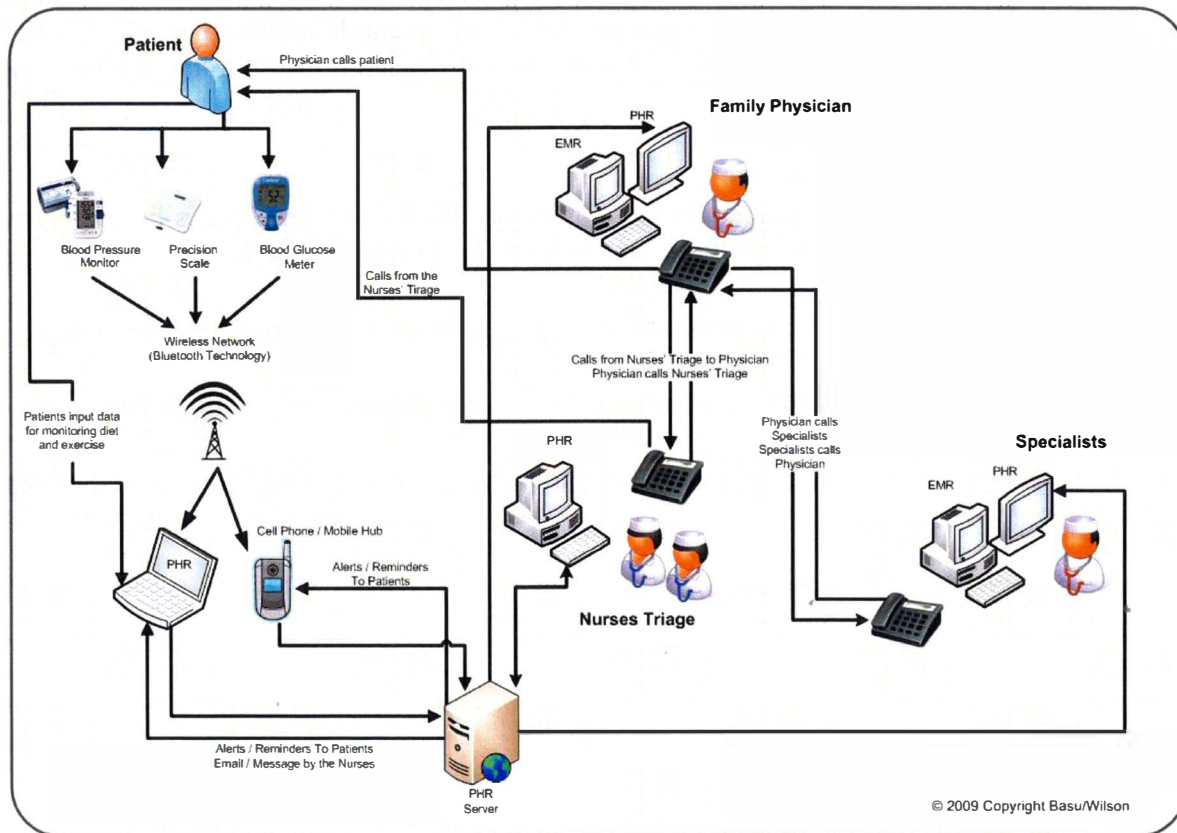


Figure 1:

System Architecture for Proposed Solution

Vendor Procurement

In the last few decades, the vendor selection process has undergone considerable changes. These include increased quality guidelines, improved computer communications, and increased technical capabilities⁵⁰.

Vendor procurement, given its size and nature, would start with forming a Preliminary Investigation Team.⁵¹ The task of the Preliminary Investigation Team would be to develop a preliminary investigation plan in order to determine what devices, new hardware, and software may be needed. A preliminary investigation plan would involve a detailed outline about the steps that the team would follow to select a limited number of vendors and then do background research on the vendors. The vendors include device manufacturers, vendors providing ePHR systems, eHealth Integrator companies, and suppliers of office hardware like computers, printers, faxes etc.

The plan is to develop a vendor analysis scope by defining some inclusion and exclusion criteria. Analysis would consider device manufacturers whose devices have been approved by Health Canada and also, whose products have been in the market for some time. Furthermore, only those devices will be considered in the analyses that are software compatible so that data or readings can be uploaded from the devices to the ePHR system. This can be done by using USB serial port or by using Bluetooth technology. For the purpose of this analysis, the preference is for Bluetooth technology. On August 31, 2009, the Medical Devices Bureau of Health Canada issued a notice to “manufacturers, importers and distributors of medical devices software and facilities that purchase patient management software”, clarifying that “Patient Management Software is classified as a medical device and is subject to compulsory licensing under the Food and Drugs Act and Medical Device Regulation³⁸. Projects should therefore include only those device manufacturers whose software for downloading data from the devices to the ePHR System is approved by Health Canada.

In order to achieve total regulatory compliance for data privacy and security, only those ePHR systems whose servers are located in Canada should be used in a project. Also the ePHR systems have to facilitate interoperability of data with other systems and must conform to acceptable standards and methodologies. Preliminary investigation considered a number of ePHR systems. However, careful application of exclusion and inclusion criteria led to the short listing of three ePHR systems, namely, Healthanywhere, MyOscar and MyDoctor.

Healthanywhere for BlackBerry® Smartphone solution was designed to help clients with chronic hypertension effectively manage and monitor their condition, while maintaining an active lifestyle. Clients are equipped with Bluetooth®-enabled blood pressure monitoring devices that are paired with BlackBerry® Smartphones. When the client measures their blood pressure with the blood pressure monitoring device, the reading is sent automatically to the client’s BlackBerry® Smartphone through a Bluetooth connection. The BlackBerry® Smartphone then transmits the reading through the wireless network to Healthanywhere’s servers, which hold the repository of clients’ electronic health information. The client’s profile is then updated to include the new information.³⁶ They have recently conducted studies using their architecture with diabetics in southern Ontario.³⁴ (See Figure 2).

