Supervisory Committee

Delivery of Laboratory Results to Family Physician EMRs in Ontario

by

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Abstract

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The timely communication and access to a complete history of lab results is at the heart of patient diagnosis, monitoring, and treatment planning. When lab results are effectively shared, in a manner conducive to family physician processes and systems, the business and clinical processes are improved, with possible value to the care of the patient. Current lab result sharing occurs through disparate and often proprietary one-to-one connections, often non-electronically, making integration of results difficult. There is broad value in coordinating efforts and consolidating processes across organizations, through electronic health record solutions. Referencing the published literature, this paper evaluates the local context of Waterloo-Wellington counties in southwestern Ontario, stakeholders, and processes, and describes the applicable standards and existing solutions. Recommendations are made for how to progress towards interoperable lab result sharing with family physicians.
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Overview

In this paper, the term “family physician” is used synonymously with terms of primary care physician and general practitioner. Where the term “physician” is used without a qualifier of type of physician, it may be inclusive of various types of physicians. Otherwise, the physician type is specified (ie. emergency physician, hospitalist, or specialist).

The use of 'electronic medical record' or EMR refers to the physician office information system (as a clinical component of the Clinical Management System (CMS)). In contrast, 'electronic health record' (EHR) refers to the inclusive patient health record, containing or providing access to information from across multiple organizations. Finally, 'electronic patient record' is used to represent the organizational health record in hospitals (also known as a 'hospital information system' (HIS)) or laboratories (also referred to as 'laboratory information system' (LIS)).

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<td>Background</td>
<td>Setting the context involves identifying the key participants and direct stakeholders, and explaining the relationships that exist between them. Information systems used by the major players are described. Numerous external influencers exist at varying levels – from national, to provincial, to regional. The nature of their involvement and interest is described.</td>
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<tr>
<td>Objectives</td>
<td>This section establishes the topic and objectives of the research and the research question</td>
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<tr>
<td>Methodology</td>
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<td>Results</td>
<td>Beginning with a summary of the published literature that was discovered through the literature review, then presenting the information obtained through consultations with industry representatives and experts in the field, this section finishes up with detailed results from the interviews with family physicians. The challenges that are being faced are detailed, and the outcome of interoperability and the potential value of this goal is presented. Current strategies to exchange results from lab service providers to family physicians are outlined, including an overview of solutions elsewhere in Ontario, and a brief comparison to strategies in Alberta, and initiatives in the US. Standards, as the cornerstone for interoperability, are outlined.</td>
</tr>
<tr>
<td>Discussion</td>
<td>This section will analyze several of the important characteristics of solutions.</td>
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Nine categories of requirements for the solution are described to serve as a starting point for considering the necessary elements and features. A series of frameworks are described that encompass the range of solutions. Various models are presented, with direct comparisons across several candidate and conceptual solutions.

**Recommendations**

A series of recommendations are made to progress towards optimal solutions that achieve interoperability.

**Limitations**

The limitations of this study are identified and described, outlining potential for comparability and applicability to other regions.

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### Executive Summary

Lab results are an essential component of the electronic records for family physicians. Lab tests, from hospital and/or community lab service providers are delivered to family physicians, and essentially support the diagnosis, monitoring, and treatment planning throughout the lifetime of health care services for the patient. In order for the full value of these results to be actualized, they must be delivered in a timely and conducive manner to support clinical decisions. Traditional methods of delivering results by courier or fax are often incompatible with family physician electronic records, and do not enable longitudinal trending and analysis of lab values.

From the perspective of the hospital sector, collectively we hear what family physicians want, and have an idea of why, but see many roads to deliver what they need. As health care and information service providers, together with our family physicians and the private labs, we share a vision for an 'electronic health record' (EHR). There is great debate as to how we may achieve this, and in many cases the family physicians, organizations, jurisdictions, the province, and the national agendas differ as to how this should occur. There is financial and political pressure to proceed and deliver, yet with limited dollars and resources, there lacks consensus on what the first steps must be. Numerous solutions exists, and it can be overwhelming to consider how these overlapping or conflicting solutions, while each inadequately meeting the requirements of all stakeholders, may somehow be implemented to move towards the EHR vision. If we can capture and describe the essential elements of the solution, and understand the state of our environment, we may define a strategy leading us toward the ultimate goal.

The study reflects the roles of three key participants: privately funded (community) labs, publicly funded (hospital) labs, and family physicians. The study also considers the actual or potential relationships with hospitals, government (LHINs jurisdictionally, eHealthOntario provincially, and Infoway nationally), and private or public solution providers.
Through the review of the literature, and interviews with family physicians, the exchange of lab results from lab service providers to family physicians is shown to be integral to modern healthcare. But, current strategies to distribute results are based on proven and traditional practices, which have not kept pace with the rapid growth and availability of new information sharing technologies. We continue to see results shared as they were twenty years ago – printed pages delivered to a hospital mailbox, couriering to the family physician office, and mailing or faxing of results. Unfortunately, the current processes of exchanging these lab results are inadequate, and improvements are required. There have been various efforts to exchange results electronically, but these methods are generally proprietary and require numerous connections for each lab to send, and each family physician to receive results. As a result, many solutions cannot meet the needs of all family physicians with different electronic medical records (EMRs), and the effort is often not feasible for an individual hospital.

The methodology of study is mixed and non-empirical. Along with various types and sources of published literature, the study will integrate interviews of stakeholders, and observations and consultations from the local environment. Critically analyzing these information sources, the scope, gaps, and potential for interoperability will be discussed. The beneficiaries of the research include family physicians who, through implementation of the recommended solution(s), may efficiently receive inclusive and integrated lab result information from multiple sources. This will culminate in a more complete and functional health record to support clinical practice. The service providers who supply the results will benefit through improved efficiency of delivery, with reduced effort to implement information exchange solutions. There may be clinical effectiveness through providing results in a timely and operable manner. Governmental stakeholders will benefit from improved understand of the clinical and business requirements for lab result exchange and awareness of ideal solutions to support. With a coordinated solution, service delivery and system support will be streamlined through improved efficiency and appropriate resource use.

The preliminary literature review describes the value of lab results to family physicians, particularly when receiving handoff of care responsibility of patients discharged from hospital. Unfortunately, clinical information is often lacking. Allowing the lab results to flow into the family physician electronic medical record provides access in the family physician's application of choice through an integrated presentation of results from multiple sources. This streamlining could minimize the initial cost for family physicians to implement an EMR, and reduce the ongoing costs associated with maintaining disparate processes. When the results are structured similarly from across sources, the presentation of results may support enhanced interpretation and functionality, and broader use of information technology (including decision support tools, internet-enabled technology, and mobile communications) in primary care. There may be improved efficiency of processes, reduced health service utilization, and stronger relationships with the
lab services. While ultimately there may be improved quality of care and patient safety, the extent and actual cost benefit is not yet clear.

This study identifies clinical and business requirements. These include the need for a centralized point of access for family physician recipients, and a centralized point of distribution/delivery for lab service providers. Results must be up-to-date, accurate, and relevant to the family physicians, and the solution must be sustainable, scalable, and transferrable. Standardized conventions across family physician electronic medical records, and lab electronic systems should support automation and integration.

There are numerous solutions that individually may be inadequate to meet the requirements, but through establishing partnerships, may reveal unique opportunities. Implementation effort and expense may be minimized, and utilization of existing functionality and current data sharing can be optimized. More advanced solutions leverage collaboration and consolidation of services and data across multiple systems. Adherence to optimal standards (such as HL7 as a messaging standard, and LOINC for metadata) will ultimately ensure all parties are 'talking the same language'. Solutions may push results to the recipients, or the results may allow retrieval by the recipient. Of greater significance is understanding who is responsible for the data, and for acting on the data to address the revealed needs of the patient. There may be an evolution towards results that are distributed based on the defined or permitted patient relationships (that is, those providers that are in the circle of care), in contrast to the traditional limited association between the order/result and exclusively the ordering physician. This depends on the development of shared infrastructure of indexing patients, family physicians, and results. A shared solution need not be limited to a particular region, group or type of physician, nor type of lab (hospital based or private). There may also be capacity to expand to include other report types.

One of the predominant outcomes of this study is the development of a better understanding of what is required, and that several eligible solutions exist. With this knowledge, there will be great value in coordinating efforts, partnering on solutions, and consolidating processes. It is the responsibility and benefit of all stakeholders to collaborate on joint solutions, acknowledging the requirements of those involved, together supporting the evolution towards standards-based, automated lab result sharing. In the end, the result delivery solution is a stepping stone on the comprehensive EHR journey. Several of the candidate solutions (such as local solutions, regional solutions such as Medseek, and provincial solutions such as eCHN, OLIS, and OntarioMD Report Manager) are described and compared. This research will describe the most effective exchange of lab results to family physicians, particularly employing provincial solutions, such that the data can be efficiently and effectively received, integrated, and interpreted, by the largest number of recipients, from all of the province's labs.
Recommendations for next steps include the need to articulate a vision, engage stakeholders under a governance structure, build partnerships, and define requirements. Evaluating the potential of interim solutions may reveal short-term opportunities to quickly deliver value to stakeholders. Assessing and contributing to the development of messaging and metadata standards will ensure the present and future needs are met. Researching the outcomes of these initiatives and studying the applicability to other clinicians (including specialists) will support the future growth and engagement of other stakeholders.

In conclusion, there are several key messages from this research. The value of distributing lab results to family physicians, though not quantified, is broadly understood to directly support business processes and indirectly support clinical processes for health care providers (including hospitals and family physicians). There is a disparity of result sharing/distribution methods, in a highly complex and unsettled environment. There is value in electronic report distribution, in particular, in evolving distribution away from traditional independent ‘1-to-1’ solutions, and towards shared methods that support ‘many-to-many’ connections. Standardization and consolidation is possible, feasible, and necessary, and coordination of efforts will support implementation, adoption for family physicians and lab service providers, and ultimately, achievement of the vision for electronic health records.
Background

When a patient moves through the health care environment, they often experience care from various providers in different organizations. The patient may have several visits to the ER department, or admissions to the hospital, and outpatient visits to specialists, clinics, and labs. The family physician is often the hub of these health care activities, of which approximately 80% of these activities occur outside institutions (Auditor General of Canada, 2010). The family physician may initiate processes through referrals to the specialists or for testing at the labs, and will receive reports from each of these hospital and non-hospital sources. Alan Brookstone, an expert of physician office electronic medical records (EMRs) stated, “The average physician in their practice probably connects with up to 40 or 50 different entities over a year. Those would include ancillary care providers, physiotherapists, occupational therapists, the hospitals, the lab systems (and) other colleagues. So there is an incredibly comprehensive network of exchange that takes place” (Leslie, 2010).

Access to information enables physicians, whether family physicians, hospital physicians, or specialists, to provide clinical services. It is beneficial, though not sufficient, for information to be merely accessible. Rather, information must be streamlined with and matched to the clinical process. Sending and integrating clinical information between information systems makes the information available to the family physician in their application of choice. The value is particularly apparent, for example, when laboratory results from each lab service provider, whether hospital or private lab, are shared contiguously with other clinical findings. When this contextual availability of information exists, the family physicians’ awareness and understanding of the patients’ health status helps to support and guide the patient through their health care.

The flow of information back to the family physician is not always reliable nor efficient, and poorly coordinated. An Ontario family physician stated, “There is rarely any communication between family doctors and specialists… We get people coming out of hospital having had treatments and procedures, and we have no knowledge of them” (Leatt, 2000). Furthermore, this flow of information often occurs in various manners, and the family physician needs to be able to consolidate the results. This is particularly apparent when considering that lab results from inpatient or emergency visits may be formatted, transmitted, and received in dramatically differing ways from those received from private outpatient labs. Each source may have unique naming conventions, processing methods, units, reference ranges, and means of delivery (typically faxing, or mailing, or potentially electronic delivery) for their test results. Each of these mechanisms has unique limitations, features, and challenges. This variability makes reconciliation and management of results incredibly difficult, particularly when family physicians are
attempting to migrate to electronic information management solutions, yet reports continue to be
distributed in ways that are incompatible with those electronic solutions.

The Electronic Health Record (EHR) has been proposed to address these issues. Various definitions
exists for what the EHR really is, but one particular functional definition by Marshall & Roch is especially
applicable. They indicate that the purpose of the EHR is to “facilitate the sharing of key pieces of health
information between multiple authorized custodians across the continuum of care, across healthcare
delivery organizations and across geographies, to support the provision of optimal care.” (Marshall &
Roch, 2006)

The journey to implement the EHR has been compared to building a road system –

“Imagine it is 1902. Imagine you are watching the first mass-produced, low cost cars roll
off the Oldsmobile assembly line in Lansing, Mich. And then imagine some transit czar
says: “To deal with the revolutionary possibilities that cars and trucks and buses are
bringing, we have to put in place a 21st century road system.” This means we need to
create: Overpasses, underpasses, superhighways, toll booths, bridges, lane divisions,
speed signs, parking meters,... gas stations, garages, rest stops, lane markers, tow
trucks, scenic vista widenings, snow plows...And oh, yes, you have to teach people
whose driving experience is limited to horse-driven buggies, mule trains and oxen
wagons to immediately understand how everything works in the new road system and
how to use it effectively. And perhaps most importantly, you must do everything without
stopping all existing traffic while you build the new infrastructure.” (Strauss, 2010)

Over one hundred years later, the road system continues to develop, with many geographical areas still
unreachable. Furthermore, lack of consistency in road systems (i.e. travel on the left vs. right, imperial vs.
metric measures, signage, and rules) continue to prevail. This ongoing effort to enable travel bears
similarity to the complexity and transformation to health care information management that is required to
enable health information exchange. Alternatively, health information system implementations have been
compared to the implementation of banking systems. With the first automated teller machine (ATM) in the
late 1960’s, and the development of ATM networks in the 1970’s and 1980’s, it wasn't until the early
1990’s that national networks were completed and universal ATM access was established (Hayashi,
2003). This thirty year development sheds some light on the scale of time challenges that may likewise
be required to achieve universal EHRs. Unfortunately, barriers exist to this development, including
traditional proprietary and typically non-electronic solutions that fail to leverage, or worse yet, conflict with
rapidly and aggressively adopted modern EMR solutions. The two provider groups of lab services and
family physicians need to share information, but a chasm exists. Brookstone referenced the road system
analogy and stated, “we’ve certainly got some of the cars for the roads but not all the roads have been
built - and there’s some places you just can’t get to” (Leslie, 2010).
This study is about how we can enable new channels of information delivery, and build bridges for the exchange of information as one part of the analogous EHR road system. A specific focus on lab results is an excellent opportunity to explore the implications and characteristics of the EHR framework, and how it applies to current processes and specific requirements of individuals. One example to demonstrate the EHR framework is through enabling lab result interoperability. Interoperability may be defined as the ability for lab results to be "shared (between systems), aggregated (into a single standardised whole), and computed upon, in such a way that originally disparate information about, say a patient, can be safely analysed by a computer program" (Beale, 2009).

There are many ways that this may be technically achieved, and it is not the intent of this study to quantitatively measure the alternatives. Instead, a description of the current state of technology and the availability of standards and frameworks will describe types of solutions. The classification will be extensible to other information types, such as radiology and medical transcription reports, problem lists and notes, and nursing and allied care summaries. It will also be scalable for additional stakeholders, such as community care access centers, midwives and other health care providers, and may link to more advanced information exchanges, such as referrals and appointments, alerts, and decision support tools. The ultimate objective is to enable access to the best patient information, in the most useful and meaningful ways across the health care spectrum.

In this study, there are limitations to the content, or the depth, of research. This study excludes pre-analytical and analytical phases of lab process. It includes post-resulting sharing of laboratory results. Detailed technical design descriptions, such as infrastructure and security are not included. Some key considerations, such as privacy, funding, and policy (including data sharing and hosting) are not comprehensively addressed. Only functional and high-level design elements are described, and detailed nuances or obscure or infrequent business practices are not covered. Not all interactions/transactions, relationships, considerations, or influences are captured through this paper, with emphasis only on the most relevant and influential factors.

There are also limitations to the domain, or the breadth, of study. The study looks specifically at Ontario, and most notably Waterloo-Wellington region. This region was selected primarily for reasons of convenience for the author, but also due to the author's familiarity with the region and initiatives currently underway, and due to the breadth and variety of solutions that have been demonstrated in the environment. The study will consider the experiences of other provinces in Canada such as Alberta, and the US. This study is directly affected by nearby and overarching jurisdictions, and influenced by regional, provincial, and national initiatives and politics. Acute-care hospitals are included, and government operated (public health) laboratories and public health information/results are excluded.
Physicians in general practice (family physicians) are within scope, with a particular focus for those with EMRs, while the sharing of lab results with hospital-based physicians and specialists is excluded.

**Environmental Scan**

An understanding of the environment and the key stakeholders is integral to consideration of the current and future states of lab result sharing. National, provincial, and regional authorities, and an overview of what they may contribute to the solution, are described below.

**Canada Health Infoway**

In 2000, the development of an interoperable electronic health record was identified as a top priority in health care. (Canada Health Infoway, Vision) Then in 2003/2004, Canada Health Infoway (Infoway) was established to “accelerate the development and adoption of modern systems of health information and to define and promote necessary standards” for the purposes of interoperability (Canada Health Infoway, Vision). Nationally, Canada Health Infoway published a blueprint that describes the standards and guidelines that compose an interoperable EHR. The Electronic Health Record Solution (EHRS) Blueprint serves as the “starting point and a common definition” for large scale health information sharing initiatives (Canada Health Infoway, Blueprint). The EHRS provides perspectives and a consolidated framework of business requirements, conceptual elements (i.e. information, processes, and system services), deployment models and potential applications. The EHRS also includes the solution architecture (the infostructure), which is tied to the 'Health Information Access Layer' (HIAL) functions (see Appendix G). This framework serves to provide guidance in planning, and establish the common elements shared between solutions. Infoway will contribute to funding an interoperable EHR that will “facilitate the sharing of data – across the continuum of care, across healthcare delivery organizations and across geographies”, built on a foundation of interoperability (Canada Health Infoway, EHRS Blueprint).

**Ministry of Health and Long-Term Care and eHealthOntario**

The Ministry of Health and Long-Term Care (MOHLTC) provides overall direction and leadership for the provincial health system, with a focus on planning and guiding resources for value to the health system. This includes establishing strategic direction, provincial priorities, and the associated legislation, standards, and funding (MOHLTC).

One branch of the MOHLTC is that of eHealthOntario (eHO). eHO evolved out of a merging of the eHealth Program branch, and the technically oriented Smart Systems for Health Agency (SSHA). eHO “will play the leading role in harnessing information technology and innovation to improve patient care, safety and access in support of the government’s health strategy. ...[and] will provide a single, harmonized, coherent province-wide eHealth Strategy and align it through a single point of accountability"
(eHealth Ontario). eHO identified a key risk to the strategy that physician EMR uptake has a moderate probability of being slower than expected. To this, eHO defined a mitigation tactic of providing “clinically valuable data and function/utility through EMRs” (eHealthOntario Strategy, 2009).

eHealthOntario's strategic plan for Ontario enables "clinician access to lab data through a variety of clinical desktops (e.g., OLIS clinical viewer, eCHN, physician EMRs)". This is a cornerstone of achieving the goals of the clinical priorities, and a comprehensive provincial EHR (eHealthOntario Strategy, 2009). One of the components that eHO provides is a portal that is intended to serve as “an integrated clinical view of health information” whereby “patients, families and providers will be able to access the clinical information they need, and are authorized to access, securely from any location at any time.” (eHealth Newsletter, 2008). The eHealth Portal will give greater access to clinical data such as OLIS and additional data repositories as they become available, and will develop a distribution model leveraging existing health services portals for clinicians. Portlet based services and a contextual framework, along with standards and processes, will enable integration with distribution partners sites such as OntarioMD, “within the short term” (eHealthOntario, 2009).

Shortly after eHO was established, it was revealed that millions of dollars were spent in untendered consultant contracts. This controversy has caused many initiatives to stagnate, and communication to seemingly halt while restructuring and re-planning are underway. In December 2009, eHealthOntario's Interim President and CEO, Rob Devitt presented that “government directives, the provincial Auditor General's report and appearances before Public Accounts have validated our measures to focus on strengthen [sic] our processes and organization for the past six months” (eHealthOntario, 2009). The priority has been to restore stability to the organization, and prioritize sound business best practices over schedule (eHealthOntario, 2009).

**Ontario Laboratory Information System**

One of the initiatives of eHO, and a key component of the eHealthOntario strategy is that of the Ontario Laboratory Information System (OLIS). The primary role of OLIS is to provide a means to transfer lab orders, such as from a family physician to a laboratory service provider, whether in the community or hospital (OHA, 2006). OLIS also stores orders and results in a repository. (Waterloo Smarter Health Seminar Series, 2006). OLIS makes results quickly available to improve health care quality and efficiency, minimize duplication, and reduce errors. (OLIS, 2009; SSHA, 2008) Dr. Murray Treloar was quoted, “As a patient moves from family physician to specialist to hospital to chronic care facility and back into the community, OLIS provides continuity for vital lab information along the continuum of care that benefits the patient and the system.” (SSHA, 2008)
In May 2010, eHealthOntario reported that the first phase of OLIS, the Foundation Adopter Program, is nearing completion, with four hospitals and three community laboratories currently loading their laboratory test results into the OLIS repository, representing a little over half of the test volumes in the province. The repository now includes over 350 million laboratory test results for approximately 5 million Ontarians. In 2010, the Ontario Agency for Health Protection and Promotion (OAHPP) will begin supplying public health lab results into OLIS, along with lab results from the LHINs in the greater Toronto area. An OLIS-EMR Integration pilot was also completed in March 2010, representing the first use of OLIS data by a clinician (eHealthOntario, 2010).

The OLIS Privacy Impact Assessment indicated that “clinics and physician offices will be able to access OLIS via Clinical Management Systems (CMS) or practice management systems that are connected to OLIS” (OLIS, 2008). The relationship is to be direct between OLIS and EMRs – “OLIS is supposed to be the interface for all lab data for EMRs.” (B. Forster, email communication, Sept 15, 2009). Beginning in 2009, OLIS intended to improve provider access to lab results by providing test reports to authorized healthcare providers, to “speed up the testing process for patients and reduce the need for repeat tests. OLIS will create a connection between the 40,000 authorized healthcare providers who order tests and use their results as well as the 650 community, hospital and public laboratories and specimen collection centres that perform tests” (eHealthOntario¹). Integration with electronic medical records was identified as one of the enabling features of OLIS - “The electronic transmission of lab results is a priority and an essential component of any clinical management system... Practitioners want tools to help them order the right test on the right person at the right time.” This functionality will translate to enhanced adoption of electronic patient records. (Waterloo Smarter Health Seminar Series, 2006).

Physician adoption targets remain under development, and the OLIS Roadmap RFP was to be released in early 2010 (eHealthOntario, 2009). In reality, there is little apparent progress within the local region of the Waterloo-Wellington Local Health Integration Network (WWLHIN). Over the past year, there has been little communicated at the hospital level about the high level plans for OLIS, with the any steps to implement OLIS locally being quietly halted. The current uncertainty of OLIS is exemplified by the lingering and indefinite replacement of the OLIS homepage with the following statement, “This section has been temporarily removed for updating” (OLIS Homepage).

**electronic Child Health Network (eCHN)**

The Electronic Child Health Network (eCHN) is Ontario's pediatric EHR, including laboratory results, doctor’s notes, radiology reports, and visit and personal information from Ontario hospitals. eCHN facilitates the electronic access of patient information by various providers through a repository-type

¹NOTE: accessed from [http://www.ehealthontario.on.ca/clients/labs.asp](http://www.ehealthontario.on.ca/clients/labs.asp), but is no longer available
model of an EHR, that conforms to provincial and federal EHR architectural standards. eCHN's vision is for a health information system that is interoperable, comprehensive, accessible, flexible, and securely controlled (eCHN, “About eCHN”). There has been conceptual and informal discussion with eCHN that they may enable collection of non-pediatric data in an effort to become the provincial electronic health record for patients of all ages, but there has been no recent activity to expand beyond being the province's pediatric EHR. Currently it is only hospitals that contribute data to eCHN, though there are plans to integrate private lab results, as well (OHA, 2006). eCHN brings a broad province-wide adoption of over 50 hospitals. eCHN maps clinical data to the LOINC and SNOMED CT standards (OHA, 2006), and normalizes lab results from disparate systems that may have varying reference ranges to enable comparability. At this time, the eCHN portal is limited to allow viewing and printing of results.

**OntarioMD**

OntarioMD is governed jointly by the Ontario Medical Association (OMA) and eHealthOntario, with a mandate to manage the implementation of the ePhysician Program (ITAC). OntarioMD manages a physician and patient portal (mydoctor.ca), provides large amounts of funding for physician EMR implementation and adoption, and supports physician offices with change management services. OntarioMD also develops specifications for certification of EMR solutions (known as the CMS Specifications), and works with EMR vendors to achieve standardization and certification. (H. Rodin, verbal communication, October 16, 2009).

OntarioMD is also in the pilot stages of implementing a Report Manager solution that leverages the compliance of all certified EMR solutions to the CMS specifications. This allows all EMRs to receive results via a common solution. The OntarioMD Report Manager is not a repository nor a viewer, but rather a broker, receiving and delivering results. With this service, laboratories (particularly hospital labs) will route HL7 message feeds to OntarioMD to be distributed to the specified recipients of each result. The integration strength of this solution is that EMR vendors and hospitals alike need only to develop a single interface with a single solution. This streamlining allows exchange of results with numerous physicians with various EMR solutions from several hospital sources (Martineau, 2010). In May 2010, OntarioMD announced the exchange of 2,500 reports per week with the local physicians from the hospital in Barrie, Ontario. While currently limited to medical and diagnostic imaging textual reports, inclusion of lab results is planned (H. Rodin, verbal communication, October 16, 2009). OntarioMD stated, “other electronic [hospital report managers] exist between Ontario hospitals and physician practices, but this is the first that can integrate any [healthcare clinical information system] with any physician practice in Ontario’s EMR Adoption Program – currently consisting of 4,000 enrolled physicians, growing to an estimated 8,700 in 2012” (OntarioMD, 2010).
Local Health Integration Networks

In Ontario, fourteen Local Health Integration Networks (LHINs) were established to take responsibility for regional health services (Ontario’s Local Health Integration Networks). LHINs, such as the local Waterloo-Wellington LHIN (WWLHIN), are responsible for coordinating health services across hospitals, community services, public health, physicians, laboratories, and provincial networks and programs (OHA, 2006), with some funding coordination as well. LHINs are well positioned to support and facilitate health care services and initiatives.

HealtheConnections

HealtheConnections (HeC) is a demonstration project to enhance chronic disease management and care coordination in the region. HeC receives the majority of funding from Infoway and eHO, and is managed under the eHealth division of the WWLHIN. HeC began in 2008 and is scheduled for completion in September, 2010. HeC is enabling the regional implementation of a personal health record (PHR) and the Medseek portal (branded as ClinicalConnects) which will provide family physicians in the demonstration project with access to hospital sourced information from across 2 LHINs (Waterloo-Wellington, and Hamilton-Niagara). This access comes in two forms — a portal for viewing clinical information, and a mechanism to download reports from the portal to be imported into the family physician EMR. The view-only portal has been implemented from a number of local hospitals for viewing by a number of FHT-based family physician offices using the PSS software, with planned expansion to other users (including hospital physicians, nurse practitioners, and home care and long term care providers). On the other hand, the requirements proved to be inadequately understood and more complex than expected for the preliminary EMR download design. Furthermore, the emphasis is on EMR download of medical transcription reports for one EMR solution, with intention but no communicated timeline for extension to lab results or other EMR solutions.

More details for each of the above organizations and their solutions are included in Appendix G.
Waterloo-Wellington Region

With a 2006 population of approximately 680,000, WWLHIN consists of three municipalities with a population of near 100,000 - Kitchener (204,668), Cambridge (120,371), Guelph (114,943), and Waterloo (97,475). The region is the fourth fastest growing region in the province. The region’s proportion of individuals under the age of 15 is greater than, and growing faster than, the provincial average, and the region’s proportion of seniors is lower than the provincial average (see Figure 1). In 2006, the region’s employment growth (particularly in Waterloo region) was faster than the province (2.0% vs. 1.6%) and the working population is disproportionately high for the province. The highest proportion of the population, and greater than the provincial average, is employed in manufacturing. With an unemployment rate in Wellington county that is 2% below the provincial rates, the region’s unemployment was significantly lower than the province overall across all age groups. Both the proportion of individuals working full-time and the incomes for males are higher than, and for females are lower than the provincial average. Household incomes are higher, and the proportion of low-income families are lower than Ontario overall (WWLHIN, Your Community in Profile).

In 2008, there were 575 family physicians practicing in WWLHIN, out of 1015 total physicians in the region. There are an average of 1,255 patients per family physician which is among the lowest of patients per family physician in southern Ontario. (OPHRDC, 2009) There are ten physician practice group in WWLHIN, ranging from an estimated two to upwards of 20 offices, with as few as one physician to as many as an estimated 20 physicians in each office. These physicians may exclusively practice in the community, or they may additionally provide services in hospitals – attending to their own family practice patients, providing emergency services in the hospital ER department, or providing part-time hospitalist services.

Environmental Scan Summary

The following summary represents the author's interpretation of the involvement of key organizations. A summary of the solutions they provide is presented in the Discussion section. Understanding the involved external stakeholders is necessary to appreciate the roles and interests in this focus of study.
Canada Health Infoway has the mandate to enable the development and adoption of health information systems and promote standards for interoperability through the EHRS blueprint and definition of the HIAL architecture. Along with the provincial ministry’s overall direction and leadership, eHealthOntario leading the provincial eHealth strategy, and OntarioMD supporting provincial ePhysician initiatives, the key stakeholders provide leadership in the direction for efforts and design. The specific solutions to achieve these directions are not absolutely defined, and the alignment needs to be confirmed between the intents of any large-scale solution and the visions and strategic plans of these stakeholders. The involvement of organizations at a provincial level will provide funding and serve to coordinate integral functions such as privacy/security, governance, and HIAL architecture elements. eHealthOntario’s efforts to refocus and rebuild has positioned the organization to once again play a key role in provincial initiatives, and OntarioMD has a successful track record and momentum to progress initiatives involving family physicians. LHINs may be able to coordinate regional efforts and advocate for provincial projects, but may be limited from driving implementation of solutions beyond a particular region.

**Context**

Key to a cooperative effort, such as the exchange of patient information, is an understanding of the relationships and interactions of the participants. The relationships between the individuals and organizations are described, and the roles of each are presented below, representing the author's interpretation.

At the simplest level, the relationships and functional interactions between health care providers are outlined in Figures 2 and 3.

![Figure 2: Participant Relationships in Larger Communities](image)

In contrast to larger communities where family physicians are more exclusively community-based, in smaller communities the family physician often plays a more integral role in the hospital. In these hospitals, family physicians take on the additional roles of an ER physician or attending physician of
admitted patients in lieu of hospitalists. As such, the utilization of hospital lab services is greater for family physicians in smaller communities.

Figure 3: Participant Relationships in Smaller Communities

The interactions of these participants may be represented in terms of their involvement in the patient's health care continuum. The family physician's involvement is continuous while the hospital physician is intermittent. Ordering and receiving results from private labs is predominantly by family physicians, while family physicians may also receive results ordered by the hospital physician from the hospital lab. Additional bi-directional communication may occur between the hospital and family physician.

Figure 4: Participant Interaction and Result Receipt

**Family Physicians**

Family physicians primarily provide community-based care, and act as the 'hub' of health care activities for their patients. Family physicians develop close relationships to local hospitals where they may have admitting privileges. Family physicians in the community will often establish mutually beneficial relationships with the private labs in the community. Family physician practices are evolving towards multi-disciplinary and alternatively funded models. These models include Family Health Teams (FHTs)
and Organizations (FHOs). (HealthForceOntario) These primary care groups, prevalent in WWLHIN, provide patients with expanded access to care, links to community organizations, and support for the navigation of the health care system. The multi-disciplinary nature of these groups emphasize health promotion and chronic disease management, and consolidate information technology services and integration (Ontario Ministry of Health and Long Term Care, 2004). Ontario's FHT/FHO models provide a means to coordinate administrative, infrastructure, implementation, and support requirements for family physician offices.

In the family physician office, electronic information solutions are gaining importance. Physician Clinical Management Systems (CMS) consist of 3 integrated components – an Electronic Medical Record (EMR), Scheduling, and Billing (Rodin & Chang, 2008). With almost 18,000 physicians in Ontario, over 10,500 are family physicians. A four year program ending in 2009 to fund EMRs for family physicians has supported EMR adoption for 3,000 family physicians (~ 30% of Ontario family physicians) and 400 groups of family physicians (B. Forster, email communication, September 14, 2009). In 2007 the EMR adoption rate for physicians was 26%, and in 2009 it had risen to 43%, in contrast to rates of 49% in Alberta and British Columbia, and at least 95% in Australia, the UK, and the Netherlands (OHQC, 2010). A new 3 year program is anticipated to fund an additional 5,000 family physicians and specialists. In the end, an estimated 50-60% of family physicians will have EMRs (B. Forster, email communication, September 14, 2009).

Laboratory Services

Laboratory Services in Ontario include the performance of over 200 million tests at a cost of $1 billion each year. Approximately 40,000 people are involved in providing lab services in doctors offices and at 377 patient service centres in the community, and testing at more than 200 hospital, community and public health laboratories (Waterloo Smarter Health Seminar Series, 2006).

Laboratory services in Ontario, within the scope of study, consist of both private and public labs. Public labs are primarily operated out of the publicly funded hospitals. See Appendix F for more details about the complex relationship between hospital labs, and with private labs.

Hospitals

Within the Waterloo-Wellington LHIN are a number of hospitals providing lab services. At an organizational level, a number of partnerships exist between the hospitals within the Waterloo-Wellington region (WWLHIN), as demonstrated in Figure 5. The Wellington Hospitals Information Network (WHIN) is an information technology-based partnership of four hospitals. WHIN includes Guelph General Hospital

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2 The term EMR will be used throughout this document to include EMR and CMS solutions.
Hospitals’ own laboratories provide lab testing services for hospital registered patients, such as inpatients and emergency patients. These tests are ordered by ER physicians, specialists, and hospitalists. Providing lab testing when referred by community providers is often not within the scope of hospital laboratory services as outpatient lab services are an expense for the hospitals, with no opportunity to recoup the costs (Ho, 1996; Lifelabs, Collaborates). Strategic alliances exist between hospitals and private labs in order to improve operational efficiencies and reduce duplication, in order for lab services to remain cost effective and affordable (Ho, 1996). The interviewed physicians identified that 10-20% of the lab results received by a family physician are received from hospitals.