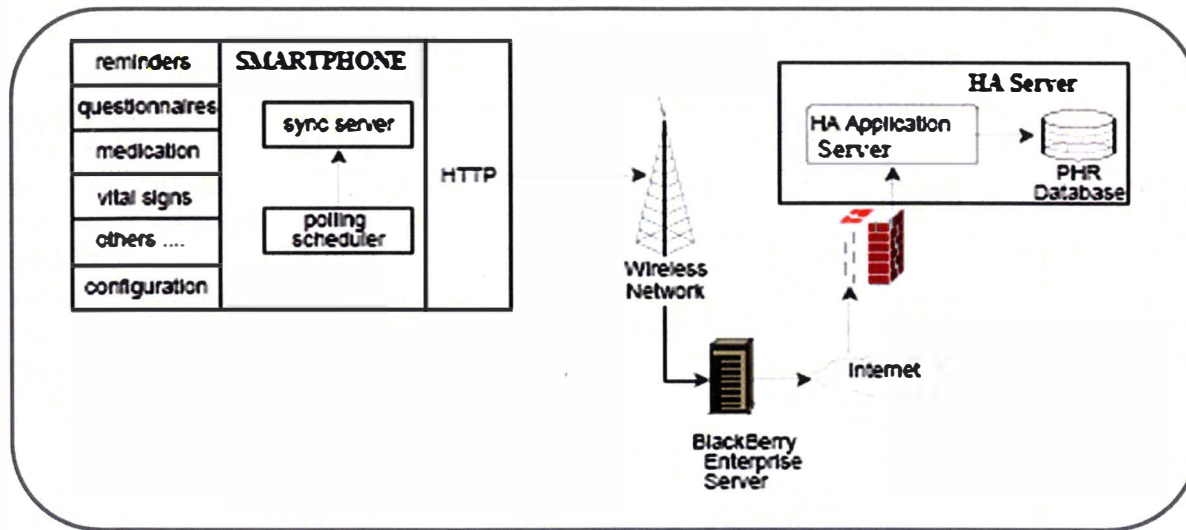


Figure 2 : Healthanywhere for BlackBerry® Smartphone³³

MyOSCAR is an open source ePHR developed by McMaster Family Health. It was based on the Indivo project from the Harvard-MIT Children's Hospital Informatics program. It is a secure, private on-line health record. Patients have total control as to who can put information into their own record and with whom they share this information. They can also communicate securely with their health care team and request copies of records from their doctor. Records may be lab results, prescription profiles, or scanned documents. It is possible as well to manage prescription renewals, make or cancel appointments. ePHR systems are also appropriately designed for accessing reliable health information or topics of interest to the patient.⁵² (See Figure 3).

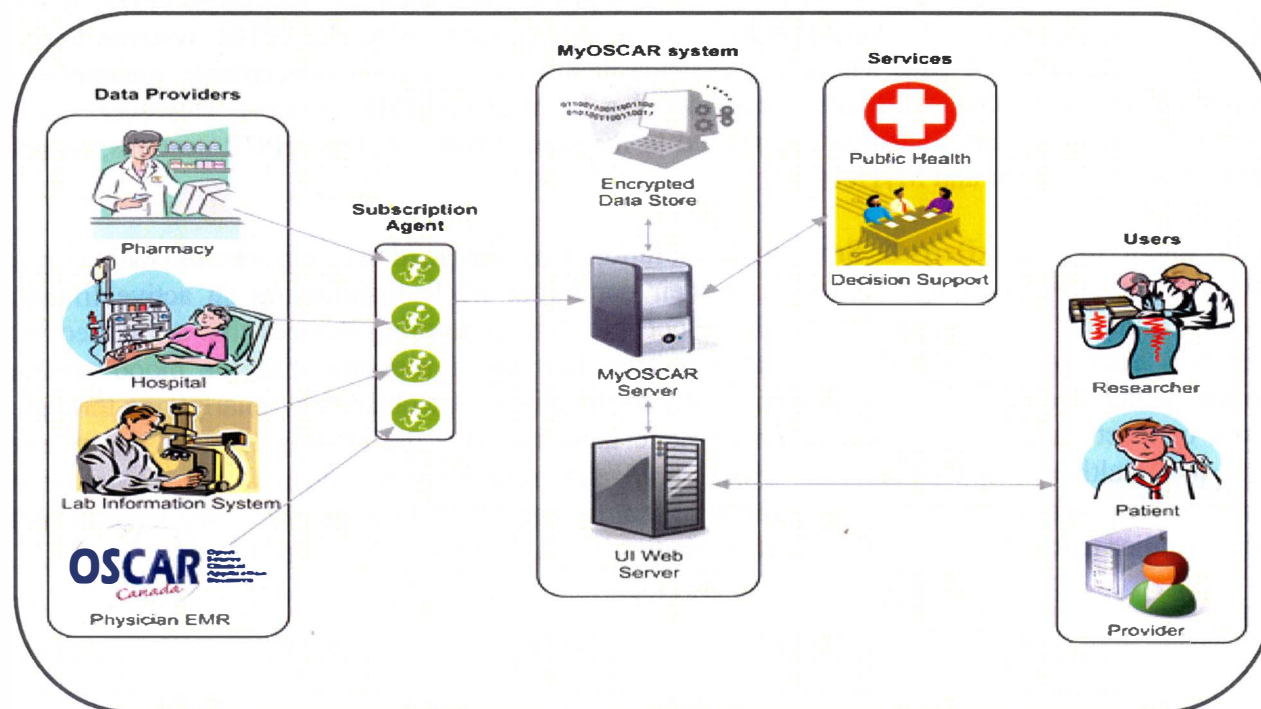


Figure 3: MyOSCAR Workflow⁵²

Self monitoring of blood glucose levels by patients with diabetes is considered the key for diabetes self management. Results of monitoring help the physicians to make necessary treatment plans including medication, diet / nutrition therapy and exercise and thus assist the patients to control their blood glucose level. Currently, the widely used method for self-monitoring of blood glucose level involves using devices to puncture or prick finger or forearm and then using the device and test strips to measure the blood glucose level⁵³.

A preliminary investigation for BG monitors found that Bayer CONTOUR[®], Bayer BREEZE[®]2 & Bayer Ascensia ELITE[®] XL, , OneTouch[®] Ultra[®]2, OneTouch[®] UltraMini[®], OneTouch[®] UltraSmart[®], OneTouch[®] Ping[™], Accu-Chek Aviva Nano, Accu-Chek Aviva, Accu-Chek Compact Plus and Auto Control Media iTest Blood Glucose Monitoring could be used for a project. All these meters have been listed or recommended by the Canadian Diabetic Association¹⁴ and are software compatible which essentially means that data or readings can be uploaded from these devices into the ePHR system. However, one important task would be to find out whether the software used by these device manufacturers are Health Canada approved.

Even though self monitoring of blood glucose level has revolutionized diabetes management, the discomfort and inconvenience associated with this invasive technique, which limits the blood glucose measurement performed by the patients, is sometimes considered the greatest barrier for effective compliance towards measuring blood glucose level.⁵³

A non-invasive technique capable of measuring blood glucose concentration with accuracy equal to or better than the current chemical glucose meters may improve compliance for glucose monitoring.⁵³ Considerable efforts have been made by several scientific research groups and organizations in the past few decades to develop non-invasive blood glucose monitors. Diverse optical approaches have been proposed to achieve this objective. These approaches include polarimetry, Raman spectroscopy, near-infrared (NIR), absorption and scattering and photo acoustics. These techniques appear to be promising, but have limitations associated with low sensitivity, accuracy and insufficient specificity of glucose measurements at physiologically relevant levels.⁵³ Non-invasive continuous Glucose Monitors like GlucoWatch G2 Biographer and Continuous Glucose Monitoring (CGM) which are FDA approved have been found unreliable for detecting hypoglycemia.⁵⁴ There are non-invasive solutions available in Canada for measuring blood glucose level by BioSign Technologies' UFIT Care.²⁵ However, this product is yet to be approved by Health Canada and therefore, cannot be used.

For BP monitors, the preliminary investigation would recommend using OMRON's Ultra Premium BP Monitor and Mark of Fitness' MF-77 Wrist BP Monitor. Life Source's Wellness Connected[™] Wireless Automatic BP Monitor is a wireless BP Monitor but currently not sold on in Canada. Some Life Source brand devices are sold in Canada so there is a possibility that the pharmacies or vendors who are selling their product would be able to arrange to procure these Wireless Automatic BP monitors.

For measuring regular body weight, the patients can measure by using any precision scale, which can be manually entered into ePHR systems. Life Sources' Wellness Connected Wireless Precision Scale can measure weight and the resulting data can then be uploaded into an ePHR system. This scale is currently not available in Canada. Since Life Source brand's other products are available, it is possible to procure this product in Canada.

Systems Integration is important for a successful project, so the project team should involve vendors who have the requisite experience necessary to deliver and support the solution. Same-industry experience or experience in similar markets or other markets that can directly cross-over to this one

Once the set of vendors to consolidate are identified, vendor requirement analysis is performed by analyzing purchasing and sourcing statistics and evaluating vendor discount terms and service areas.

Preliminary investigation would also involve analyzing the options between Insourcing and Outsourcing. While Insourcing is considerably cheaper, it involves more time and more risk since the team may not have the experience or expertise needed to integrate the output from the devices and the ePHR systems. Typically, for integration, a project would require a Project Manager, a Business Analyst, a DBA Programmer and a QA Tester. The estimate for the time required to complete integration would be approximately 12 weeks. The hourly industry rates for hiring a Project Manager is \$80/hour, a Business Analyst is \$60/hour, a DBA is \$70/hour and a Quality Assurance (QA) Tester is \$50/hour. Table 2 below shows the hours each of these consultants would work to integrate the system. For a smaller project, it can be assumed that the Business Analyst will train the key stakeholders and Nurse(s) at the Nurses Triage. Given this assumption and the industry rate, the cost to integrate would be approximately \$71,000 to recruit the consultants and do the integration of the system in-house.

Table 2: Cost of Insourcing

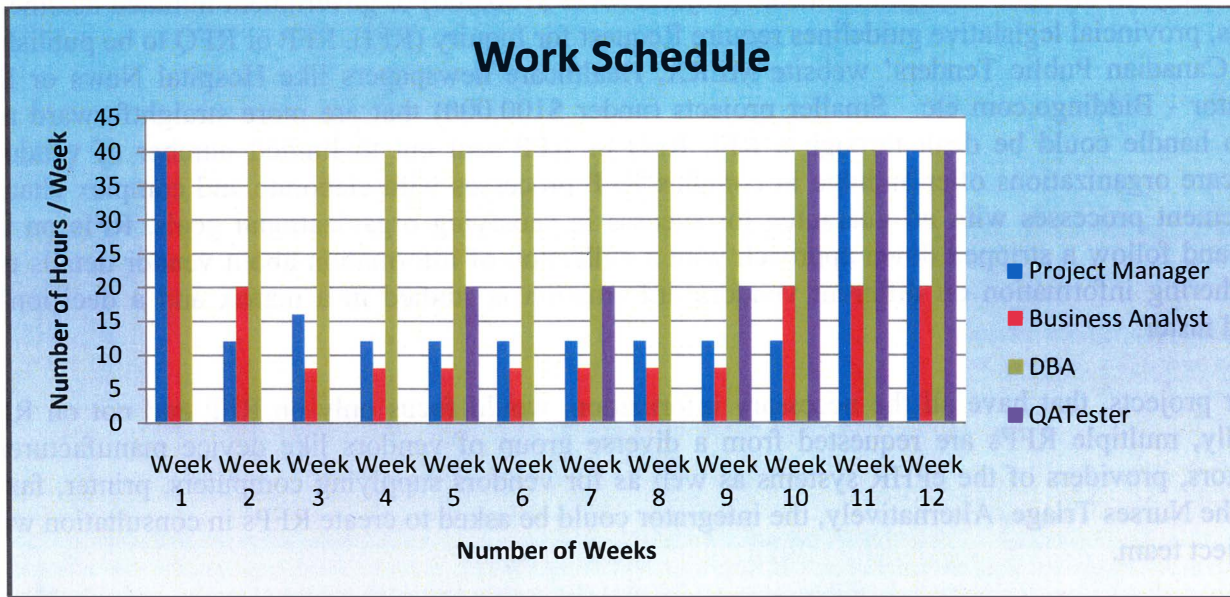


Figure 4: Work Schedule for Insourcing

The other option would be to outsource the solution to an external integrator who would be responsible for integrating the data from the devices with the ePHR systems, possibly using Bluetooth Technology. While Outsourcing is an attractive proposition for eHealth applications, it normally costs at least 30-40% higher than Insourcing, requiring lesser calendar time since the integrator would have more experience and expertise. The solution has to be based on standard technologies to enable interoperability with other systems. SLAs are very important for Outsourcing. Prior to entering into agreements, it is important to identify the service levels required e.g., develop providers' responsibility, methods for reporting service failures and resolve problems, guarantees, responsibilities, timeline for Return Merchandise Authorization (RMA). For example, in case of a faulty device that has to be replaced within 24 hours. Such considerations have to be clearly identified and mentioned in the SLA. Another important factor to outline are the options in the contracts as to what happens after the term of the agreement is over.⁴

The next step in procurement is selecting vendors, which is a long drawn process and involves many steps. After the preliminary investigation team compiles the list of vendors, the next step is to form the vendor selection team who would review and analyze the RFP or Request for Quote (RFQ), contracts, agreements etc. For vendor selection technical specification, guidelines will be developed to determine the following factors impacting the vendors:

- financial credibility or stability criteria,
- performance, support and maintenance criteria,
- risk assessment criteria.

It is very important to define a capability matrix that methodically compares vendors on the basis of assigning scores to different criteria as discussed above. All these would be included in the RFP. The next step would be to create an RFP or RFQ as the case may be, and distribute it to the limited vendors being considered.

Request for Proposal

Traditionally, in the case of large healthcare projects (over \$100,000) or government initiated healthcare projects, provincial legislative guidelines require Request for Inquiry (RFI), RFP or RFQ to be published in the Canadian Public Tenders' website MERX, Healthcare newspapers like Hospital News or Bid Navigator - Biddingo.com etc. Smaller projects (under \$100,000) that are more straightforward and easy to handle could be dealt through a RFI, RFQ or RFP sent out to limited number of vendors. Healthcare organizations often indulge in complex RFP processes with elaborate and complex change management processes with no guarantee for success in satisfying organizational goals. RFIs on the other hand follow a stripped down approach with a collection of information about vendor details etc. On gathering information on different vendors, information is studied in a matrix and a decision is reached faster.

Smaller projects, that have all the necessary information, would focus only on RFP and not on RFI. Typically, multiple RFPs are requested from a diverse group of vendors like device manufacturers, integrators, providers of the ePHR systems as well as for vendors supplying computers, printer, faxes etc. at the Nurses Triage. Alternatively, the integrator could be asked to create RFPs in consultation with the project team.