**Private Labs**

Private laboratories provide about half of lab testing in Ontario (Richardson, 1999) and receive payment from the public health care system to provide laboratory services. The private labs may partner with hospitals to provide lab services in the hospital environment, but primarily focus on outpatient lab resulting services, with a greater utilization for chronic disease management, monitoring, and follow-up testing (such as cholesterol, thyroid, and pregnancy testing). There are 3 dominant private laboratory service providers in Ontario – CML Healthcare (CML) and LifeLabs are prevalent in the WWLHIN, and Gamma-Dynacare exists elsewhere in the province.

Each of the three primary private laboratory service providers have been contributing to OLIS since 2007/2008 (OLIS Fundamentals), and has individual mechanisms to provide results electronically to family physicians. The family physicians interviewed identified that 80-90% of the results a family physician receives are from the private labs. On average, for a single family physician, 90-95% of these results are received from one of two private labs. A family physician's reliance on a single lab depends on
a number of factors – including geographic presence, the interface(s) that have been purchased, and the convenience of the lab for the family physician and their patients.

**Summary of Relationships**

For each family physician, multiple private labs and hospitals may be involved in sending results, each with disparate capabilities. Likewise, each lab service provider must send results to many family physicians, many of whom have disparate capabilities of receiving results.

![Figure 6: Result Reporting Relationships (Family Physician Perspective)](image)

![Figure 7: Result Reporting Relationships (Lab Perspective)](image)
Objectives

**Research Questions**

The primary question to be addressed in this research is:

| In the current environment of southwestern Ontario, how can lab service providers best provide electronic laboratory results to family physician offices, such that the data can be efficiently and effectively received, integrated, and interpreted? |

The answer to this question depends upon understanding of several secondary questions, that will be addressed in this document:

1. From the published literature, what is the current knowledge on this subject?
2. How does the optimal communication of lab results from labs to family physicians support the office-based processes?
3. What are the requirements for this communication to occur?
4. What are the relevant and available standards to support lab result sharing between health care providers, and how are these standards currently being used?
5. What is the envisioned future state, and what strategies will enable its achievement?

Each of these questions will be specifically addressed in the following sections of this document.
Methodology

This study is qualitative in nature, so as to investigate how, why, and with what features or characteristics result sharing does, and is to, occur. This type of research is well suited for new topics such as this, where insight or theories may be lacking or inadequate (Giacomini, 2000). Glaser's Grounded Theory was considered as the methodology for this study. It would have been an appropriate method due to the need to collect data from multiple sources, including a literature review of scientific and industry publications, consultations with service providers, and interviews with recipients. The constant comparative method would integrate this information into future searches and inquiries by clarifying, confirming, and expanding on concepts, extracting key points and grouping into themes. From these themes, an analysis could form through frameworks (including figures and tables) that describe the interactions, requirements, components, models, and solutions. Though the methodology that was used may be similar to Glaser's Grounded Theory approach in the aforementioned ways, the methodology that was employed diverged from Glaser's approach in several significant aspects. This study is descriptive, and oriented towards information systems, as opposed to a behaviorally-oriented study. This research is time sensitive and place specific whereas Glaser's approach is traditionally not. Finally, the various sources of data collection occurred in series (that is, first the literature review, then the consultations, and finally the interviews) rather than in parallel as with Grounded Theory methodologies where the literature review occurs in conjunction with key stakeholder interviews. As such, the methodology may be described as an unstructured multi-source qualitative study. It is interpretivist due to its determination and interpretation of the subjective and time-sensitive interactions/relationships between competing situations (standards, stakeholders, systems, and solutions), and may be described as a field study of a particular jurisdiction at a point of time (Chen, 2004). Limitations are described later in this document.

Literature Review

The industry and scientific literature were reviewed to understand the current state and published knowledge of result sharing, in order to encompass both the technical and clinical contexts of lab result sharing.

Scientific literature searches using multi-database search tools were completed, augmented by more detailed and targeted searches of the MEDLINE and CINAHL databases. These databases were chosen because of the breadth, comprehensiveness, and applicability of their content. Literature since 1990 was selected to encompass the methods in current use. A search of the industry literature was also performed, through a series of searches using the Google search engine. A targeted search revealed additional relevant articles from specific websites, including but not limited to the official websites of LOINC, OLIS, OntarioMD, Infoway, eHealthOntario, HL7, and various ‘blogs’. These blogs may present
as opinion editorials or interviews that provide incipient analysis and commentary from individuals (such as chief information officers and physicians) with front-line exposure to interoperability, electronic records, and information management. Articles were included if full-text was available or accessible, and the article was written in English. Content was abstracted from the articles, and quotations were extracted, synthesizing findings into common themes.

The searches were based on terms within three concepts – the roles of family physician and labs, the electronic record systems, and the purpose, nature, and value of lab result sharing. The terms were searched in various combinations.

<table>
<thead>
<tr>
<th>Roles</th>
<th>Systems</th>
<th>Purpose/Values</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physician</td>
<td>Information management</td>
<td>Lab results/reports</td>
</tr>
<tr>
<td>Primary Care</td>
<td>Information systems</td>
<td>Exchange, Sharing, Delivery, Distribution</td>
</tr>
<tr>
<td>General Practice</td>
<td>Clinical information management</td>
<td>Integration, Interface</td>
</tr>
<tr>
<td>Family Practice</td>
<td>Electronic health record (EHR)</td>
<td>Data Interchange</td>
</tr>
<tr>
<td>Family Medicine</td>
<td>Electronic medical record (EMR)</td>
<td>Data transmission systems</td>
</tr>
<tr>
<td>Hospital</td>
<td>Electronic patient records (EPR)</td>
<td>Electronic data processing</td>
</tr>
<tr>
<td>Laboratory</td>
<td>Clinical management system</td>
<td>Clinical benefit</td>
</tr>
<tr>
<td>Hospital care</td>
<td>Medical records</td>
<td>Business value</td>
</tr>
<tr>
<td>Hospital &amp; Community</td>
<td>Computer architecture</td>
<td>Confidential Communications</td>
</tr>
<tr>
<td></td>
<td>Electronic records</td>
<td>Electronic Data Interchange</td>
</tr>
<tr>
<td></td>
<td>Electronic systems</td>
<td>Health Information Exchange</td>
</tr>
<tr>
<td></td>
<td>Telecommunication systems</td>
<td>Facsimile Transmission</td>
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<td></td>
<td>Information Technology</td>
<td>Electronic messaging networks</td>
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<tr>
<td></td>
<td>Information retrieval systems</td>
<td>Medical Care</td>
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<tr>
<td></td>
<td>Peer-To-Peer Architecture</td>
<td>Technological Innovations</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Health Services Administration</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Medical informatics</td>
</tr>
</tbody>
</table>

Table 1: Literature Review Search Terms

The literature review took an exploratory and ‘iterative approach’ – whereby a series of progressive, and more detailed searches were performed to pilot test search terms, explore various sources, and build a database of articles while drilling deeper into the study focus. The review identified relevant background knowledge, and provided an overview and interpretation at a particular point of time, built on the specific context of the study. A manual review of bibliographies and related articles was completed, as applicable, to further identify articles.

As a result of employing an exploratory and iterative approach, the literature review was not formally structured to be reproducible and comprehensive. This method was employed due to the author's initial unfamiliarity with the laboratory-related topic, and due to the variability in the usage of terms within the literature. For example, there are numerous potentially synonymous terms for electronic records, yet the usage of the different terms may be exclusive in various contexts. To inclusively search the terms that are
used variably resulted in a high number of inappropriate results, but to limit the search would exclude appropriate results. In taking this approach, the author conceded that the literature review was not a comprehensive review, yet maintained particular applicability to the topic according to the author - a limitation acknowledged as a potential source of bias. Additional notable limitations are described later.

Consultations

Consultations were performed in the early stages of research, prior to the ethics approval process. The intention was to explore issues related to the context and environment of study. Individuals were contacted directly, with unstructured dialogue in person, by phone, or over email. Consultations occurred with two private labs (Lifelabs and CML), two hospital lab systems experts (a systems analyst and a systems team lead), two lab result exchange solution providers (OntarioMD Report Manager and Interbit), one EMR vendor (Practice Solutions), and one additional Alberta physician who provided an alternative regional perspective. These consultations served to define the family physician interview questions and establish baseline knowledge of services, issues, opportunities, and existing methods.

Interviews

For the interviews, ethics approval was obtained from the University of Victoria Research Ethics Board to interview family physicians. Three family physician groups and two independent family physicians were invited to provide additional insight and understanding from a front-line clinical and business perspective. Of the eleven candidate participants contacted for interviews, nine individuals (eight family physicians and one family physician office staff) provided consent and participated in interviews (see Appendix B for more details). Interviews were conducted in person, in the interviewee’s office during regular work hours. All interviewees were asked the same foundational questions (see Appendix B), but variable follow-up questions were asked to expand on comments that were made. The interviews were not recorded, but interview notes were taken at the time of the interview, and within two days expanded to include details of all responses. These responses were then consolidated, grouped, and integrated as applicable into the local context, current state, requirements, and discussion sections of this paper. All content that proved relevant was included in the results below. Interview findings were not presented back to the interviewees (except in one case, upon request of the interviewee) in order to validate the interpretation after the interview had concluded.
<table>
<thead>
<tr>
<th>Major Group</th>
<th>Sub-Group</th>
<th>Invited (request for interviews)</th>
<th>Identified (selected to participate)</th>
<th>Interviewed (detailed discussion, with consent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Guelph FHT</td>
<td>Speed River FHO; Royal City FHO</td>
<td>1 lead</td>
<td>4 family physicians</td>
<td>4 family physicians</td>
</tr>
<tr>
<td>Phoenix FHO</td>
<td>1 lead</td>
<td>4 family physicians, 1 staff</td>
<td>3 family physicians, 1 staff</td>
<td></td>
</tr>
<tr>
<td>Upper Grand</td>
<td>2 family physicians</td>
<td>No response</td>
<td>No response</td>
<td></td>
</tr>
<tr>
<td>FHT</td>
<td>Ontario</td>
<td>1 family physician</td>
<td>1 family physician</td>
<td></td>
</tr>
<tr>
<td>Independent</td>
<td>Alberta</td>
<td>1 family physician</td>
<td>1 family physician</td>
<td></td>
</tr>
<tr>
<td>TOTAL</td>
<td>3 major groups, plus independents</td>
<td>6 family physicians or leads</td>
<td>10 family physicians, 1 staff</td>
<td>8 family physicians, 1 staff</td>
</tr>
</tbody>
</table>

Table 2: Interviews

These interviews demonstrated relevance by the selection of direct recipients of lab results from both hospital and private lab sources. Many of the family physicians had close affiliation with the hospital (due to their credentialing, or the ability to order hospital services, or admit or refer patients to the hospital). The interviewed family physicians had some diversity in their roles, with inclusion of one family physician who was the chief of staff and a regular attending of their own patients in hospital, one part-time hospitalist, and one uncredentialed family physician. The interviews were rich and comprehensive with depth of discussion and breadth of coverage, demonstrated by the identification of unique concepts. The formation of common themes suggested corroboration between the interviewees. There was strong representation from a single region (within the city of Guelph), suggesting local saturation. The limitations are notable, and described in a later section.
Results

Literature Review

From the published literature, what is the current knowledge on this subject?

Through the review of the literature, this section will show that communication is integral to modern healthcare, and there is a high need for information exchange, particularly for lab results. The current processes of exchanging these lab results are shown to be inadequate, and that improvements are required. The close relationship between improved exchange of lab results and the adoption of family physician office electronic records is presented. When these electronic records can receive lab results, an integrated presentation is enabled that is greater than solutions that only offer view-only access to results. Achieving this integration is a critical success factor for the electronic health record journey. Numerous benefits that have been observed and are expected from interoperability will be detailed, including improved efficiency, enhanced functionality, reduced system utilization, stronger relationships with the labs, and improved patient safety. The actual cost benefit of this integration will be shown to be unclear.

As with many health care relationships, the communication and sharing of information is critical to support the ongoing continuity of the patient's care. Hospitalists, ER physicians, and specialists may communicate with the family physician about the care the patient received in the hospital, and the patient's discharge status. In any hospital, there is also opportunity for the hospital laboratory to communicate directly with the family physician by sharing results/reports from the care provided in hospital. Farquhar (2005) described the information sharing that occurs between the hospital and the family physician for patients receiving treatment for cancer, but the same principles may apply regardless of the health condition. Farquhar identified opportunities in three particular phases of care -

1. Pre-diagnostic and diagnostic stage: the need for prompt information regarding the results of tests and diagnoses, and clearer guidance on the use of tests and fast-track referrals
2. Active treatment phase: family physicians can lose touch with their patients, and effective communication is needed to provide moral support and crisis management
3. Withdrawal of treatment and shift in focus back to the community: family physicians need information to "enable them to pick up the baton of care." (Farquhar, 2005)

As treatment shifts from the community to the hospital, and back to the community, communication is essential. Brookstone noted that, "the work that health-care providers do all the time is about exchanging information" (Leslie, 2010). This quantity of information being exchanged is complicated by the number of people involved. A clinician, quoted by Infoway, stated, "There are so many people involved in care that
communication is a large challenge. We need information that is more easily shared among providers. It saves time and helps us deliver quality care to our patients.” (Infoway)

Supporting coordination of care between health care providing organizations (such as hospitals) and family physicians is well appreciated. Furthermore, the lab services, and the provision of results are recognized as an essential part of what hospitals offer the family physician community (Park, 2004), and are one of the top information elements desired by family physicians (Lang, 2006). In spite of the relevance of these services, there lacks an awareness of the specific information needs of family physicians (Farquhar, 2005). As the electronic exchange of health information between family physicians, their practices, and hospitals is in its infancy, there is much to learn about the needs, expectations, and motivations of these participants (Rudin, 2009).

Lab results are particularly valuable to family physicians. Lab results constitute about 70 per cent of an electronic health record, while 80 per cent of all medical decisions are based on lab information (SSHA, 2008). Furthermore, public demand for lab testing grows by more than 10% annually due to greater focus on early detection and improvement monitoring and disease management. (LifeLabs, Funding Agreement). Results of laboratory tests were one of the pieces of information identified as necessary for providing adequate follow-up care by family physicians, yet 38% of discharge summaries were missing diagnostic test results, and 65% of discharge summaries were missing pending tests. (Kripalani, 2007) In one study, 41% of patients had test results pending on the day they were discharged from hospital, with nearly 10% of these results identified as potentially actionable, some requiring urgent attention. In the same review, another study found that 75% of patients had a lab report that was made available after the patient was discharged, with 15% of the reports containing an abnormal result. The results were not known to 60% of hospital-based physicians and family physicians, and if they had known of the results, the patient’s diagnoses or treatment was expected to have differed in 1%-2% of cases (Kripalani, 2007). There is great value for family physicians to be aware of these results when they see the patient in the community.

Oftentimes, primary care in the community must continue with delayed, missing, or incomplete information when patients are discharged from the hospital (Lang, 2006). This causes care to be disorganized, inefficient, and patients to feel their times is wasted, and places patients at risk of oversights and mistakes (OHQC, 2009). In addition to the impediments to patient safety, continuity of care, and patient and provider satisfaction, resource use is also impacted (Kripalani, 2007). When traditionally the hospital care details are mailed to the family physician, the information still needs to be transferred into the EMR, with adverse implications for the quality of information, due to delay and process failures (Kljakovic, 2004).
The results of a recent survey in Ontario found that 86% of hospital emergency department chiefs felt that communication improvements were needed with family physicians (Lang, 2006), and in another survey 77% of respondents felt that there were problems, primarily slowness, with the flow of information from the hospital to primary care (and only 16% denied that problems existed). Disappointingly, only 25% of respondents were optimistic that it could be improved. A few felt that phone or fax communication could make a difference, while the majority look to electronic transfer of information (Kljakovic, 2004).

Intricately connected to the roles of each participant and the access to information is the use and capabilities of the family physicians’ information system. Family physicians in the community environment with an office EMR depend heavily upon the EMR for many aspects of their clinical services – including administrative and clinical uses. The Canadian Medical Association (CMA) found in the 2007 National Physician Survey (NPS) that only 28.2% of Ontario family physicians have electronic records to enter and retrieve clinical patient notes, and 26% of Ontario family physicians use electronic records. (CMA, 2007) The limited adoption of EMRs was identified by OHQC (2009) as “one of the biggest roadblocks to a more efficient system with high-quality care”.

Family physicians with EMRs require integrated lab results as the EMR is the primary information source for their care provision. The EMR captures the patient health care information across multiple care episodes and from numerous care providers, in many cases through the lifetime longitudinal care of the patient (Farquhar, 2005). But traditionally, these details are sourced within separate organizational information systems, requiring family physicians to access more than one system. For the family physician to cross-reference results in one system with findings in another, they must do so simultaneously which is inefficient and increases the risk of error (Tcheremenska, 2009). Even within the family physician’s office, parts of records are often still stored non-electronically. It is clear that family physicians want a single system for patient information to support the majority of care they provide (Carefx, 2009; Tcheremenska, 2009).

In 1994, McLure (1994) outlined some of the lab result sharing options that were present at that time. Fifteen years later, little has changed. Mail, courier, and telephone delivery of results have been the primary traditional approach (Grossman, 2006). These methods face limitations related to timeliness and difficulty in consistently being able to deliver the results to the family physician (whether due to wrong numbers, misfiling, lost reports, or delays in mailing). Facsimile machines were proposed as a new option, and are still being extensively used today, with the advantages of eliminating transcription errors by the receiver when receiving results by phone, and improved timeliness relative to mailings. Some of the solutions McLure proposed weren't adopted until many years later. For example, the installation of a
laboratory information system terminal in the family physician office, or software that allows the family physician to connect to the laboratory information system are considered still relatively new today.

The British Columbia Medical Association (BCMA) published a position statement 'Achieving Interoperability in the EMR Context'. In a related podcast, Brookstone and Tcheremenska (2009) discussed that unintegrated clinical viewers are not used as they are too cumbersome to login and access information, the format of information is not useful, so paper/fax solutions continue to be preferred. Viewer solutions also require error-prone transcription or effort-dependent methods, such as printing and scanning or screen captures in order to copy the content into the EMR. View-only solutions may offer "some limited value for paper-based practices but are an obsolete way of transferring information in an EMR environment". These view solutions “are not practical and do not support care quality and safety” and may actually “delay the realization of a fully-interoperable EMR.” (BCMA, 2009). The BCMA’s prescribed ideal future state is for each care provider to have all the information in their EMR in a useful format, available at the point of care. Furthermore, there are medico-legal requirements to document the information that is used to make a decision, so merely viewing results is inadequate and information needs to be stored in the EMR (Tcheremenska, 2009). It may well be that both data transfer and access methods of communication must be supported (Ruotsalainen, 2004).

An interoperable system allows for prompt and reliable automatic transfer of data directly into the EMR (Kljakovic, 2004; BCMA, 2009). Family physicians indicate that this electronic transmission of lab results is a priority and an essential component of any family physician office electronic record (Campbell & Knight, 2005). Eight years ago, 85.4% of EMR users and even 76.2% of EMR non-users agreed with the statement: “I am interested in an EMR that would connect all physician practices, labs, x-ray facilities, and hospitals in my area securely for the exchange of patient data” (Loomis, 2002). In spite of this, the number of family physicians with interfaces is still quite low. Only 27% of family physicians in Ontario have an electronic interface to external laboratory or diagnostic imaging providers. Electronic interfaces to other external systems (such as hospital systems) are used by only 16% of physicians (CMA, 2007). These low rates may be related to low EMR adoption rates, as only 10% of Ontario physicians use electronic records, and 30% use a combination of paper and electronic records. (CMA, 2007). Brookstone stated, “Once you get systems enabled, the next critical piece is data exchange and allowing the systems to intra-operate with one another” (Leslie, 2010). In fact, the relationship also goes the other way -- that is, improved exchange of lab results may provide incentives for new EMR adoption and use. Brookstone stated, " as soon as there is the ability to exchange information, people buy EMR systems," leading to significant uptake (Leslie, 2010).
Interoperability between EMRs and other information systems is necessary for the growth of the Canadian e-Health environment (Rodin & Chang, 2008), and the lack of information exchange from the hospitals has been cited as a concern in the Canadian health care system (Lang, 2006). The anecdotal evidence from a connectivity project in southwestern Ontario claimed that a critical success factor was the extra effort made to connect the hospital system to that of the physicians. “Without this connectivity the time savings would have been much less. The physicians would likely claim that receiving lab and imaging results electronically — from proprietary sources like [private labs] as well as the local hospital — has been the most advantageous feature of the project.” (Gamble, 2004)

Populating the family physician EMR with their patients’ lab results will reduce the effort for the family physician to adjust their mindset when toggling between systems and record formats, allowing them to be more effective at absorbing and using information (Tcheremenska, 2009), and interact more effectively and efficiently with the patient (Miller, 2004). As Dr. Thorogood stated through OntarioMD, “I would say the biggest benefit is the increased efficiency in how I manage my lab data and reports which has translated into more time for my patients.” (OntarioMD) Furthermore, patient education using optimal presentation of electronic data can have a miraculous impact on compliance with treatment (Tcheremenska, 2009). In preliminary studies of time savings, OntarioMD has found that traditional processes can require between 15 and 30 hours per week per family physician for an office to manage reports and results. Interoperability will dramatically reduce this amount of time and cost for managing incoming results. (H. Rodin, verbal communication, October 16, 2009). A survey of 150 health information exchanges in the US in 2009 concluded that “health information exchange has had a positive impact on family physician practices allowing them to become more efficient without disrupting care” (eHI, 2009). This may also translate to improved quality of practice life for health care providers (i.e. less trouble finding information, and getting home sooner at the end of the day).

**Value Categories for Interoperability**

1. **Enhanced Care Quality**
   - Information available when needed allows to provide better care during a single visit
   - Advanced EMR features can be used (such as clinical decision support and population health analysis)
   - Improved Chronic Disease Management

2. **Improved Patient safety**
   - Right information into right chart
   - Fewer transcription errors

3. **Respect of medico-legal obligations**

4. **Containment of costs**
   - Reduced repeated testing (lab and imaging)
   - Reduced unnecessary visits
   - Decreased paper record handling

| Table 3: Value in Achieving Interoperability (BCMA, 2009) |
Information exchange may improve chronic care and prevention guideline compliance, and improve care outcomes to patients (eHI, 2009).

Tests are reordered at a rate of 10% when communication of lab results is lacking (McClure, 1994). Therefore, delivering results electronically into the family physician EMR could reduce the costs and patient impact/risk of duplicate testing (AHIC, 2006). An American health system CIO presented an alternative viewpoint – though delivering results electronically certainly can reduce duplicate testing through instant access to lab results from other sources, just because they have access does not prevent the ordering. He went on to say, “I have overheard other organizations leaders suggest that they should not trust results from other providers and that re-ordering expensive tests is the best care.” (Weider, 2010).

Similarly, when results are available within a longitudinal EMR, physicians would alter their ordering practices in order to gain access to the integrated viewing of lab results within the patient record, due to the reduced effort that is required, and improved ease of use (Jones, 2005). This preferential access based on the availability of results provides incentives for lab service providers (particularly private labs) to enhance relationships with physicians on a foundation of result exchange (Park, 2004). Where strong business relationships exist, there is a greater demand for interoperability of results, and vice versa. This may support the findings of the 2009 survey of health information exchanges in the US, that concluded that the greatest return on investment (ROI) may exist for physician practices and the hospitals that provide the health information exchange (eHI, 2009). Differences between Canadian and American health care make cost-savings comparisons difficult, so the actual ROI in Canada may not be the same.

A cost/value study in 2005 evaluated healthcare information exchange and interoperability of paper/phone, fax, and unencoded and encoded electronic peer-to-peer solutions. It studied national initiatives specific to the US environment and funding formulas. It concluded that “the clinical payoff in improved patient safety and quality of care could dwarf the financial benefits” (Walker, 2005). Unfortunately, it has also not been demonstrated that providing lab results to family physicians translates to direct value for the hospital. Walker explained, “electronic exchange of clinical data between organizations is nascent, and few data exist about the clinical impact it would bring. It will be important for future inquiries to explore such impact in depth” (Walker, 2005). The evidence is weak for information exchange to improve organizational efficiency, practitioner performance, or “indeed any clinical patient outcome” (Car, 2008). No results were found with the employed literature review methodology to support or disprove the lack of quantitative evidence for the business and clinical process improvements that may be associated with lab result sharing. Lang found that electronic information sharing between a hospital emergency department and a primary care network failed to reduce workload on either side, and in fact,
the cost of doing so is not recoverable through either reduced lengths of stay, admissions or return visits, or reduced duplication of tests and consultations (Lang, 2006). To achieve optimal information exchange through seamless transfer and access to data across all settings, cost-savings may be realized in the longer run, but “will inevitably require considerable upfront investment in hardware and software capabilities.” (Car, 2008) One key to enabling the sharing of information is the established partnership and joint prioritization and effort across organizations, and even across jurisdictional borders (Ruotsalainen, 2004). Grossman weighed in, “from the hospital’s perspective... the benefits of a RHIO accrue to the community; the hospital doesn’t necessarily benefit from those investments.” (Grossman, 2006)

McCarter highlighted that shared solutions focus on developing a technology that is “capable of serving the widest range of users”, with greater consistency and improved access to data (McCarter, 2009). But these joint initiatives and the interfaces that connect to multiple systems are not simple – as was cautioned, “don’t under-estimate the complexity of implementing new interfaces - particularly first-time implementations for the vendor” (King, 2003). McCarter described the migration from decentralized to shared solutions as “one of the most critical issues … to be resolved early” (McCarter, 2009). With shared solutions comes unique security challenges. Ruotsalainen (2004) identified that “the major security barriers are the lack of: a harmonised legal and ethical framework; a harmonised policy on trust, privacy and confidentiality; security services for trans-border communication; [and] common security standards.”

Looking to learn from the efforts of other regions, in the region of London, Ontario, the hospitals have identified the automated feed from the hospitals’ Cerner system to the physician offices’ systems “as their highest strategic priority” (SWLHIN). As a result, the Southwest LHIN (specifically Grey Bruce Health Services, with expansion to the Thames Valley Hospital Planning Partnership) is leading a project, branded SPIRE, to implement direct interfaces with 50-90 physician office EMRs for the exchange of radiology reports, lab results, and clinical notes (SWLHIN eHealth Webcast; SWLHIN Backgrounder).

In the United States, the relationship between family physicians and the labs are very different than in Canada, but delivery of results is similarly a key focus. The eHealth Initiative (eHI) has been monitoring and supporting the progress of Health Information Exchanges (HIEs). On a nationwide scale in the US, the Nationwide Health Information Network (NHIN) is being developed (SUN Microsystems, 2009). HIEs are often enabled and supported through Regional Health Information Organizations (RHIOs), and are characterized by governance by a broad set of stakeholders, common technical and policy principles and standards, a standards-based and interoperability-focused technical infrastructure, a sustainable model, and performance measurement (eHI, 2005). In 2009, almost 200 HIE initiatives were identified. The
most common service of HIEs was results delivery (i.e. lab results, diagnostic study reports) with the number of laboratory exchanges almost doubling since 2008, followed by access to electronic health records. Hospitals and family physicians are the top two participants in HIEs (eHI, 2009). Of 150 HIEs that were studied, only 57 (38%) are reportedly operational, though this is a 40% increase over 2008. Almost 60% of the operational HIEs required 2-3 years to become operational, and 18% required four or more years, while only 20% required just one year or less (eHI, 2009). A survey in the US of HIE initiatives found that it cost 24 HIEs less than $200,000 to start, 13 HIEs reported start-up costs of between $200,000-$500,000, 10 HIEs required $500,000-$1 million to implement, and 12 reported costs of $1-$2 million, 18 of $2-$5 million, and 17 required more than $5 million. (eHI, 2009). Grossman (2006) identified that clinical data exchange solutions may fail when there is not agreement on who should cover the costs. Grossman proposed a cost recovery model based on “collecting per transaction payments from subscribers who may send or receive data”, that may be more viable when efficiency gains have not already been realized by other electronic solutions (Grossman, 2006). While the efforts to distribute lab results to family physicians is similar between Ontario and the US, Adler-Milstein et al. (2009) described the foundational difference: “in countries with more socialized approaches to health care, those pursuing HIE treat it as a public good. In contrast, the United States has pursued a market-based approach in which RHIOs are expected to find stakeholders willing to pay for the value they create.” As an example of the costs of a market-based approach, the 2009 survey of HIEs found that of the 57 operational initiatives, only 18 required physicians to pay for use of the service (three had an annual fee of $100 or less, nine HIEs charged $101-$500 per year, two required $501-$1000, and one cost the physician over $1000), with 32 allowing free of charge access. (eHI, 2009). A comparable survey of HIEs in Canada was not identified in the literature review. Another survey from 2009 identified a number of barriers to HIE, including: lack of funding, concerns about privacy/security, legal or regulatory changes, higher costs than expected, lack of a clear business model, stakeholder concerns about competitiveness, and technical architecture or infrastructure challenges. These barriers may account in part for a calculated 20% failure rate of HIEs (Adler-Milstein, 2009). As a result, it is not within scope of this document to comprehensively describe and analyze the state of HIE initiatives in the US, as the drivers and models may be very different even though the technology and clinical/business value may be similar. Rather, the prevalence, time and costs required, barriers, and the lessons learned through these initiatives have been highlighted.

**Standards**

| What are the relevant and available standards to support lab result sharing between health care providers, and how are these standards currently being used? |

To seamlessly exchange information across the continuum of care settings there must be standard coding structures that enable the communication, storage, and retrieval of information (Car, 2008). In the
absence of standards, proprietary interfaces become more common, and this “presents a big problem” (Rodin & Chang, 2008). Brookstone places the responsibility at a national level to define which standard specifications must be used, stating, “we need to push Canada Health Infoway to improve the prioritization of this. What they call POSR—or Physician Office System Requirements—is about number 50 on their priority list from their technical standards perspective. This needs to be number one or two—especially if they are going out and asking for hundreds of millions of dollars from the federal government to enable information exchange” (Leslie, 2010). A coordinated strategy at a national level (such as with Infoway) brings value to both EMR vendors and provincial organizations such as eHealthOntario and OntarioMD. Brookstone warned that, “it is critical that we do this now. If we don’t, the provinces are going to be forced to go along their own pathways. They will out of necessity define the messaging specs they need in order to get the work done. And we’re going to end up with vendors now having to support five different types of messages across the country” (Leslie, 2010).

**Messaging Standards**

PDF documents provide a limited means to standardize the exchange of information, but these documents lack the structured messaging that is commonly required in healthcare. HL7 (v2 and v3 CDA) messaging, and the locally relevant standard defined within the OntarioMD CMS specifications, carry particular relevance and potential in Ontario.

PDF (Portable Document Format) documents provide a means of encapsulating formatted text and images in a hardware, software, and operating system independent format. PDF enables convenient sharing of reports, with aesthetic consistency to traditional paper/fax reports. PDF documents are currently used within WHIN to send hospital reports (medical transcription and radiology reports) to physicians to be manually imported into the EMR. Since basic PDF files do not support encoding, lab results delivered in PDF files cannot be parsed. As a result, there is limited ability to integrate data transmitted within a PDF into the EMR, thus failing to support advanced EMR functionality, such as graphing/trending and reminders/alerts. Many offices opt out of receiving lab results via PDF.

To address the requirement of encoded lab results, HL7 messaging is a common solution. HL7 standards are designed to support the exchange and integration of electronic health information. HL7v2 was designed specifically for hospital information systems and workflows, and has expanded into use with laboratory information systems and physician EMRs. HL7v2 consists of delimited text strings, and supports standardized nomenclatures, such as SNOMED CT, LOINC, and ICD-9 and ICD-10. In the Wellington Hospitals Information Network, development is in progress for use of HL7v2 for laboratory results for the eCHN pediatric EHR. Unfortunately, variations from the standard specifications are
common, and limit the capacity for a truly standard HL7v2 feed to work for all information systems. The prevalence of HL7 messaging does not necessarily suggest that HL7 messaging is the best approach. Sanders stated, “the unfortunate downside to HL7 is its fragility—errors are frequent and occur easily—leading to mismatched patient records, delayed delivery of vital results, and lost delivery of the same” (Sanders, 2010).

HL7v3 provides a dramatically new standard to evolve messaging (in the HL7v3 message standards), but also to specifically exchange documents (through the HL7 CDA standard). The CDA (Clinical Document Architecture) provides a means to exchange clinical documents between health care systems and providers. It defines the structure and semantics of a complete information object (a ‘document’) that can include text, images, sounds, and other multimedia content (Dolin, 2006). CDA uses Extensible Markup Language (XML) as the syntax foundation, but also enables integration of non-XML content (HL7 FAQ). Various types of clinical information are supported, such as history and physical or discharge summaries, progress notes, diagnostic imaging reports, and lab reports (Dolin, 2006; HL7 Library). Canada Health Infoway’s Blueprint (2006) states that “HL7 v3.0 facilitates the rigor and robustness required for true standardization of messages for system-to-system communications”. The primary use of CDA is for information exchange across organizations, especially between office electronic medical record (EMR) systems and hospital information systems (Dolin, 2006). Germany was implementing an XML-based method of communication between physician offices and hospitals (called SCIPHOX) (HL7 CDA Brief). In the USA, the Mayo Clinic is recognized as a leader in CDA adoption, with expected delivery of up to 50,000 CDA documents per week. Mayo reports that CDA is a "strategic investment in information that will increase in value over time and which can be reused in multiple applications" (HL7 FAQ). HL7v3 will be supported by OLIS “when it is sufficiently defined and accepted in the laboratory domain by the HL7 standards organization” (OHA, 2006). At this time, there is no apparent adoption or current capacity within WWLHIN to send or receive HL7v3 CDA messages. HL7v3 and CDA may hold future promise as an optimal standard for clinical document exchange, including that of lab results.