An RFP typically contains a title, an identification number, a release date, a close date, a close time, name, address and contact information of the procurement officer, usually a statement requesting proposals from qualified vendors for the provisions of the goods and services outlined in the RFP and also a Table of Contents (see Table 3). The Table of Contents usually has four sections, namely, Instructions to Vendors, Term of Reference, Proposal Evaluation, Informative Appendices and Response Appendices.^{61,62, 63}

Table of Contents	
Instructions to Vendors	▶ Instructions specific to submission of the RFP
Terms of Reference	▶ Background ▶ Purpose of the project ▶ Vision of the project for which the procurement will be done ▶ Expected benefits of the project ▶ Statement of Work (SOW) ▶ Architectural representation and the steps involved ▶ Objective of this RFP
Proposal Evaluation	▶ Selection Method ▶ Rating
Informative Appendices	▶ Pro-Forma Agreement ▶ Proposed Approach ▶ Proposed Implementation/Delivery Timeline ▶ Proposed Core Network
Response Appendices	▶ Corporate Overview ▶ Requirements Instructions ▶ Privacy and Security Requirements Instructions ▶ Operational Requirements ▶ Financials Instructions

Table 3: Table of Contents (RFP)

The section of RFP containing Instructions to Vendors is an important part that typically contains information about different submission criteria.^{61,62,63}

- Proposals must be received before a certain date and within a certain time which would be specified in the RFP. Usually it is about a month from the release date within which proposals have to be submitted.
- Proposals would have to be submitted to the specific department or office and addressed to the Procurement Officer as mentioned in the RFP.
- Proposals received after the exact time and date mentioned in the RFP would be rejected.
- An original along with (usually) three copies of the proposals would have to be submitted, quoting the RFP number, RFP title, closing date and the vendor's name on the outside of the envelope.
- Once closed, only the identity and addresses of the vendors will be posted.
- Any proposal that does not indicate the RFP title, closing date, vendor's name, on the outside of the envelope or delivered to any address other than the one mentioned in the RFP would be rejected.
- Facsimile transmitted proposals will be accepted only if the proposal is received at the fax number stated in the RFP before the submission deadline. The RFP issuing authority will not accept liability for any claim, demand or other actions if the fax transmission is interrupted, not received in its entirety, not legible, received after stated closing time and date, received by any other fax unit other than that stated in the RFP, or for any other reason. The RFP issuing authority will also not guarantee the complete confidentiality of information

contained in the proposal submitted received by fax. The vendor shall submit an original proposal and the number of copies to the address stated in the RFP immediately following the fax transmission.

- A notice would be sent to a vendor followed by written agreement that would constitute a contract.
- The project team or the PI has the right to cancel the RFP at any time and to reissue it for any reason whatsoever, without incurring any liability and no vendor will have any claim as a consequence.
- Any change or amendments made by the project team or the PI to the RFP would be in writing and would be sent to all the vendors who received the original RFP.
- The PI or the project team is not liable for any costs of preparation or presentation of proposals.
- Proposals will be evaluated by the vendor evaluation committee.
- Vendors may change or amend their proposal till the closing date and time but cannot do so after that.
- Proposals can be withdrawn by the vendor at any time prior to acceptance.
- The Access to Information and Protection of Privacy Act will define the Contract Authority's responsibilities with respect to any information received by it pursuant to the RFP process.
- Vendors who would be short-listed would be requested to make a formal presentation at the cost of the vendor.
- The proposal and accompanying documentation submitted by the vendors are the property of the project team and will not be returned.

The Terms of Reference (TOR) section of the RFP talks about the background, the purpose, the vision, expected benefits, Statement of Work (SOW), architectural representation of the project and the objective of the particular RFP. In case of Outsourcing, the intent of the RFP would be to receive submissions for devices, software and services related to the supply, installation, integration and ongoing support to the solution that will be provided to the users. The scope includes procurement of devices, software and services for the ePHR capable of integrating with the data received from the devices and the devices for measuring BG, BP and body weight from which data can be uploaded to the ePHR. The scope also includes professional services related to implementation of all components like Project Management, Customization, System Integration, Testing, Implementation and Support and Maintenance. In case of Insourcing, the intent of the RFP would be to receive submissions for devices and that will be provided to the users by the research team. The scope includes procurement of devices and software and services for the devices for measuring BG or BP or body weight from which data could be uploaded by integrating them with an ePHR.

Proposal Evaluation is the section of the RFP that talks about the procedure that would be followed for selecting the vendors. The goal is to acquire the best solution / device for each of the components that are part of this procurement. The preferred solution is a comprehensive set of devices/products and services to be delivered by a vendor or a group of vendors providing a single point of accountability to the PI or the project team. Rating is used to evaluate the vendors. Ratings will be confidential and no details will be released to any of the other vendors. Vendors have to comply to certain mandatory requirements that are set out in the TOR. Proposals that fail to provide these requirements shall be deemed non-responsive and will not be evaluated. The evaluation team will utilize specific criteria defined in the RFP to rate each proposal. For example the proposals could be evaluated using the following criteria:

Corporate Profile - 5 %
Functional Evaluation - 25 %
Technical Evaluation - 20 %
Methodology/Approach Evaluation - 30 %
Financial Evaluation - 20 %

Informative Appendices of the RFP usually contains Proforma Agreement, Proposed Approach, Proforma Contracts, Number of User Accounts to be generated, Proposed Implementation/Delivery Timeline, Proposed Core Network etc. The Pro-Forma contractual agreements outline key contractual requirements that are considered important and would substantially be incorporated into numerous contracts required for the project.

Response Appendices section of the RFP usually requests information from the vendors about Corporate Overview, Requirements Instructions, Privacy and Security Requirements Instructions, Financial Instruction and Operational Requirements. Vendors would be asked to provide narrative responses to some questions. For example, in case of Outsourcing, they have to provide data backup and recovery operational procedures, server and application monitoring, configuration and alert management approach, proposed testing methodology, training, maintenance and support plans and procedures, sample SLAs and so on.

Vendors may be asked to score themselves in “matrix requirements” using some scoring system. Each vendor’s self-scoring will be validated. For example, the following could be a scoring system (“NOW” refers to the RFP closing date). Vendors are asked to directly explain how they will meet each requirement or provide a page reference in their proposal.

4 = commercially available, installed and operational in a clinical environment NOW
3 = commercially available within 12 months from NOW
2 = commercially available within 24 months from NOW
0 = commercially available in more than 24 months from NOW

Once the RFP is created, it is distributed to the list of vendors finalized in the earlier stage. The vendors can send their questions to a designated person within a certain time frame and all Q/As are made available for all vendors who have collected or shown initial interest for the RFP by email notification. Format for submission is well defined. If the format does not comply, then it may be rejected. Once the RFP is released to limited vendors and proposals are received from these vendors within the timeline defined in the RFP, the RFP process closes. It has a timeframe within which a vendor has to submit the proposal. Vendors in most of the cases can submit their proposal individually or form a consortium. Vendors cannot contact anyone other than the designated person. In case they do, their proposal may be rejected.

Review Vendor Responses & Finalize Contract

The process for vendor evaluation and selection is very well defined in the RFP. The vendors are shortlisted according to certain evaluation criteria involving the Weighting and Scoring systems, Rating system, and Screening systems for comparing vendors. This selection can be in stages. The more complex the RFP, more important the stages become. When reviewing vendors, one has to be careful about low cost bidders. Some have low cost models to penetrate the market but others will purposefully under-scope the amount of work needed. Once the project begins, these types of vendors may create new requirements because of their previous under-scoping. Subsequently, they would formally revise their

scope and estimate along with the management fees. Eventually, the low cost bidder could exceed the original highest bidder.⁵⁵

Other factors to consider would be find out the vendor's capability with respect to training, support, help and maintenance. Vendors who focus merely on the technical installation of a solution may deliver a product that while technically correct, fails due to ignoring process issues. It is important to also take into consideration the vendor's presale customer service. If the solution requires 24X7 support, then consideration should be given to the vendors who would be able to provide that kind of a support. An important question to ask at this point would be how the vendor handles upgrades, and whether the vendor offers it as a part of an annual plan.