OntarioMD’s CMS Specification, to which all EMR solutions in Ontario must comply to qualify for funding, defines standards for data portability “to serve as a building block towards interoperability” (Rodin & Chang, 2008). OntarioMD’s interoperability strategy consists of three components – to provide data portability among certified EMRs, to establish a standard Core Data Set (including lab results and other reports) for data portability, and to use this Core Data Set as the basis for messaging between EMRs and the broader eHealth environment (Rodin & Chang, 2008). Data Portability Requirements define an XML-based schema that details the structure/composition of the messages for exchange (OntarioMD, CMS 3.02). The Data Portability Requirements are the foundation of OntarioMD’s Report Manager solution, enabling exchange of reports between hospitals and physician EMRs.
Meta-data Standards

Meta-data standards allow the comparable content of the documents/messages to be interpreted, classified, or coded for tracking or trending - even when local terminologies may vary. LOINC is a standard with the greatest relevance to lab result sharing, but SNOMED CT may also carry some future value.

The purpose of the Logical Observation Identifiers Names and Codes (LOINC) code system is to identify observations in messages (such as HL7) or coded reports/documents. LOINC is the only publicly-available and worldwide-adopted standard for laboratory test terms. It contains more than 33,000 test results (called "observations") within various classes or groups (e.g., Chemistry, Microbiology), and several test attributes (Khan, 2006). This common test identification allows recipients, such as family physician offices, to receive from multiple sources and automatically and appropriately identify and code test results in the EMR. Every laboratory system uses it's own unique codes for each test, but LOINC allows for the organization, pooling, and analysis of results from various lab sources without requiring time consuming and potentially erroneous manual mapping of thousands of tests to be performed by each office (McDonald, 2003). LOINC has been adopted in many large North American hospitals, including the Hospital for Sick Children in Toronto, and is “part of a province-wide laboratory information standardization in Ontario and British Columbia” (McDonald, 2003). Infoway has developed the Pan-Canadian Laboratory Observation Code Database (pCLOCD) to specifically address Canadian laboratory ordering and reporting requirements, particularly for HL7v3 based laboratory data exchange. It is expected that LOINC will become “the defacto standard in Canada for laboratory ordering and reporting” (LOINC, Canada Health Infoway). Locally, LOINC adoption by the hospitals is in progress, driven by eCHN implementation. Private labs have already mapped their tests to LOINC as a consequence of already populating OLIS with results. LOINC offers great value in the standardization of terminology, but adoption of LOINC by the receiving EMRs and sending laboratories (in particular, hospitals) is a prerequisite.

Systematized Nomenclature of Medicine -- Clinical Terms” (SNOMED CT) is a much larger and broader collection of terminology, including approximately 380,000 medical concepts, 1,130,000 descriptions of these concepts, and 1,380,000 relationships relating each of these concepts and descriptors within a hierarchy (also known as a "taxonomy") (UVIC-HTG). The SNOMED CT vocabulary describes the care and treatment of patients, including diagnoses, symptoms, surgical procedures, treatments and drugs across time, clinical disciplines, and healthcare settings (Lau, 2008). This representation of clinical words and phrases extends to a very granular level, and enables communication in a standard and consistent way between individuals and electronic healthcare systems (NHS, 2007). Unfortunately, there has been
minimal effort at adoption of SNOMED CT in Canada (Lau, 2008), and there are no current known uses of SNOMED CT locally in WWLHIN. The vision for SNOMED CT is for convergence across terminologies, but a standard such as LOINC is more granular than SNOMED CT, and as such, mappings can not always be completed, or a loss of detail may occur (Bodenreider, 2008). There should be an opportunity to re-evaluate the role of SNOMED CT in the exchange of results, particularly non-lab reports, in coming months and years.

Various provincially and nationally endorsed standards are available to support information exchange. An integrated approach to standards avoids the undue burden of proprietary message packaging and coding, and further drives market requirements and opportunities (King, 2003; Park, 2004; Christensen, 2005). Public health reporting, and locally through OLIS interfaces with various labs, messaging and coding standards (such as HL7 and LOINC) have been demonstrated to be an effective pairing (Miller, 2004; Overhage, 2001). It is important to evaluate the appropriateness of each standard, considering the needs and capacities of the sending and receiving systems as well as future opportunities for a particular situation.

Consultations

Consultations with OntarioMD shed some light on the prevalence of EMR solutions in the WWLHIN region. Using funding as an indicator of EMR adoption, and since OntarioMD funding through from April 2005 through June 2009 was limited to family physicians, the rates of adoption may be cross-referenced to the family physician populations from the 2008 Registry (OPHRDC, 2008). This comparison reveals that 44% of all family physicians in the region of focus for this paper (Waterloo-Wellington) were funded for EMRs, which is the second highest rate for a region in the province (LHIN 12, North Simcoe-Muskoka LHIN, has the highest with 49%) (B. Forster, email communication, September 14, 2009; OPHRDC, 2008). For 80% of the physician groups and 83% of the physicians in WWLHIN that were funded for EMR adoption by OntarioMD, Practice Solutions was the EMR of choice. This is the highest saturation for Practice Solutions of any region in Ontario, and may relate to the fact that Practice Solutions was originated by a local family physician in Cambridge, and the region received extensive marketing, and had a number of installations even prior to the availability of funding. The neighbouring LHIN (Hamilton-Niagara, LHIN 4) is next highest with 59% of groups and 62% of physicians choosing Practice Solutions. The provincial average saturation by Practice Solutions of groups and physicians who received OntarioMD funding is 47%. When expanding the analysis to include all family physicians (those with and without OntarioMD funded EMRs), 37% of WWLHIN family physicians have selected Practice Solutions for their office EMR. LHIN 12 (North Simcoe-Muskoka) is second with 21%, LHIN 4 (Hamilton-Niagara) is third with 20%, and LHIN 2 (South West) follows with 16%. Across the entire province, 13% of family physicians have been funded for Practice Solutions as their office EMR (B. Forster, email communication,
September 14, 2009; OPHRDC, 2008). The same data from OntarioMD detailed the prevalence of group practices in WWLHIN and across the province. Of all the family physicians funded by OntarioMD for EMR adoption province-wide, there are an average of 7.3 physicians per group. Family physician groups using the Practice Solutions EMR consist of an average of 7.4 physicians per group. By region, WWLHIN has 8.7 family physicians per group (B. Forster, email communication, September 14, 2009).

Regarding the importance of delivery of lab results to family physicians, a consulted family physician stated, “I’ve said many times, I cannot practice if I don’t get the results returned to me on the tests I order. A repository is nice, but getting the tests back to me in an inbox (paper or electronic) is necessary for me to practice.” (M. Price, email communication, August 6, 2009). Though lab results are of great value, all results are not equal. In regard to whether all results should be delivered, another family physician from Alberta indicated that to receive all lab results for a patient may be equated to pointing “a “fire hose” at the physician’s EMR. The physician stated that “a summary of results at discharge are sufficient for ongoing care. What we really want are the results from Lab and DI that have been performed on patients as outpatients.” (S. Edworthy, email communication, August 1, 2009).

There are a number of differing processes elsewhere in southwestern Ontario to exchange lab results with family physicians. Sunnybrook Hospital in Ontario has a direct interface to distribute lab results and reports with the family practice unit that operates directly out of the hospital’s infrastructure. (A. Chan, email communication, March 23, 2009). Elsewhere in WWLHIN, Cambridge Memorial Hospital (CMH) is delivering lab results formatted as HL7 files, into an internet-portal accessible inbox, for physicians to download and import into their EMR, similar to the private lab, CML. The same solution was implemented in other regions - in Thunder Bay Health Sciences, Huron Perth Health Alliance, and with the private lab Gamma Dynacare (A. Chan, email communication, March 23, 2009). A pilot project is currently underway in the Barrie, Ontario area with OntarioMD’s Report Manager to receive HL7 feeds from one or more hospitals, extract the result's recipients, convert the reports to a standardized format (derived through the EMR certification specifications), and encrypt and transmit the reports to a SFTP folder. The physician office EMR authenticates and polls the folder for new results, and the reports are retrieved, decrypted, and automatically imported into the EMR. The project is currently receiving results from one hospital and distributing to 2 FHTS (expansion is planned to include 3 additional hospitals and 2 more FHTs in another LHIN). The pilot project is currently scoped to include each of medical transcription, radiology, and in the future, laboratory reports (H. Rodin, verbal communication, October 16, 2009).

Private lab solutions provide lab results to physicians across the province. In addition to an HL7 feed using an existing fax line, CML also provides an online lab results page, where results may be viewed electronically. In contrast, Lifelabs uses a dedicated modem connection to push results, and
automatically import the results, into the EMR. (N. Berner, verbal communication, October 21, 2009).

Similar to CML, LifeLabs offers a free web-based tool, called iLablink to securely and conveniently view recent and historical lab results at any time (LifeLabs, Online Results). Finally, Gamma Dynacare similarly shares results with physicians by mail and courier, telephone, fax, electronic transmission, and an online viewer. One of the private labs commented on the direct value they have realized from going electronic, tempered by the challenges of doing so. Eliminating paper based processes and electronic entry has helped private labs to realize an estimated savings of $1 per requisition, but transition to electronic result distribution does not realize the same savings as the savings of paper costs is offset by the increased cost of the electronic infrastructure. (N. Berner, verbal communication, October 21, 2009).

In British Columbia, the private lab Excelleris distributes results electronically across the province using HL7v2 messaging, in combination with a limited access repository (The Medical Post, June 16, 2009). VIHA, one of the BC health authorities, pushes outpatient labs by HL7v2 messaging, and Interior Health Authority has also developed distribution using a Web Services protocol to allow vendors to retrieve lab results and reports from hospitals that they service (O. Beninati, email communication, 2009). MediNet, British Columbia’s Health Information Network, likewise distributes results, but without HL7 messaging or discrete data. Result distribution is not in scope for BC’s Provincial Laboratory Information Solution (PLIS) (M. Price, email communication, August 6, 2009).

Consultations with stakeholders revealed some of the challenges to fulfilling family physician requests for electronic lab results. Some EMR solutions require the provider billing number in a field that is not normally reserved for that purpose, thus requiring custom development on a standard feed to meet the idiosyncrasies of various EMR systems (O. Beninati, email communication). EMR vendors in Canada are waiting for consensus on the requirements and growing demand by clinicians and health care organizations in order to develop solutions to receive electronic lab results from various sources (J. Gallagher, email communication, April 30, 2009; A. Chan, email communication, March 23, 2009).

**Interviews**

| How does the optimal communication of lab results from labs to family physicians support the office-based processes? |

Considering current methods in southwestern Ontario, we see demonstrations of several typical and potential solutions. Locally, the hospitals within the VWWLHIN region have begun the evolution from traditional to more advanced approaches. The family physician interviews revealed key details of what happens to lab results received by the family physicians from the private and hospital-based labs.
The most traditional process was for the hospital lab to print the reports and place the printed copies into a family physician mailbox in the hospital, according to one interviewee. This is a frequent practice particularly for credentialed family physicians who may make visits to the hospital, or who use a courier to pick up paper reports, stated one interviewee. Depending on the frequency of visits, the results may be retrieved as many as a couple of weeks after the tests were performed, according to one interviewee. It was also not uncommon for printed reports to be misplaced. For other family physicians, the traditional process of receiving reports by fax is still very common. In each of these scenarios, there is notable effort and cost for the lab to generate and distribute, and the family physician office to receive and file the results. When family physician records were all paper, it was easier for family physicians to insert the report into their chart, but in a hybrid environment with electronic records and paper reports, it becomes quite a challenge, said one interviewee, and an unintended complication and extra cost of EMR adoption. Management of paper records in an EMR-based office is particularly problematic, as articulated by two of the family physicians in the interviews - "paper is obsolete and has no place in the family physician office", and "we detest getting anything in paper form, and face a conundrum of what to do with it".

Once the report is received, the family physician peruses the report to interpret the results and determine relevancy, said one interviewee. CPSO identifies the responsibility for the ordering physician to follow-up on the tests they ordered, according to two interviewees, so the family physician (if not acting as the patient's attending physician) may not need to do anything further for hospital-sourced results, confirmed one interviewee. One interviewee identified that in some cases, the family physician may choose to act on the results by calling the ordering physician if there is relevant information the family physician may offer (such as a patient's normal test values). Alternatively, one interviewee said they may call the patient to follow-up, possibly leading to a duplication of effort as the ordering physician may be doing the same, said another interviewee. If the results are not notable, the report is sometimes shredded, according to three interviewees. Two family physicians interviewed indicated that College of Physicians and Surgeons of Ontario (CPSO) guidelines require that they retain copies of every result they view, and the burden of receiving results and responsibility to subsequently import the results is much greater. As stated by three interviewed family physicians, the value of having a longitudinal record of lab results justifies transcribing all results into the EMR. For another interviewee, the family physician may initial the document, or for two other interviewees, the family physician may circle the results and have his/her nursing (or less often, clerical staff) import particularly relevant or unusual results into their EMR. Sometimes the report is scanned as an image, reported two interviewees, and some EMR solutions automate the import of fax reports as images. Some offices then convert the image to text via object character recognition (OCR), at which point the textual data may be copied into the EMR. Office practices to manage report versioning are also variable, with some offices creating a new report while other offices simply replace the draft or preliminary report. In some cases, results are still filed into a paper chart, said one interviewee.
Management of paper reports is estimated to take an average of 60 minutes per day for family physician office staff, including 15-20 minutes or more per day for lab results, estimated one interviewee, or up to one hour per day if the result for each lab test is manually entered/encoded, added another interviewee.

There are several challenges that may occur with processes to integrate traditional hardcopy reports:

- The manual steps require considerable time, and entry of result high/low ranges (from which the abnormal flag may be automatically determined) and the test units is unduly time consuming and often omitted, according to one interviewee.
- Scanned in images are not searchable, and copying report content into the EMR does not populate the encoded lab results section of the EMR. Results can not be trended or graphed, and do not support advanced case management processes.
- Object character recognition (OCR) conversions are not foolproof, and manually typing in results is also prone to transcription errors.
- Once the results are entered in the EMR, a notification is generated to the family physician, resulting in a requirement to re-view the results that have already been evaluated – leading to duplication and some wasted effort, as identified by three interviewees.

While the results are still of value to the family physician, the burden of managing them is notable.

The ability to view results in the hospital's EPR has long been offered to credentialed family physicians, providing them with up-to-date access to hospital-generated results and reports. Since 2008, a Digital Reports solution was implemented in WHIN whereby PDF files are created of reports that are delivered or pushed to the family physician. Credentialed family physicians are also now able to retrieve or pull content from the EPR on-demand in the same PDF format. Each of these digital report types are made available for download over the hospital's secure network. The family physician office may import them into their office EMR, similar to some of the steps to manage traditional hardcopy reports, by copying the text or attaching the PDF to the EMR. Overall, offices describe these processes as saving several hours per week previously allocated to managing faxed or hardcopy reports.

The challenges with these 'digital report' management processes include:

- the number of manual steps requires considerable time
- some EMR solutions do not permit files to be attached into the patient chart
- PDF files are not searchable and consume much more storage space
- copying PDF text is not foolproof, as content may inadvertently be excluded, admitted one interviewee, and formatting is often lost
- copying does not populate the coded lab result section of the EMR
- limited to a specific network, precluding other hospitals or labs from joining
Digital Reports are often the method of choice for textual reports such as medical transcription and radiology reports, but fax or hardcopy delivery is preferred for laboratory results. Two family physicians interviewed felt that it would be better to receive unencoded electronic results as an interim step.

In the case of CML, family physician offices connect via modem using an existing fax line, described one interviewee, to retrieve results via a manual download process, performed for each family physician in the office. It is not infrequent for the connection attempt to be met by an error or busy signal, stated one interviewee. Another interviewee identified that Lifelabs uses point-to-point interfaces and HL7 messaging over an expensive dedicated modem connection. For these private lab results that are delivered electronically, each family physician, according to one interviewee, views their own results and individually acknowledges each result, and finalizing the import of results into the patients record. Interim results are displayed on viewing the results, but are not imported into the EMR or are overwritten by the final results, said one interviewee. Abnormally high or low results are flagged in red as a visual alert was the comment of one interviewee. Three interviewees described that the family physician may connect from the import file into the patient's record to cross reference results to other clinical findings, or to display the results in a table or graph format. In this way, the import, review, and response/action on the results is streamlined, explained two interviewees. This process, including follow-up, consumes 30-60 minutes per day for each family physician, admitted an interviewee. In some cases, offices continue to receive paper copies as duplicates in order to audit what has been received, said one interviewee, and/or to serve as a check of what was imported by one family physician while covering for another's vacation, clarified another interviewee.

The interviewed family physicians identified many examples of the value of electronic and encoded lab results. These include improved efficiencies and business processes for the office and nursing staff with the elimination of manual entry of results into the EMR, described three interviewees. Transcription errors are not uncommon, and could be eliminated by improved exchange of information, one interviewee stated. When manually entering results, it is not possible to enter ‘normals’, admitted two interviewees, so one interviewee said the family physician or nurse needs to look up the normals when viewing manually entered results. Even though hospital results constitute a smaller percentage of the total lab results, the inefficiencies are greater since the process is not as familiar, expressed one interviewee. It would also save time for the family physician (corroborated by Miller in 2004), as in some cases it is the family physician that logs onto the hospital network to view results and then manually imports the results into the EMR – a process that takes an estimated five minutes for the first result, and another minute for each subsequent result, estimated an interviewee.
If the solution merely provides a repository, one interviewee stated that the recipient may not know when results are available, and they may need to separately track which tests are still outstanding. Family physicians commented that it is easier to reorder a test than to refer to paper reports or the hospital system to see if there were recent hospital lab results. Five interviewees admit that family physicians ‘train’ their patients to access their preferred lab in order to receive results electronically, providing incentives for private labs. In terms of incentives for the health care system as a whole, three interviewees agreed with the article by AHIC (2006) that delivering results electronically into the family physician EMR could reduce the costs and patient impact/risk of duplicate testing.

The prompt delivery of results to the family physicians is ideal, particularly when the results are available to the family physician before the patient is discharged from the hospital – which rarely occurs with paper-reported results, as stated by one interviewee. The availability of the results is more timely as results would be available daily, instead of every week or two when the family physician picks up their results from the hospital, according to one interviewee.

Two interviewed family physicians contrasted view and delivery solutions. They identified that view only solutions are a lot of work to look up results, and are limited as they do not integrate and may be difficult to cross-reference with other components of the patients record (such as medications and clinical assessments). It would enable a more comprehensive health record for the patient and their family physician, improving quality care, stated one interviewee. Another interviewee identified that a table or graph of a patient’s complete lab result history is beneficial to send to a specialist. The family physician is able to cross-reference lab results to other components of the patient record for improved decision making and patient education – such as comparing kidney function or diabetes related lab results to a patient’s medications or blood pressure, as explained by an interviewee. A complete electronic record, including hospital lab results, enables tracking of quality indicators – for example, the family physician may run reports to identify patients that meet criteria, such as diabetics with or without a recent HbA1C, patients with thyroid conditions listing their recent TSH results, cross referencing patients with hypertension with creatinine/electrolytes results, and identifying when a patient last had a CBC done. In each of these cases, relevant results from the hospital could significantly improve the identification and reporting for quality indicators, compliance with best practices, according to two interviewees.

The family physicians also identified potential benefits for patient safety. Firstly, there is improved handoff from hospital to community care. This occurs through an awareness of the patient’s ongoing care while in the hospital. As one interviewed family physician stated, “the results will keep me abreast of my patient’s care”. In some cases, the lab results are the first or only indication that a patient is, or has been, in the hospital, according to one interviewee. Improved handoff also occurs when the patient is discharged.
from hospital and the family physician takes over responsibility for care, expressed one interviewee. Secondly, when reviewing results performed in hospital, an interviewee described how they may phone the hospital physician to inform them of relevant primary care results (i.e. that a result that appears high may in fact be normal for that patient), minimizing unnecessary treatment. Thirdly, hospital ordered tests may reveal some surprising results that may trigger the family physician for further investigation that would not otherwise have been done. Stated one family physician, “this happens all the time”.

One of the common themes of discussion during the family physician interviews was that of which tests, visits, and how many results would be included if hospitals were to be able to provide lab results electronically. Labwork done on outpatient visits in the hospital (including ER, clinical, and ambulatory care visits) are sent to the family physician, but results on inpatients are not, according to two interviewees. Family physicians often receive lab results from the hospitalist, specialist, or ER physician within textual discharge summaries, consults, and clinic notes, though these may be handwritten (such as ER records) and therefore often difficult to read, or may include only a synopsis of a patients lab results and therefore are not necessarily inclusive of all the test results, said one interviewee. One family physician stated about inpatient results, “What's the value to the family physician of 4 blood draws per day?”

In terms of which results to receive, there was a feeling by one interviewee that to receive reports including many 'normal' results would be ineffective, and possibly redundant as the ordering physician was responsible for follow-up. Interim results may be reported if one or more test in a batch take longer to process, indicating initial test results and a notice that the other tests are pending, with a final report displaying all test results. Two interviewed family physicians felt there was some value in knowing that more test results were coming, and appreciate receiving the initial results quickly. But ultimately, since they did not order the test, there is limited need to be notified of pending results, and the re-reporting of all results leads to unnecessary duplication for the office, said two interviewees. Some family physicians that were interviewed felt that abnormal results and unusual tests would certainly be of value, and when results are to be made available electronically, there was consensus by several of the interviewees that the convenience, and the value for the family physician of having a complete laboratory record for their patients, would justify inclusion of all results. To receive all these results would not be an issue as the inconvenience of receiving paper reports was greater than the value of the information buried within the reports. The opposite may also be true - “if it's electronic then there's no problem with receiving all results”, particularly if the process requires minimal effort on the part of the family physician or their staff. The interviewed family physicians also expressed that so long as the results are delivered electronically and are capable of being effectively analyzed in the EMR, it does not matter whether the solution is fully automated or if it requires a minimal number of manual step to download. This is because, particularly for
hospital results, the results are not as numerous nor as critical to the family physician, and a few hours difference in receiving the results is unlikely to be clinically relevant, confirmed three interviewees.

In contrast, an interviewed family physician from Alberta stated that while receiving results that they ordered (or on which they were directly copied) is desirable, in other situations they do not know the context and reason for the test. In these cases they do not know whether the ordering physician has already actioned the abnormal test result, and what is the most appropriate follow-up given the ordering physician's reason for ordering the test. Furthermore, the volume of test results may "consume an inordinate amount of time reviewing". Inclusion of all hospital-sourced results could also skew a patient's lab result trends with results that are obtained while the patient is unwell and receiving intense treatment. When trending results, even though EMR solutions may not have the ability to 'flag' the results as occurring during a hospitalization, three family physicians described that the high frequency and high variability, and potentially different 'normal ranges' of these results could lead them to interpret the results in the context of what they know to be the patient's hospitalization and numerous hospital-related factors.

Considering how the results will be expected to be used, there may be debate as to how tests that were not ordered by the family physician should be used to trigger Clinical Decision Support alerts in the family physician's EMR, said one interviewee. In essence, automated delivery of results is of value, while ownership of and responsibility for the results must continue to be driven by the clinical process and the role of the physician that initiated the result. Whether the results flow in automatically (passively for the family physician), or the family physician office has a few steps to retrieve them (a more active process for the family physician) is not as significant as what the requirements/expectations are of the family physician in relation to the results. The family physician's acknowledgement of the results should be sufficient for tests they did not order. The role of the ordering physician (or the physician to whom they designate the follow-up) will be tied to the responsibility to follow through on it. This is a question of information and order/test ownership and roles, more than the means to exchange as a business/system process, expressed an interviewee. A family physician commented that there may be value in offering options for family physicians to receive different sets of results – such as excluding notification of 'interim' results, or presenting a discharge summary of lab results from an inpatient visit instead of all inpatient results. It would also be beneficial for the EMR design to accommodate hiding of results, customized views, advanced searches and various levels of filters, suggested one interviewee.

The challenges of maintaining different sources was explained by an interviewee, that each sender/receiver of encoded messages may have slightly different specifications/requirements. The interviewed family physicians broadly suggested that a consolidated solution used by both private labs and hospitals would greatly improve efficiencies for the family physician office. One family physician
realized there may be a cost to them to receive hospital-sourced lab results, as there is to enable electronic receipt of private lab results ($600-$1000). One family physician reported a willingness to cost share with the hospitals, but another interviewee felt the funding model should recognize the value to the hospital (including savings on paper/transmission costs).

Contrasting methods in place in Ontario with those of other provinces reveal some interesting comparisons. One interviewee described how several Alberta regions implemented an FTP-based solution that pushes results on a daily basis to the EMRs of the test's ordering or copied physicians. With the consolidation of Alberta's health regions, the FTP mechanism is being replaced with a coordinated and standardized real-time HL7 messaging on the province's health information exchange (PHIE) “hub”, with management at a provincial level. In a single region, there was also an initiative to implement a real-time feed from the region's lab repository to the eCLINICIAN EMR, with some similarities to London's SPIRE project. Concurrently, results are also available to be viewed by any physician across the province in Alberta's provincial EHR (Netcare). This is typically used only to access results that were not delivered to the physician's EMR. Quebec, Saskatchewan, and the maritime provinces have similar initiatives underway.

Looking ahead, another interviewed family physician identified the opportunity for a two-way realtime integration with care processes, such as the ordering of tests, consults/referrals to other health care providers, and integration with decision support tools. Another interviewed family physician also expressed a desire to include nutrition and physio in the report exchange process, and to be able to use it for electronic referrals to specialists and electronic submission of prescriptions to pharmacies.

In summary, view-only solutions are inadequate and if they are the only solution, can increase workload. Receipt of results by the family physician in a timely manner is necessary. Interviewed family physicians described current processes related to the management of electronic and non-electronic lab results. Paper reports are problematic, and the import of results into the office electronic medical record in a way that enables analysis, trending, reporting, and referencing is key to clinical care. Results need to be reviewed, and may require action, particularly if the recipient ordered the test or the ordering physician requires them to follow-up. There was some discrepancy whether family physicians retain all results they receive or just the most relevant, and depends in part upon whether the family physician wishes to maintain a complete record of results. Manual import of results is common, and consumes several hours per week of a resource's time, and results that are electronic but not encoded (i.e. plain text) may offer little advantage over the ideal automated electronic imports (such as, by private labs). There was debate as to whether all results should be received or selected results, largely dependent upon whether there was an expectation or responsibility to take ownership of the results. If the results were available to
support future decisions, and there was no inherited responsibility to act on the results they did not order, and if the receipt of these results did not require undue time to import, physicians agreed that all results may be valuable to include. The interviewees described several clinical and business process improvements that occur with interoperable results, including improved efficiency, less time consumed by the physician, the ability to cross-reference results to other elements of the patient record, tracking of quality indicators, reduced duplicate testing, and improved patient safety. A coordinated solution, as demonstrated by Alberta's pairing of viewing and receiving solutions, across all lab service providers is ideal, and there may be opportunity to distribute costs of the solution according to the realized value. Future opportunities to expand functionality beyond lab results should be considered.
Discussion

The following discussion represents the author's interpretation and analysis, in the context of the evidence and literature, previously discussed and included inline.

**Requirements**

![Requirements Homunculus](image)

Figure 8 demonstrates a classification and inter-relationship of requirements, that may constitute the core elements of the desired solution.

**Strategy** describes the need for the solution to align with the strategic objectives of the stakeholders and influencers. It includes the need for engagement of the players, and partnerships between individuals and groups, through cooperation and collaboration. The eHealthOntario Strategy (2009) highlights guiding principles that include a focus on clinical outcomes for patient care value and not technology for its own sake, early engagement of clinicians, and partnerships. Other principles include the leverage of legacy systems, relevant and complete clinical content, early clinical benefits, and varying deployment models. These principles contribute to the strategic requirements for a solution.

The regulatory requirements and the drivers constitute the motivation, or the rationale for the solution.

**Regulatory** requirements include the satisfaction of those requirements defined by Ontario Lab Accreditation (OLA) as regulators of private and public labs, and the College of Physicians and Surgeons of Ontario (CPSO) as physician regulators. OLA requirements include the need for results to identify the patient, the laboratory, the specimen, and result details. OLA also requires that the results be provided to authorized recipients, that procedures exist for releasing results by telephone or electronically, that copies of the results be retained, and that corrected/altered results clearly identify that they replace previously
reported incorrect results (OLA Requirements and Guidance Information, 2008; see Appendix C). Privacy requirements are an essential component of a solution that exchanges patient information. The importance of these requirements must not be understated.

The *Drivers* represent the requirement of delivering value, or a desired outcome or benefit, to the health system. There must be an understanding of what constitutes sufficient value, possibly including a realization of return on investment, and measurable or appreciable outcomes of quality of care, improved efficiency, and patient safety.

These 'arms' converge at the family physician *Practice*, the 'heart' and hub of community-based health care. These solution requirements include a need for the processes to align with the clinical sequence of the patient-family physician interaction, delivering information when, where (i.e. via the EMR), and how it is needed by the clinician. The solution must enable the exchange of data in order to support handoff/transition and continuity of care.

Intricately connected to the value to the family physician practice are the requirements for *Use*, that is how the family physician and their office staff interact with the system to support the business processes. These requirements include alignment with the business sequence, elimination of hardcopies and manual processes, optimal task workflow & efficiency, and broader accessibility to various sources of information. Reduced complexity, improved usability of the system, and overall cost effectiveness are also required. The use of the solution must minimize duplication and improve efficiencies. Use Cases and Case Studies (see Appendix D) may be effective tools in the definition of Use requirements.

There are two 'legs' that partner to support the above requirements – generically, 'information management' and 'information technology'.

Information management (the right leg) consists of system *Functions* that are enabled, whether on the back-end or front-end. Some of these requirements are functions of the EMR, but are dependent upon the format of the information within the message or document (discussed in the Information requirements). Back-end functions include the requirement for the EMR to store results, track results to their source orders, and generate notifications that new results are available. Storage requires a means to update results when they are modified or corrected in the source system. Tracking ensures the results fit within the ordering sequence, from the triggering clinical event through the initiation of the order to the post-result action and follow-up. Tracking supports the clinician's awareness of the status of orders, including those that are pending or in progress. Notification was identified by Canada Health Infoway's Blueprint (2006) as a key function of the EHR infrastructure to "support the accuracy of data as well as
Front-end functions include the need for the EMR to be able to present the results with appropriate display and formatting, including reference ranges. These ranges describe the normal levels for lab tests based on samples of many health individuals, stratified by age and sex, and may vary by lab source and even for a particular patient. For example, ’a patient who, due to certain health issues, has a high level or low level, which is “normal” for that particular patient, even though the lab’s reference intervals put that level in an abnormal range.” (Rogoski, 2009) On the front-end also lies the need for trending and searching. Trending may take the form of tables or graphs of one or more results, and enables interpretation of a single result within a context of other tests and/or past results. Searching allows cross-patient compilation of reports of patients and their results that meet specific criteria for monitoring.

Supporting the Functions are the Information requirements – that is, data and messaging standards, and content requirements. At a high level, the information that is exchanged must have a clinical significance, a relevance to the recipient, data quality/integrity, and timeliness. It must also be inclusive of the spectrum of lab results (that is, not limited to merely a few specific tests), and scalability for additional document types (such as radiology or transcribed reports). Data and messaging standards are discussed in the next section, and may enable standardized terminology and normalization. Canada Health Infoway states that “Information is normalized (consistent semantic meaning) whenever possible on input to optimize timely and accurate delivery of information” (Canada Health Infoway, Blueprint) Information that is exchanged must be accurate, and include identification of the source and recipient(s), date and time stamps, test names, values, normals/ranges, and critical/abnormal flags.

Information technology requirements (the left leg) consist of Design elements, including adherence to IT standards such as those of the Information Technology Infrastructure Library (ITIL). This includes characteristics of availability, fail-over, and recoverability. Errors and exceptions must be handled, along with logging, tracing, and auditing of user activities. Design must also accommodate the limited and often absent information technology capacities in family physician practices by ensuring appropriate support and maintenance requirements. There are a number of HIAL-type components that are included in the design requirements. The ability for the solution to integrate with other solutions - that is, with various solutions that supply information and other solutions that access or receive information - must be included within the design capacities. Other HIAL-type components include identity management of both provider and patient (ie. Enterprise Master Patient Index, or EMPI), for record matching with 100% accuracy with matches (Tcheremenska, 2009) and a method to address when matches cannot be made. Privacy and security are pivotal requirements, including authentication to protect the system from unauthorized accesses, and consent to protect components of the patient’s record according to the patient’s stated wishes and requirements. The solution must also define ownership of the information, the process of
ownership handoff, and the responsibilities for use of the information. Grossman described the failure of clinical data exchange solutions in part due to differing opinions about who controls the data. Aligning with this grouping of requirements, Sanders described ten specific characteristics of a safe software environment including testing, validation, change control, reporting, and response procedures (Sanders, 2010). Governance is another key requirement for the implementation of the solution, and includes the consideration of trust and sharing between stakeholders. An Institute of Medicine (IOM) report in 2002 called for the creation of local governance structures to be established to precede data exchange initiatives. (Miller, 2004) OHA identified that “...integration management and governance structure that supports and compliments the laboratory medicine and institutional structures, will need to be developed. Governance may consist of simple service level agreements (SLA) that spell out the required levels of performance and the consequences of failure or a full memorandum of understanding (MoU) that provides a detailed understanding of ownership, control, and protection for partners.” (OHA, 2006) Finally, sustainability must be addressed in the solution, and one key element of sustainability is that of cost management.

The final category of requirements includes that of Technology. This includes the communication and exchange standards, the associated systems and subsystems architecture, networking and interfaces that have appropriate capacity and performance to enable in- and out-bound delivery and interim storage for the exchange of data. The technical details of the solution at this level are not within the scope of this document.

The general elements described above constitute nine groupings of requirements for an exchange solution. These may serve as a guideline for comprehensive requirements identification through the evaluation and development of solutions.
Alternative Solutions

Health information exchange must do more than just combine standards and meet requirements. In fact, "because the various standardization formats may be in conflict with one another, the situation today is akin to wanting to buy a car but instead being offered a bunch of car parts. And this batch of parts may or may not come together to produce an operating vehicle" (Strauss, 2010). Determining how the parts fit together requires a clear idea of what the vehicle will do and principally how it works. The following review of solutions and their characteristics will illuminate the possibilities and limitations.

Frameworks

Walker et al. (2005) described a framework with four levels for how information may be shared amongst health care entities, classifying the sophistication of technology and the levels of standardization.