Documentation is another key factor that would have to be taken into consideration at the time of selection of vendors. It is essential to find out what type of document the vendors would provide in terms of the work performed, configuration done, instructions given to the operations team about how to maintain the system, user guides created, online or offline and so on.⁵⁵

Another factor to consider is their implementation capabilities and find out whether they have a structured methodology for implementation.⁵⁵

It is also important to consider the risk associated with each vendor and the vendors' experience and financial credibility. Risk management is an important factor for a successful project.

A complex project may involve managing multiple contracts or subcontracts. The contract may contain inputs like major deliverables, key milestones, cost objectives or it can limit the project team's options. For any significant outsourcing activity, it is essential to prepare a plan to administer contracts. Some of the key points for contract management are performance review and reporting to monitor schedule, cost, technical performance and quality, integration of change control to assure that changes are properly approved and also risk monitoring and control to ensure that risks are mitigated. Payment schedules need to be worked out as well as termination clause. Early termination of a contract is a special case of contract closure and can result from a mutual agreement of the parties involved or from the default of one of the parties. The rights and responsibilities of the parties in the event of an early termination are contained in the termination clause of the contract.⁴

Shortlisted vendors, based on the evaluation criteria discussed above, may be asked to give a presentation or develop a prototype for the solution. Based on the prototype, the final vendor is selected. Terms and conditions are negotiated and the master agreement, contracts, SLAs are signed and the vendor selection process is completed.

Finding the Right Solution

There are many advances in the world of medical devices and gadgets, and many for the diabetic solution can be found on an internet journal of emerging medical technologies called medgadget.com.²³ Diabetics are hopeful that research will lead to safer, more convenient, and easier to use technology for self-management. Prominent among these are the non-invasive blood glucose monitors that do not require a blood pin prick test. Hopes are very high for improving quality of life through the use of these kinds of breakthrough devices. This paper will not discuss or analyze these for implementation because so far none of these devices has been approved by the FDA or Health Canada, although it appears research is in the later stages of development. This is true of Biosign's UFIT® TEN-10 wrist cuff which measures not only blood pressure (BP), but also blood glucose (BG) and other hemodynamics. The

blood glucose measuring metrics through the cuff have been in studies for some time, even a 2002 RCT at McMaster.²⁴ The BG component of the device has still not been approved by Health Canada.²⁵

Wireless mobility, for example, transferring glucose meter data to physicians and/or patients, either manually or automatically and continuously, is the current trend in telemedicine approaches to diabetes self-management. Garcia-Saez, though referring to mostly type 1 diabetes applications, mentions the OmniPod system, which is an insulin pump which delivers insulin readings wirelessly to a hand held receiver.²⁶ Another device mentioned is the One Touch Ultra (Lifescan) “which transmits BG measurements automatically to the PA (Personal Assistant) application using a serial cable or Bluetooth.”²⁶ In any feasibility trial of this sort, patient user satisfaction is important and questionnaires were administered to test their PA application for reliability, usability and utility. The study chose an iPAQ hp2210 PDA, which had a 12 hour battery charge, a critical factor in any implementation of such a system. More technical specifications of their PA device:

“The user terminal used for technical validation and clinical evaluation is an iPAQ hp2210 PDA with wireless communication facilities, such as infrared and Bluetooth. And is provided with the AudioVox RTM 8000 module for mobile GPRS communication capabilities. The Java Virtual Machine CrEme v3.24 for embedded platforms has been chosen to run the application in the Windows CE environment.”²⁶

The study by Garcia-Saez et al only used commercially available medical devices approved by the FDA but they noted the lack of same with wireless capabilities for remote control, therefore limiting tests to a laboratory instead of a clinical environment. The platform developed in the study was a wireless integration of medical devices, in fact an “ambulatory artificial pancreas”, yet the wireless continuous glucose monitoring sensors and insulin pumps are not commercially available.²⁶ Interestingly, their cost-benefit analysis was based on HbA1c reductions and estimations over a 30 year time frame.²⁶ In thirty years, many diabetes related diseases could be prevented. They recommend devices with more RAM, because systems are using a lot of memory, especially the CORBA system, and to do Electromagnetic Interference studies before any clinical use.²⁶ But interventions don't have to have as complex an architecture as the Garcia-Saez study, even though it was for insulin dependent type 1 diabetics. A Medtronic continuous glucose monitoring system has been used for some years now and has improved the quality of life for many diabetics, even without the PA and other wireless capabilities.²⁷

If lowering HbA1c indicates cost-benefit, not to mention improvements in patient health, the Kim 2008 study showed that a Short Message Service (SMS) for the control of type 2 diabetes in obese Koreans significantly lowered HbA1c over a 12 month period.²⁸ The longer term cost of using cell phone and wireless internet access is greatly less than for a wireless Bluetooth medical device application for type 1 diabetics. The Kim study required a personal care program as well as weekly communication from the nurse/researcher who monitored the blood glucose data, as well as other self-reported measurements on diet and exercise etc. The control group did not receive such attention. There was no addition of an ePHR system, patients could only login to see the data and the recommendations. The physician spent five minutes a week monitoring and sending messages to adjust plans per patient.²⁸ SMS studied by Cocosila and Archer examined the adherence and motivation behaviour of participants who use such systems, as well as mobile models for self-management of diabetes.^{29, 30} The next step would be to study if the addition of a ePHR system and a SMS reminder/monitoring system would lead to even greater user satisfaction. The study has implications for procurement decisions, especially if clinical evidence suggests simple text messaging can lead to very good adherence and outcomes.

The Kim study also suggests that the SMS system for type 2 diabetes they created could be used as a platform for other chronic diseases such as hypertension, hyperlipidemia, obesity, and metabolic syndrome.²⁸ It would be ideal if a model for type 2 diabetes for self-management could be serve a s prototype for a platform solution for other chronic illnesses. This suggests, from a technical point of view, system architecture that has greater inter-operability, medical device standards using an Application Program Interface (API) or programming languages like Java. IBM's Personal Care Connect has just such a "platform".³¹ An exclusion criteria for patients in the Kim study is if they had been using insulin but it is need not be used as exclusion criteria some studies or projects as many type 2 diabetics take insulin. The Kim study was described as being "quasi-experimental" even though designed much like a clinical trial, having a control group, with a cross-over design, that is, controls later received the intervention and vice versa.

When it comes to a "Make or Buy" decision for procuring a system, or even an Insourcing or Outsourcing decision, IBM has always been there to provide solutions. Historically, IBM has provided turnkey and service systems mostly to larger corporations, including healthcare institutions. In their research and development IBM started a trial using a system for remote sensing and monitoring of patients called Personal Care Connect. (PCC).³¹ The PCC system platform has relevance for vendors and software developers because it is an open standards based platform so different commercially available home-based medical devices can be integrated to it. As a platform, it can be used for other chronic disease monitoring, and not just for diabetes, which has relevance for licensing a novel solution. It also leads to faster time to market because of less development expense since there is greater compatibility with APIs. The IBM systems journal article on PCC notes that for active patients, mobile phones are the best solution. The basic premise for this is that electronic records of daily journal entries by diabetics are great improvements over illegible and incomplete written logs.³¹ These electronic records lend themselves to better clinician monitoring. IBM has worked with university researchers before, typically building the solution, while letting the researchers do the clinical study. From a university researcher's perspective, this is an outsourcing model that would be ideal for a pilot study. On the downside, IBM might be an expensive company to work with, especially on a small project, so a smaller company that does integration might be sought.