1. Non-electronic data (i.e. mail and telephone).
2. Machine-transportable data without standardization – not easily manipulated (i.e. faxes, scanned documents, pictures, or PDF files).
3. Machine-organizable data - sharing of structured messages enabling import, but still without standardization requiring mapping of the data from the sender's vocabulary to that of the receiver (such as HL7 messages without coded vocabularies/terminologies).
4. Machine-interpretable data - structured messages containing coded data, standardized for both the sender and receiver enabling automated import and classification. This is the desired point at which interoperability may be said to exist. (Walker, 2005)

Alternatively, the American Health Information Community (AHIC, 2006) described a framework based on a hierarchy of ownership and governance. This may be adapted to the local environment by describing organizational, regional, provincial, and national models (see Appendix H).

eHealthOntario seems to combine the above two classifications into “Application Delivery Models” (eHealthOntario Strategy, 2009). These include:

- province wide applications managed/hosted by eHealthOntario that use provincial standards (such as OLIS, and OntarioMD Report Manager),
- province wide applications that are not managed/hosted by eHealthOntario using provincial standards (i.e. private lab systems such as Lifelabs and CML),
- regional (more than 1 LHIN) applications using provincial standards (ie. Medseek's ClinicalConnect portal)
- LHIN, hospital, or family physician office applications that use provincial standards (ie. Cambridge Memorial Hospital's HL7 delivery of lab results)
LHIN, hospital, or family physician office applications that do not use provincial standards (ie. WHIN’s digital reports)

Peer-to-Peer vs. Shared
At the intersection of ownership and technology lies the functional design of the solution. At this point, solutions may be broadly described as either peer-to-peer or shared.

Peer-to-peer (or point-to-point) solutions at their simplest may include traditional methods such as mailing, couriering, and faxing results. There is no consolidation of effort across lab service provider, and a family physician can receive several mailings/faxes a day from different senders. These solutions typically are formed at the organizational level, and until recently, have been able to sustain a design not necessarily based on broadly accepted standards. With recent efforts to distribute results electronically, each family physician establishes a connection to individual lab service providers for their respective results, and each lab service provider establishes one-to-one send/receive relationships with each individual EMR instances (Ruotsalainen, 2004). Each system is developed according to individual sender preferences/capabilities and standards are not consistently enforced. The eHealthOntario blueprint (2008) classifies these as “Multi-point sharing across enterprises”.

Examples of the peer-to-peer models may be described as direct or indirect, depending on whether an intermediate delivery point exists. If the hospital and family physician information systems are compatible, the results can flow directly to the EMR (Grossman, 2006), such as with point-to-point messaging or the manner employed by the private lab, Lifelabs. Alternatively, the solution may utilize an intermediate delivery mechanism, such as shared folder or ‘inbox’ accessible by a secure connection, mediated by manual processes (printing/scanning or downloading reports and importing them into the EMR). This form of peer-to-peer is in place with the private lab CML and Cambridge Memorial Hospital’s distribution of lab results.

Peer-to-peer has proven effective and is quite common for physicians with affiliation and regular interactions with a lab service provider, or to hospitals and physicians that partner in a joint network (ie. WHIN). (Grossman, 2006). Rudin describes how the peer-to-peer approach, or at least a hybrid solution, may provide an alternative means that avoids dependencies on the shared solution. Where this applies is for providers that are not eligible or do not wish to participate in regional HIE solutions (Rudin, 2009).
Peer-to-peer is also a quick way to allow early access if prerequisites of the shared solution are not yet available.

When results are received by a physician from more than one lab service provider (McLure, 1994) or when physicians are not directly affiliated with the lab or hospital organization(s), the peer-to-peer solution fails to provide adequate functionality (Grossman, 2006). The individual model increases the efforts and costs for each of the parties, maintains numerous lists/registries for patients and providers without a means to ensure consistency, and often depends upon mapping of terms within each physician office. Rudin (2009), in a review of community HIE projects that were initialized (but not yet operational), commented that the relatively high complexity of the peer-to-peer approach was expected to result in delays and difficulty in implementation. eHealthOntario (2010) stated that, “point-to-point interfaces to connect the different systems and interpret their data from one system to another is not manageable or sustainable.” Figure 10 presents a comparison on the basis of complexity between individual and shared solutions.

One of the private labs using the direct peer-to-peer approach (with an interface into each physician's EMR) noted the high burden of support with these direct point-to-point connections, though it is not preventing them from adding more physicians. It is on their radar to evolve towards an internet based solution in order to lower support requirements (N. Berner, verbal communication, October 21, 2009).

Some of the electronic peer-to-peer options are compared (darker shading represents significant limitations, lighter shading has mixed limitations, and no shading indicates fewer limitations):
<table>
<thead>
<tr>
<th>Description</th>
<th>Point-to-point (direct interface) HL7</th>
<th>PDF documents delivered to an organizational 'inbox'</th>
<th>HL7 Spec messages delivered to an organizational 'inbox'</th>
</tr>
</thead>
<tbody>
<tr>
<td>Examples</td>
<td>Lifelabs</td>
<td>WHIN</td>
<td>CML, CMH</td>
</tr>
<tr>
<td>EPR Messaging</td>
<td>HL7v2 (requirements vary somewhat by lab solution)</td>
<td>Proprietary reports</td>
<td>HL7v2 (requirements vary somewhat by lab solution)</td>
</tr>
<tr>
<td>EMR Messaging</td>
<td>HL7 v2 - requirements vary somewhat by EMR/lab solution</td>
<td>Non-standard - PDF</td>
<td>HL7v2 (requirements vary somewhat by EMR/lab solution)</td>
</tr>
<tr>
<td>EMR Compatibility</td>
<td>All EMRs (each EMR slightly different)</td>
<td>None</td>
<td>All EMRs (each EMR slightly different)</td>
</tr>
<tr>
<td>Standardization/ encoding/ importability</td>
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<td>None</td>
<td>Yes</td>
</tr>
<tr>
<td>Normalization</td>
<td>None</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Lab Support</td>
<td>High</td>
<td>Low</td>
<td>Low-moderate</td>
</tr>
<tr>
<td>Physician Support</td>
<td>Low</td>
<td>Moderate</td>
<td>Low-moderate</td>
</tr>
<tr>
<td>Implementation Readiness</td>
<td>HL7 feed available, dependent on connectivity</td>
<td>Completed</td>
<td>HL7 feed available, ready for development</td>
</tr>
</tbody>
</table>

**Table 4: Peer-to-Peer Solution Comparison**

More recently, standards have become more integral as sending and receiving systems become more aligned, such as the standardization of family physician office EMRs through CMS certification. AHIC described an evolution, starting with a hospital-centric approach, and then linking these solutions or building new regional models based on regional standards (AHIC, 2006; Grossman, 2006). This has led to support for the development of shared solutions that centralize methods and infrastructure across multiple organizations – for instance, OLIS for lab service providers, and eCHN and Medseek for hospitals on a provincial and LHIN-wide scale, respectively. eHealthOntario describes these as “Systems-Wide sharing amongst authorized stakeholders” (eHealthOntario, 2008).
In contrast to peer-to-peer solutions, shared solutions bring together data from multiple sources, providing a consolidated single integration point for the laboratory service providers, and a single point of access for each recipient. These solutions may be specific to lab result sharing, or they may be inclusive of various types of reports. A service such as OLIS replicates and stores the data in a repository. Solutions like Medseek’s ClinicalConnect solution act as a query portal that link to source information systems by searching for results. Infoway describes this as a virtual EHR - "each time that a caregiver is accessing this client’s EHR, the EHR ... will compile all the data relevant across any number of [sources] where relevant data is kept. From the system’s perspective, and more importantly the users of those systems, the person’s data is perceived as being in one EHR" (Canada Health Infoway, Blueprint). Both query portal and repository systems may allow viewing of results. In contrast, a broker enables the exchange of data receiving from and sending data to multiple systems. A broker does not store in a repository nor allow viewing of the data directly, rather the results are delivered into and viewed within the family physician EMR. OntarioMD’s Report Manager is an example of a broker.

Similar to peer-to-peer solutions, shared solutions may exist on various jurisdictional scales, from LHIN to multi-LHIN to provincial. Shared solutions may differ from each other in terms of the means of connection, messaging, and methods of retrieval and import (manual vs. automatic). The shared model requires reconciliation across EPR (or LIS) databases, and as such, depends upon common components – including patient and provider registries, standardized nomenclature, and potentially normalization of data. Furthermore, governance, HIAL elements including privacy and security, and support and sustainability are of prime importance.

The following summary compares several of the existing candidate ‘shared’ solutions (darker shading represents significant limitations, lighter shading has mixed limitations, and no shading indicates fewer limitations):
<table>
<thead>
<tr>
<th>Candidates</th>
<th>Limited-region EHR</th>
<th>Limited-content EHR</th>
<th>Domain Specific Repository</th>
<th>Report Delivery Solution</th>
<th>Hybrid [conceptual]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Examples</td>
<td>Medseek</td>
<td>eCHN</td>
<td>OLIS</td>
<td>OntarioMD Report Manager</td>
<td>OntarioMD Report Manager with OLIS</td>
</tr>
<tr>
<td>Solution Type</td>
<td>Query Portal</td>
<td>Repository</td>
<td>Repository</td>
<td>Broker</td>
<td>Broker Hybrid</td>
</tr>
<tr>
<td>EPR Query/</td>
<td>Proprietary</td>
<td>HL7v2</td>
<td>HL7v2</td>
<td>HL7v2</td>
<td>HL7v2</td>
</tr>
<tr>
<td>Miessaging</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>EMR Messaging</td>
<td>HL7v2</td>
<td>None</td>
<td>None</td>
<td>CMS 2.0 Specs</td>
<td>CMS 2.0 Specs</td>
</tr>
<tr>
<td>EMR Compatibility</td>
<td>Practice Solutions only</td>
<td>None</td>
<td>None</td>
<td>All CMS 2.0+ compliant</td>
<td>All CMS 2.0+ compliant</td>
</tr>
<tr>
<td>Normalization</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Download/Import</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Functionality</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other Report</td>
<td>Yes</td>
<td>Partial – paediatrics only</td>
<td>No</td>
<td>Yes</td>
<td>Partial – with other sources</td>
</tr>
<tr>
<td>Type Inclusivity</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Private Lab</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Inclusivity</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Relationship to</td>
<td>Result</td>
<td>n/a</td>
<td>n/a</td>
<td>Result</td>
<td>Result</td>
</tr>
<tr>
<td>Patient vs.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Result</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>View</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Local Implementation Readiness</td>
<td>Phased rollout in progress</td>
<td>Nearing completion of sending results, and viewing</td>
<td>Deferred</td>
<td>Regional pilot projects</td>
<td>Conceptual only</td>
</tr>
</tbody>
</table>

Table 5: Shared Solution Comparison
An enhancement of the shared model may be described as a shared portlet. In this model, the EMR makes a context-sensitive query (for example, identifying the patient being viewed in the EMR) to the portal solution. A portal application that is embedded in the EMR (called a 'portlet') displays results, documents, and images within or alongside the current EMR display. It may be interactive, allow import of selected data into the EMR, integrate with decision support tools, or connect to ordering, scheduling, or referring functions. As with query portals, results would be real-time, and would avoid EMR management and storage of result data until it has been accessed. The implementation of portal solutions and HIAL services, and collaboration with EMR vendors may lead to the development of this functionality in the near future.

The following is a high-level comparison of the current types of solutions:

<table>
<thead>
<tr>
<th>Type of Solution</th>
<th>Fax, hardcopy</th>
<th>PDF via Inbox/Folder</th>
<th>Point-to-Point HL7/CMS via Inbox/Folder</th>
<th>Portal Retrieval</th>
<th>Portal View (Portlet)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Examples</td>
<td>Hospitals</td>
<td>WHIN</td>
<td>Lifelabs</td>
<td>CML,CMH</td>
<td>OntarioMD n/a</td>
</tr>
<tr>
<td>Quality</td>
<td>Non-Digital</td>
<td>Digital</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Evolution</td>
<td>Traditional</td>
<td>Modern</td>
<td>Future</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Collaboration</td>
<td>Individual</td>
<td>Shared</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Integration</td>
<td>Manual</td>
<td>Manual</td>
<td>Automated</td>
<td>Automated</td>
<td>Integrated</td>
</tr>
<tr>
<td>(Import)</td>
<td></td>
<td></td>
<td>Low</td>
<td>Low</td>
<td>Low</td>
</tr>
<tr>
<td>Exchange/Import</td>
<td>High</td>
<td>Medium</td>
<td>Low</td>
<td>Low</td>
<td>None</td>
</tr>
<tr>
<td>Import Effort</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Support Effort</td>
<td>Medium</td>
<td>Medium-High</td>
<td>High</td>
<td>Medium</td>
<td>Low</td>
</tr>
<tr>
<td>Timing</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 6: Solution-Type Comparison
The distinction between viewing results and delivering results to family physicians may warrant further discussion. Furthermore, the differentiation between pushing results to family physicians, and allowing the family physician to pull the results bears consideration. There are numerous solutions that allow the family physician to view results from lab sources – including eCHN and the hospital remote access portal. Future solutions, such as Medseek and OLIS will also provide this functionality. It is important for a family physician to both have access to their patients' results through access to view solutions, but also to made aware of what is happening to their patients in the health system. In some cases, it is the delivery of reports or test results that give notification to the family physician of their patients' health care events. Delivering results are necessary, and it is inadequate to merely provide access to lookup results. Furthermore, a view only solution prevents the integrated view of results in the viewer with other clinically relevant information external to the viewer, such as in the family physician EMR. View solutions do have value if a family physician was not identified as a recipient of a patient's results, and if a provider accepts care for a new patient or implements a new information systems and needs to access historical results. Some solutions are offering both methods – such as Lifelabs result portal and direct interface, and Medseek's view portal and proposed EMR download. On the other hand, Alberta has separated the two into distinct solutions, and several solutions in Ontario offer either view-only (OLIS, eCHN, remote access to the hospitals' Meditech system) or result delivery (OntarioMD Report Manager, or the hospitals' Digital Reports).

Viewing is an example of a pull, or retrieval of information from an information system. In such a view system, the information is not pushed or delivered to the recipient (this may be described as passive sending), rather the receiving family physician queries the lab system for new results through an active process by the family physician. In contrast, a purely push model delivers results to recipients by the sending lab, for example by fax (such as traditional hospital delivery) or direct interface (such as Lifelabs). The delivery by the lab is an active process, and the retrieval of the result by the family physician is a passive process (that is, the report simply appears within their office or the office's information system). A hybrid model, that actively delivers or queues the results from the sending lab but requires an active process of retrieval, has been demonstrated by the retrieval from a portal inbox (such as the hospital digital reports) or by modem connection (such as the private lab CML).
Pushing results to recipients depends upon identification of the recipients, determining who should or should not receive the results. Traditional result sharing (such as faxing or point-to-point type solutions) depends upon defining recipients of the result at the time the lab test is resulted. There may be manual or rules-driven processes to accomplish this, such as identifying the family physician, the ordering physician, and any other requested recipients that may receive the results. These rules and/or manual steps may exclude a recipient if that individual's relationship to the patient is not known to the lab facility. A possible alternative is for the provider to 'sign-up' or 'subscribe' to the patient's results, and thereby automatically receive results for that patient. With this model, there is a shift from delivering the results to the physicians that are associated to the result to instead deliver the results to the providers that are associated to the patient. The latter is a more patient-centric model that ensures access to the latest results by all providers who are involved in the patient's care, and is associated more commonly to a shared solution than more traditional peer-to-peer solutions. It may also contribute to patient-driven privacy through audits or controls that allow the patient to specify valid recipients, and view who has subscribed to receive their clinical information. Unfortunately, all candidate solutions at this time utilize a result-centric model.

In Figure 13, the results that lie within the intersection of physicians (results A and B) represent results that are tied to two or more of the physicians within the patient's circle of care, while the remaining results are linked to only one...
physician. In a result-centric view, the results are not shared with the other physicians. In a patient-centric view, all six of the results would be available to all of the involved physicians.

The need to address laboratory reporting requirements is apparent, but the future demand for other reports (such as discharge reports and operative reports), points towards an optimal strategy that “meets all the information needs of the hospital-physician relationship” (McLure, 1994). The concepts of lab result sharing can, and inevitably will be extended to the sharing of other types of reports. In the hospital environment, there are several types of reports, including textual lab reports such as pathology reports and medical transcription reports (such as consults, admission history & physical, and discharge summaries), and diagnostic imaging reports (such as radiology, CT, MRI, and ultrasound). These reports may benefit greatly from SNOMED CT and HL7v3 CDA based standardization. Each of these report types are currently being considered for distribution to other repositories or portal solutions, such as Cancer Care Ontario, eCHN, Medseek, and a regional Diagnostic Imaging repository (DI-r). Other reports such as ER Reports and ECGs are generated in hospitals (and in some cases, private labs) and have value to family physicians, particularly if exchanged with interoperability. Unfortunately, many of these reports are not yet available electronically. The value of report exchange extends beyond the delivery of reports from hospitals and private labs to family physicians. Information may be exchanged to and/or from other organizations and providers such as Community Care Access Centers (CCAC), Long-term Care (LTC) facilities, and ER physicians, hospitalists, and specialists. Delivery of results to patients’ personal health records (PHR) may also be on the horizon. If identifying solutions for lab result exchange is equated to the building of a bridge within the EHR ‘road system’ as the background of this paper described, consideration of other information sharing opportunities is necessary to prepare for how else these bridges may be used in the near future.