The iPhone 3.0 Lifescan prototype application is an example of a mobile healthcare system for the self-management of diabetes (mostly type 1 insulin dependent) that is bound to win customers because of the popular iPhone technology. The iPhone app for diabetic self-management developed by Johnson and Johnson's Lifescan group and Apple's iPhone is leading edge.³² This technological solution might be good for a project which has participants who are still within an active age range. The mobility and usability of the iPhone for self-management of diabetes allows for the following features: sending Blood Glucose readings from a meter via Bluetooth or 30 pin connector, recording readings for fasting, before or after meals, allowing notes to be added, recommends what to eat in terms of caloric in-take, automatically calculates insulin dosage, adjusts for lifestyle measures like exercise which lowers BG in dosage recommendation, stores a history of past readings that can be graphed and accessed for analysis, and it can be used to communicate to physicians and other healthcare providers. All that information is accessed through the iPhone touch screen.³² This is a prototype that has not been fully approved by the FDA, but it is a promising technology for managing a complex disease like diabetes.³²

Another promising solution is the MedApps' *Telemedicine 2.0* system. Here is a description of this system from a June 2009 MarketResearch report on "High Tech Patient Monitoring Systems", but the D-PAL can also be found on medgadget.com: "The system uses Bluetooth wireless technology, enterprise level interactive voice response, and intelligent call routing. The Body Area Network connects the patient to the healthcare provider using a cell phone that acts as a device hub. The system

will support glucose meters, implantable devices, blood pressure monitors, and scales. Data will be collected via Bluetooth wireless technology and sent to the cell phone hub, then transmitted to a central server, then to a portal for healthcare providers. The *D-PAL* device for monitoring diabetes is the first module to receive FDA clearance. *D-PAL* will be followed by the *H-PAL* monitor for congestive heart failure, *A-PAL* for asthma and COPD, and *T-PAL* for tremor and Parkinson's Disease."¹¹ The trend towards Bluetooth integration with monitoring solutions is well underway, but the solution needed must be approved within Canada. Currently, this platform system can only be bought over the counter in the U.S.A.

The Healthanywhere solution appears to be the best match for the kind of solution proposed for this paper. HIPAA (they also do business in the United States) and HL7 compliant, Healthanywhere is an Ontario (Ottawa) based company. It uses hardware agnostic platforms that enable existing PCs and BlackBerry Smartphones to function as telehealth equipment. Healthanywhere has partnered with Waterloo Ontario based Research in Motion to design and implement self-management solutions for patients with chronic conditions using the Blackberry Smartphone. Their "Health on the Go" program sounds well suited for adults with type 2 diabetes.³³ Healthanywhere is a software solution that integrates different outsourced hardware platforms. This company contracts to third parties for servers (some owned by Primus), healthcare professional monitoring (to companies like Sykes Assistance Services Corporation or We Care Health Services) medical devices are third party (i.e. Nonin Medical, A&D Medical, Polymap Wireless, etc). The Healthanywhere software allows for the hardware integration. End users often use their own existing Blackberry Smartphones and cellular phone plans through the telecoms.³⁴

Healthanywhere enables wireless Bluetooth transfer of biometric measurements including blood glucose, blood pressure, pulse, weight and blood oxygen. Manual entry also includes temperature and pedometers. Healthanywhere also includes customizable exercise and nutrition plans, streaming videos, wound management and questionnaires. Healthanywhere is back ended by the Health Canada Drug Database. Reminders include both drug and general reminders that are received by the end user. Information is accessible on the Healthanywhere portal. Integration is possible with other personal health records including a partnership with Microsoft Healthvault. Open source integration through an API to MyOSCAR is possible, according to both Healthanywhere, and Dr. David Chan.³⁵ David Chan, chief developer of OSCAR would prefer seeing patient data on the ePHR, preferably on the physician's own server, and not on a third party server.³⁵ At present, Healthanywhere has not had too many requests for the ePHR integration.³⁴

During any systems analysis before the decision to choose vendors, one area that always needs careful examination is privacy and security of personal health information. What have the vendors done to ensure their medical devices or systems are Personal Health Information Protection Act (PHIPA) compliant? Healthanywhere has also met these requirements, and their wireless healthcare system is held as a model in the Information and Privacy Commissioner of Ontario report on "Innovative Wireless Home Care Services: Protecting Privacy and Personal Health Information".³⁶ Any assessment of vendor technology would have to evaluate this level of what the privacy commissioner Ann Cavoukian calls "Privacy by Design".³⁶ The following list contains safeguards that have been put in place for blood-pressure readings, but the same can be applied to blood glucose data transmissions:

- Data travelling between Bluetooth connection and BP device and Blackberry Smartphone is encrypted.
- BP data travels only as numbers without identifiable information
- Data is linked with client data only once in the Healthanywhere server

- Data travelling to and from Blackberry Smartphones or Web browsers is encrypted on a wireless network
- Uses Verisign Secure Socket Layers for online applications (such as used for financial transactions)
- Passwords to login to Healthanyware applications by We Care staff are changed often
- On-line access levels are given to authorized users only to view client data on a need to know basis
- Sessions are timed out after brief inactivity

Evaluation of a Project or Pilot Study

Evaluation of a project or pilot study is essential to determine whether the objective for which the project or study was conducted has been achieved. Earnest House classified evaluation into eight approaches, namely, Comparison based, Objective Based, Decision Facilitation, Goal Free, Quasi-Legal, Art Criticism, Professional Review, and Responsive Illuminative approach. Even though most evaluation studies or surveys can be undeniably tied to one of these approaches, these eight categories are not mutually exclusive. There are studies that show evidence of properties of numerous approaches and are thus not exclusively classified.⁵⁷

The first and foremost step would be to assess if the solution was developed as per specification or scope, on time and within budget. Project quality is affected by balancing of these three factors: scope, schedule, and cost.

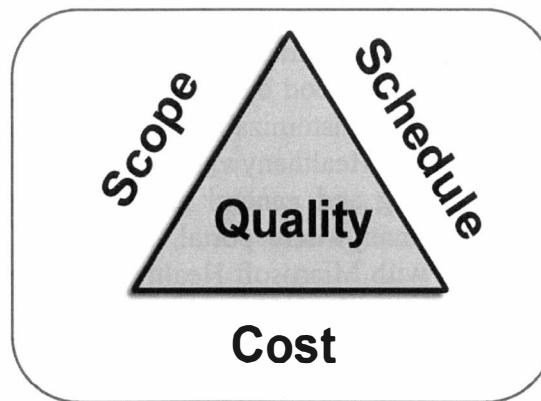


Figure 5: Project Quality

Also, it is necessary to see if it complied with all regulatory bodies and maintained privacy, confidentiality and security while conforming to certain accepted standards, guidelines, policies and methodologies. Questions arising out of the implementation and completion of the project from all the stakeholders should also be addressed during the evaluation process. Healthcare is a safety-critical area so it would be significant to assess whether adequate proof of safety was taken into consideration during the course of the project.

Another way of categorizing evaluations studies are the three stages of Technology Assessment, namely, Evaluation of Characteristics, Efficacy of Effectiveness and Evaluate Effectiveness via Health and Economic Outcomes. Examples of Evaluation of Technical Characteristics could be the response time of an information system to a query. Efficacy of Effectiveness could include computer-assisted drug dosing; preventive care reminder systems, and computer-aided quality assurance programs for active medical problems. Evaluate Effectiveness via Health and Economic Outcomes would include a study that evaluates the cost effectiveness of an information resource in terms of dollars per quality-adjusted

life year saved, would enable clinicians and policymakers to compare the cost effectiveness of an information resource to a wide variety of other interventions.⁵⁷

It is also necessary to evaluate whether the project was able to improve the “Quality of Life” (QoL) of the participants and whether the patients adhered to the self management regime. How many fall outs were there since the inception of the project? It is very common in projects that initially a large number of participants sign-up but down the line after a few months some participants drop out.

It is necessary to find out the level of user satisfaction with respect to using the ePHR system and devices. An evaluation survey can be designed based on the Jacob Neilson’s five components of usability, namely, Learnability, Efficiency, Memorability, Errors and Satisfaction.⁵⁸

It is significant to evaluate whether physicians and nurses helped the patient in monitoring, reminding, educating, consulting, supporting informing, and educating as outlined in the purpose of the project.

Finally, it is important to find out whether “Proof of Concept” has been satisfied, that is, whether the project was successful in accomplishing the purpose for which it was conducted so that the solution can be considered for commercial availability.

Commercial Certification

For decades, human drugs and medical devices needed to be approved by the health authorities before they could be released in the market. For medical software this was not required. The main argument to resist all attempts to regulate medical software has been that it is impossible to guarantee that software is error-free. This is true of all software. However, in medical software the correctness of medical knowledge is at least as important as the correctness of the code itself. The medical contents of the software could usually be evaluated but the end-users do not have the time or possibilities to do so. The Internet makes it possible to provide commercial services designed by non-professionals. For health care, there are already several commercial services on the net. Since there is no quality assurance or regulation of medical software anyone can sell medical software on the net. Even if physicians were cautious enough not to use untested software, there is a possibility that patients do. It is impossible to remove poor services from the Internet and therefore, it is essential to guide the users to use high quality services.⁵⁹

The authenticity of software to be used in medical applications is vital as it can often impact authentic treatment of the patient. For the sake of patient safety and quality medical care, it is important to facilitate commercial certification and guide users towards the use of certified products.

Health Canada Class II Medical Devices

The software solution or overall system needs to be registered with Health Canada as a Class II medical device.³⁸ New regulations for licensing patient monitoring software came out in August 2009. Given that a lot of data will be charted, graphed, and analyzed, the proposed solutions would require a Class II license, because it goes beyond mere archival storage of images. These are considered Active Diagnostic Devices because they are used for the purpose of monitoring a physiological condition, state of health, illness or congenital deformity.³⁸ “This includes any patient management software involved in data manipulation, data analysis, data editing, image generation, recording of measurements, graphing, flagging of results or performing calculations. Any primary workstation that interfaces directly with a system (imaging or other type) by acquiring data and then sending data to an image generating, viewing or storage device, is also classified as Class II.”³⁸

Canada Health Infoway Certification

Even though it is not mandatory to get the solution certified by Canada Health Infoway (*Infoway*) for commercial certification, it would be advisable. In 2008, the Deputy Ministers of Health requested *Infoway* to take a lead in determining the best approach towards implementing consumer health solutions in Canada. As part of this mandate *Infoway* works together with Health IT vendors to ensure that consumer health solutions implemented in Canada could be trusted and were complementary to the jurisdictional e-health deployments that are underway. In November 2008 *Infoway* issued a press release announcing that it will launch a Certification Service for Consumer Health Platforms in early 2009.⁶⁰ The scope of *Infoway's* e-Health Certification Services for 2009/2010 is limited to pre-implementation certification only. This applies to technology solutions that are “market ready” and may or may not be in a specific production environment. The pre-implementation certification service assesses a product’s compliance with pan-Canadian standards for privacy, security and interoperability and management. It does not address jurisdiction-specific legislation (e.g. privacy). It does not address added solution features or functionality, beyond what is required for privacy, security and interoperability. *Infoway* has added four new offerings to its pre-implementation Certification Service. Health information technology vendors can now receive certification for consumer health applications, client registries, provider registries, and immunization registries.

The pre-implementation certification process for consumer health platforms involves four steps, namely, “apply”, “assess”, “certify” and “maintain”.

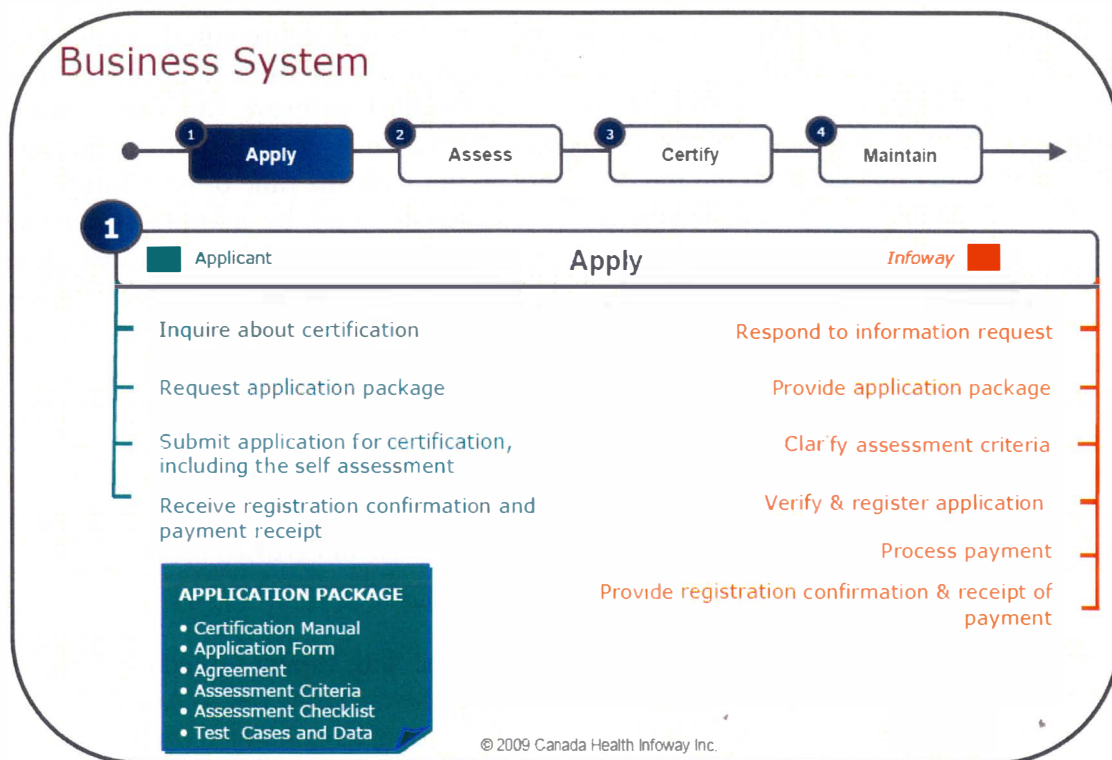


Figure 6: Canada Health Infoway Certification Process⁶¹

Once the application is submitted it is assessed based on criteria consisting of two classes:

- **Solution:** This refers to the aspects of functionality, privacy, security and interoperability that need to be assessed.

for an ethics board approval, an RCT methodology, and a team of researchers waiting to publish papers. The dilemma MOHLTC has, with the Aging at Home initiatives they need to promote, is that they are capable of only sponsoring projects that are three years long, as in the recent North Simcoe Muskoka LHIN 12 ReACT mobile healthcare project that We Care and Healthanywhere were involved with.³⁴

Patients with chronic illness are willing to pay their own expenses for the technology, because there has been no long term health impact assessment of the ehealth technology on the economic costs or benefits in order for MOHLTC to say they would be willing to pay for the technology for all citizens in Ontario with those chronic conditions. This is again the point made by Holbrook that more cost effectiveness analysis of ehealth studies is needed.¹⁵ Being a clinical researcher, Holbrook also advocates for more clinical trials of ehealth technology, rightly worried that people will jump on the latest technological solution without proper evaluation.¹⁵

Maybe one day MOHLTC or the Community Care Access Centers (CCAC) will become major procurers of Bluetooth medical devices for such mobile configurations as has been discussed, to supply patients with chronic conditions without personal cost, and the RFP for that would be quite expensive and extensive. The scope for this might be a realistic prospect if compared to a recent eHealth Ontario RFQ for a Diabetes Registry for all Ontarians with diabetes.⁶² As an Outsourcer or Integrator interested in the resultant RFP would only need to be a “pre-qualified team” in order to have a chance of winning the bid.⁶² Incidentally, the pre-qualified teams invited to bid on the RFP on November 25, 2009 were CGI Information Systems and Management Consultants Inc, Telus Health Solutions GP, and xWave, a Division of Bell Aliant Regional Communications, LP.⁶³ The diabetic population for the registry in Ontario is 900,000, but strangely the ehealth initiative isn't synonymous with LHIN/CCAC initiatives involving smaller IT players, even with smaller LHIN diabetic populations.

Centralization of all diabetic patient data on servers procured and managed by large IT corporations also goes against the principles of Dr. David Chan and the open source ePHR program MyOSCAR, where patient data is best conceived as being most safe and secure on the physicians' own server.³⁵ In case of hacking, fire and flood or other breaches of security, which is better, to lose hundreds of thousands of records on a centralized database system, or just one server holding a family practice medical records?

CONCLUSION

Procurement for healthcare IT requires a business solution but it needs to develop and assess business models in significantly different ways from usual supply chain management practices. At stake in healthcare are healthy outcomes for patients, not the bottom line profit for a board of directors meeting. As well, procurement for a university-based research pilot study will not have the same buy-in from key stakeholders as procurement for a commercial market implementation. In order to succeed in any IT project, project management guidelines are highly recommended, as well as recourse to legal consultation on key risk management issues. Projects that are complex and produce RFPs over one hundred thousand dollars require special attention because of recent provincial requirements.

It is expected that the quality of life for diabetics using mobile technology will be much improved in future, and perhaps as well the process by which physicians, nurses, CCACs, and healthcare teams, interact, monitor, and document that improvement. Chronicling this in terms of cost-effectiveness would be extremely useful.

There are a multitude of players in a diabetes strategy to develop a mobile ehealth platform to enhance self management. Diabetes is a significant and costly chronic condition for the healthcare system, but it

- **Management:** This refers to how the organization providing the Consumer Health Platform Product manages risk, data, system security, as well as third party solutions and services

A number of pan-Canadian standards and international best practices were used to develop the assessment criteria. The assessment criteria were shared and reviewed with four jurisdictions, one vendor and a Privacy Commissioner.

The certification term is one year with the opportunity to extend for up to two additional years. The certification terms expire June 30 and December 31. A product must undergo complete certification every three years. Any changes to the Product must be communicated to *Infoway* and may require new certification.⁶¹

Receiving the '*Infoway* Certified' mark provides vendors of health information technology products a competitive advantage because of the *Infoway* recognition and would prove their commitment to pan-Canadian standards and best practices. For healthcare organisation it would mean trusted, standardised interoperable software solutions.⁶¹

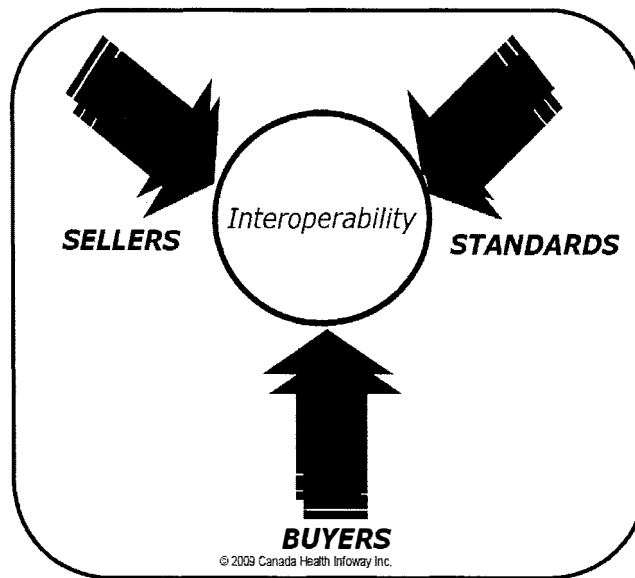


Figure 7: Benefits of Canada Health Infoway Certification⁶¹

From Clinical Research to Commercial Market

It can be debated though whether or not a project would need a RCT to provide clinical evidence based outcomes, as it would appear that as long as the medical devices that would be used have already met Health Canada approval, there would be no need to reprove their clinical significance. The market for mobile healthcare solutions has been shown to be already using configurations of medical devices and Smartphone technology. Some of these have received limited funding from the Ontario MOHLTC, but what is the extent to which new projects need to prove that there exists a new configuration of medical devices, Smartphones, and ePHRs for improved diabetic outcomes? Of course, clinical researchers need to see the evidence from these outcomes in order to safely prescribe the ehealth solution to others: that is the knowledge translation. The business community and the more activist healthcare leaders would see on the other hand an opportunity to permit willing clients the use of approved technology for their own self-management, with the subsequent cost savings and health benefit outcomes which have been documented already. If the MOHLTC decides to sponsor a company like Healthanywhere to implement a study using commercially available medical devices, for type 2 diabetics for example, there is no need

is only one of many chronic conditions that can be supported on a mobile ehealth platform. The objective is to find the most economical, effective, and most important of all, acceptable configuration for patients. This paper has demonstrated the feasibility of using the Healthanywhere solution as a best practice. There is flexibility in applying this model using an Insourcing approach, but that would be a more expensive application to develop than contracting to a reputable but small IT outsourcer. Networking multi-vendors together for an RFQ has been shown to be the preferred method. These are recognized market leading vendors with commercially available, Health Canada approved and certified, medical devices and software solutions. Commanding a detailed knowledge of the RFP process is critical for ensuring that the project is completed on time, within cost, and to the satisfaction for all.

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