There is a high demand for lab result exchange, but many participants (whether hospitals or family physicians) may not be ready at this time for the future state. Interim solutions may be considered, even if they do not meet the long-term requirements. Not all physicians are at the same stage of EMR adoption, so traditional solutions such as faxing may continue for some time. Locally developed solutions (such as peer-to-peer models of report delivery) may meet the needs for a short-term and limited scope implementation, and build on existing processes. The higher priorities for EMR vendors, family physicians, and hospitals alike are organizational objectives and regional solution development. With the anticipation of LHIN and provincial initiatives and limited funds, it is difficult to justify committing funds and resources for an interim solution that will likely be superseded by a regional or provincial solutions in what may be a short period of time. If interim solutions are to be considered, they must be developed with low cost and effort. Unfortunately, there are few options that meet this criteria in terms of peer-to-peer solutions. Partnering with other local hospitals (such as Cambridge Memorial Hospital) that have
developed such distribution mechanisms, or replicating their processes may be viable with reduced development requirements.

Whether a small-scale organizational solution may best utilize resources and funds, or a shared solution will most effectively and efficiently meet the needs should be considered. When LHINs as regional coordinators and eHealthOntario as a provincial enabler look to cooperate on broad solutions, these solutions may migrate from distributed (or independent) solutions to ones that are shared. Decentralized or organizational systems allow for stand-alone applications that are customized to the needs of a specific group of users, but may foster information silos that are not designed to integrate with the breadth of involved systems (various family physician office EMR solutions, hospital EPRs, and lab LISs). There is also a risk that systems, applications, and efforts are duplicated. On the other hand, streamlining efforts of multiple groups includes a high priority on the development of HIAL solutions, such as portals for front-end access to various sources and services, connectivity on the provincial network, joint privacy/security processes, and registries. Several of the provincial organizations offer or enable solutions that may play a role in exchanging lab results to family physicians EMRs. Four provincial-scale initiatives (OLIS, eCHN, the eHealth Portal, and OntarioMD’s report manager) have been highlighted and are particularly notable in terms of their contribution to the desired future state.

- **OLIS** is Ontario’s provider of the provincial laboratory information system, exchanging orders and storing results. OLIS is poised to move forward from the first phase, and beginning in 2010, expand services to other hospitals and begin providing access to results. If OLIS may be engaged in a discussion of result-delivery capabilities, opportunities for lab result exchange may be revealed, perhaps in partnership with one or more solutions, such as eCHN and OntarioMD’s Report Manager.

- **eCHN** has successfully demonstrated the capacity to manage and share health information with providers across Ontario. With a high level of hospital adoption, confidential record management, and standards-based and normalized result management, there is potential for eCHN to disable their pediatric filter and begin to include information for individuals of all ages. With this change, eCHN may well become the provincial electronic health record.

- **OntarioMD’s Report Manager**, though planning but not currently delivering lab results, offers a solution inclusive of all OntarioMD certified family physician EMRs. This may potentially reach 60% of Ontario family physicians, or 8,700 physicians by 2012, contrasting with local and regional solutions.

- The eHealth portal bears consideration for it's contribution to enabling access to information and functions, on a foundation of HIAL-compliant services. The portal lacks in terms of current solutions, but should be re-evaluated in the near future and on an ongoing basis.
Medseek has strong local interest and has the potential, like eCHN did, to grow from a regional initiative into a province-wide solution. The design model of Medseek to link and display content from hospital information systems is unique and offers some simplicity of record management. With the HealtheConnections project coming to a close, and inadequate resolution of issues related to confidentiality, security, governance, and change management, there are some significant challenges that do not bode well for short-term possibilities. Furthermore, with the alternative record management model that Medseek depends upon for result delivery, the fact that the solution is currently designed for a single EMR solution with a single report type, and that the appropriateness, usability, and current design have not been rolled out or even fully evaluated, the solution is quite a way from being considered capable of meeting the current needs of family physicians.
Recommendations

The recommendations discussed below are also built on the author's interpretation and analysis, in the context of the previously presented evidence and literature.

What is the envisioned future state, and what strategies will enable its achievement?

There are numerous solutions that currently overlap and individually inadequately address the broad requirements of result sharing. The strategic visions of LHINs locally, and eHealthOntario provincially may serve to avoid fragmented efforts and coordinate these various initiatives. Strategic partnerships may reduce duplication and streamline investments of effort and dollars.

OLIS is intended to be the province's comprehensive laboratory information system, but lacks a viewer and a result delivery mechanism. eCHN has demonstrated a robust viewer with broad provincial adoption – with expansion to include adult records, it is a viable solution. Medseek offers a local viewer solution but has struggled with rapid growth and the challenges of providing a viable report distribution solution. On the other hand, OntarioMD's Report Manager is a promising result delivery solution that while not yet inclusive of lab results is inclusive of a very broad set of of physician recipient EMR solutions. The eHealth Portal has limited implementation at this point, but may provide a key front-end for access to some of the above solutions, and may support the coordination and development of essential provincial HIAL services (including integration, governance, privacy, and security) across providers. The below conceptual model, using a few of these candidate solutions, demonstrates how in alignment with

Figure 14: Conceptual Model of Candidate Solutions
Infoway's EHRS blueprint and eHealthOntario's strategy, in the current environment of southwestern Ontario lab service providers can deliver electronic laboratory results to family physician offices, such that the data can be efficiently and effectively received, integrated, and interpreted. The result distribution component is presented at the top, and result viewing below. Utilizing three provincial solutions, expanding the scope of eCHN to include adults patients, and progressing the implementation of OLIS, existing feeds from the private labs and planned feeds from the hospitals into OLIS can be rapidly translated for delivery via OntarioMD's Report Manager, and for viewing in eCHN's viewer portal. These two functions of viewing and receiving results may be wrapped within the provincial eHealth Portal and its associated HIAL services. This conceptual model depends upon four integrations:

- **Short-term:**
  - from OLIS to OntarioMD's Report Manager, to enable rapid delivery of lab results to EMRs that are compatible with the OntarioMD CMS standards, configured to automatically retrieve and import results into the EMR.
  - from OLIS to eCHN, to enable comprehensive viewing of lab results, particularly from private labs, alongside other hospital sources of information

- **Longer-term:**
  - from eCHN to OntarioMD's Report Manager, to expand scope beyond lab results
  - via enhancement of the OntarioMD CMS Specifications, viewing from the physician EMRs of the eCHN viewer with streamlined access. Context-sensitive linking from within the EMR could be available to display in-line results from the eCHN portal within the family physician EMR. This 'portlet' functionality will enable on-demand viewing and retrieval of additional results that were not otherwise imported.

A further integration, from the family physician EMRs into OntarioMD, may be developed whereby family physician EMRs would auto-subscribe to receive results for the patients identified in their EMR roster, a patient-centric approach to delivering results.

To take advantage of the existing momentum, strategies are required. These include the need to define a vision for integration and exchange of information, gain input and engage key stakeholders, and consider the existing strengths, weaknesses, opportunities, and threats of solutions and solution components:

1. **Vision:** Understand and align with the vision of Infoway and eHealthOntario to develop and/or consolidate existing solutions including result delivery or HIE solutions, and EHR infrastructure elements. Consider developing, contributing to, or leveraging core EHR infrastructure (and HIAL) elements, such as a regional provider registry, patient registry, and the eHealth portal. Existing work on privacy and security (in WWLHIN and other LHINs across Ontario), and data sharing agreements will be key.
2. **Stakeholders/Governance**: Expand the regional partnerships to investigate and establish the most appropriate governance model to oversee HIE and health information viewer solutions. Working groups, reporting to the governance structure and representing physicians (family physicians and specialists), community care and access centers (CCACs), informatics specialists in hospitals, and local LHINs, will serve to provide support the governance with specialized and representative perspectives. These groups will consult and participate in the development, testing, and enhancement of the provincial and/or regional viewer and result delivery/HIE solutions.

3. **Expanded Regionalization**: Open channels for partnership and a shared vision for solutions with other key stakeholder groups, including neighbouring LHINs, the Ontario Medical Association (OMA), the Ontario Hospital Association (OHA), and the Ontario Association of Medical Laboratories (OAML, representing the community labs). Pilot projects of integrated provincial solutions in particular regions of excellence may be key to solution development and demonstration.

4. **Requirements**: Comprehensively define the requirements for lab result exchange, including evaluation of the nine categories of ‘requirements’ discussed above.

5. **Interim Solutions**: Evaluate the role of developing interim local standards-based solutions, leveraging WHIN's digital reports or partnering with or replicating CMH's HL7 messaging.

6. **Messaging Standards**: Evaluate candidate messaging standards that are inclusive of all EMR solutions, and for all lab service providers, such as the CMS specifications, and potentially HL7v3 CDA.

7. **Metadata Standards**: Evaluate the standardization of metadata using LOINC codes. The implementation of OLIS and/or eCHN may facilitate this messaging. LOINC functionality for EMRs that is available within the CMS specifications must also be determined, and SNOMED CT should also be considered.

8. **Research**: Expand the knowledge of the current state and readiness from diverse perspectives through The National Physician Survey, study by OntarioMD for physicians, and the OHA surveys for hospitals. Collaborate with eHealthOntario to study initiatives occurring across the province. Measure the clinical and business impact of interoperable result delivery through a research focus and research efforts embedded in the solution implementation. Research should also investigate the status and parallel progress in other provinces, and contrast to the development of HIE and related models in the US and around the world.

9. **Extension to other Clinicians**: Evaluate the lab result exchange requirements and opportunities for specialists and other physician groups (hospitalists, ER physicians, etc.) and other clinicians.
10. **Advanced Functionality**: Discuss bi-directional data flow (i.e., ordering and receiving tests and referrals). Innovate with EMR and solution vendors on the development of portlet functionality to integrate across EPR and EMR solutions.
Limitations

The risk with the chosen methodology and the author's limited and preferential exposure to solutions and environments is that preconceptions are unavoidable in the collection and analysis of the data. As such, author bias is acknowledged and may present through the results, discussion, and recommendations. The exploratory nature of the literature review and consultations lacks rigor and reproducibility, which may present as limitations in comprehensiveness of the study and results. That is, the line of investigation may have forsaken relevant alternative viewpoints and evidence.

The interviewed physicians, in several respects, represent a homogenous group. The physician characteristics were not sufficiently identified, but what is known reveals that this study provides no representation of physicians that:

- do not belong to FHT/FHO practice groups
- are associated to other hospitals
- practice in more rural geographies
- also practice as ER physicians in a hospital

With one family physician exception (that is, the physician from Alberta), none of the interviewed physicians use an EMR other than Practice Solutions nor currently receive electronic lab results from a hospital. In spite of attempts to engage physicians that may offer different perspectives due to varied roles, environments, services, and practices, this study was unable to complete interviews beyond the interviewed individuals. WWLHIN has average family physician group sizes, but in numerous ways it is clear that WWLHIN is not typical of other regions in terms of EMR adoption. WWLHIN has one of the highest rates of EMR adoption in the province, the highest saturation by Practice Solutions in any region, and the highest rate of family physician adoption of Practice Solutions. These exceptional characteristics explain the inclusion of only a single EMR and for selecting the WWLHIN region, but these unique characteristics must be acknowledged when generalizing the results and recommendations to other environments. The possibilities and issues with other EMRs and in other regions in Ontario, provinces in Canada, and regions worldwide may be quite different.

The author was unable to make contact for information from individuals from eHealthOntario, OLIS, and eCHN, so some of the related results may provide inadequate coverage of these organizations and the solutions they provide. The author was unable to receive timely approval and/or responses from the local hospitals' two Research Ethics Boards. As such, the research was modified to exclude interviews with the laboratory directors who may have been able to provide valuable insight into lab relationships, practices, trends, and opportunities from the hospital perspective.
Conclusion

The EHR journey has been likened to the building of a road system in the early 1900's. In the health care environment, family physicians and service providers in hospitals and private labs are separated by chasms of incompatibility between their information systems. We need mechanisms to connect these participants. Over the past decades, individual bridges have been built to accommodate requirements of particular groups, but these methods are disparate and require significant effort to continue to use and maintain. This has worked well in small-scale initiatives, but as regionalization of health care services is recognized as key to improving quality, efficiency, and accessibility of services, larger scale initiatives are required.

With improved capabilities, particularly by family physicians with EMRs, there is growing demand for changes to traditional information sharing practices. Furthermore, opportunities are arising with regional, provincial, and national stakeholders to coordinate efforts and consolidate solutions. Aligning the capabilities of both the information senders and receivers requires adoption of technologies that can send and receive with standardization. Standardization must recognize the requirement to structure the information so that it may be analyzed and manipulated, as well as using the same terms for content so that information from multiple sources may be compared.

It is not enough to merely provide views of organizational data as results need to be integrated with other types and sources of information. Enabling access to this consistently presented and consolidated information in the recipients application of choice will bring value. It will enhance the usability of the results for family physicians through EMR features and timely communication of results, and will improve business processes to process the information for all involved. Together these benefits may translate to measurable improvements in patient care. Private labs have been demonstrating this electronic delivery to family physicians for several years. Delivering results electronically from hospitals, while of lower volumes than from private labs and for different clinical purposes and with unique role definitions, will offer unique benefits to the continuity of care for patients as they transition from hospital to community.

In order to build these bridges of information exchange, all participants need to be engaged in a vision that demonstrates the value, aligns with current requirements, has appropriate governance, is scalable for future information needs and additional participants, and clearly defines next steps. The regional, provincial, and national stakeholders need to understand the current state and take an active role in enabling progress. With a network of shared bridges supporting information exchange between family physicians and lab service providers, development of the EHR's analogous road system will be underway.
Bibliography


Christensen T, Grimsmo A. "Development of functional requirements for electronic health communication: preliminary results from the ELIN project." Informatics in Primary Care; Sep2005, Vol. 13 Issue 3, p203-208, 6p


Farquhar MC, Barclay SIG, Earl H, Grande, GE, Emery J, Crawford RAF. "Barriers to effective communication across the primary/secondary interface: examples from the ovarian cancer patient journey (a qualitative study)." European Journal of Cancer Care; Sep 2005, Vol. 14 Issue 4, p359-366, 8p


Giacomini MK, Cook DJ. "Users' Guides to the Medical Literature: XXIII. Qualitative Research in Health Care A. Are the Results of the Study Valid?" JAMA. 2000;284:357-362.


Klijakovic M, Abernethy D, de Ruiter I. "Quality of diagnostic coding and information flow from hospital to general practice." Informatics in Primary Care; Dec2004, Vol. 12 Issue 4, p227-234, 8p


McLure M, Barnett P. "EDI provides strategy for laboratory results reporting" hfm (Healthcare Financial Management), 07350732, Jan94, Vol. 48, Issue 1


Rogoski RR. “Emerging technologies push data integration”. MLO: Medical Laboratory Observer – Online; June 2009, Special Feature, pg 37.


Appendices

Appendix A: Thesis Background

Audience
The primary intended audience and beneficiaries for this document are the key stakeholders, including the involved hospitals, labs, and family physicians, and the jurisdictions (from Local Health Integration Networks to the Ministry of Health). The lessons learned and concepts presented will be applicable to other jurisdictions, and the larger informatics community.

Context/Perspective
In the summer of 2008, for the HINF 591 course, the author completed a major literature review on Physician EMR Adoption. The result was a realization of Canada's lagging status relative to other first-world countries in terms of adoption and integration of physician office EMR solutions (Mitchell, 2008). In 2009, the Ontario Health Quality Council highlighted that “for the fourth straight year… the lack of system-wide information technology tools, such as electronic medical records, [are] one of the biggest roadblocks to a more efficient system with high-quality care. In 2007, just 25 percent of family-practice doctors in Ontario had electronic medical records, compared to 50 percent in Alberta, 98 percent in the Netherlands and 89 percent in the United Kingdom.” (OHQC, 2009) Initiatives by Canada Health Infoway, the Canadian Medical Association, and the provinces have resulted in inconsistent gains with varying incentives -- though consensus exists on the importance of adoption and integration. The next steps that were identified from this study were four-fold - "designing EMR applications and integration around physician practice models, standardization of systems and communications, integration through the continuum of patient care, and incentives for adoption." (Mitchell, 2008)

Physician e-Health is struggling with a broad lack of adoption, related to the lack of available integration. In other words, it is easier to continue with traditional practices of information management since there are inadequate opportunities, advantages, and incentives to adopt electronic solutions. Hospitals are also traditionally lacking the infrastructure and systems necessary to extend the access and use of patient information beyond internal boundaries and away from old-fashioned means of information sharing.

Recently, the author participated in an IM/IT Strategic Planning project to identify and propose a roadmap for key projects at four hospitals within the regional network. Projects related to the integration of hospital systems with physician offices represented four of the top seven priorities for the physician stakeholders. One of the author’s primary responsibilities in the role as Guelph General Hospital’s Integration Analyst, has been to implement a solution to provide hospital reports in a digital format to physicians, primarily
those within the family health teams (FHTs) within the region. Four hospitals now provide Medical
Transcription and Radiology reports in an electronic format to over 120 physicians in more than 40
offices. The sharing and integration of laboratory reports has been identified by the community physician
partners as a primary opportunity for maximum value. Another key initiative for the author includes
representing the four hospitals on the testing and implementation of the Medseek ClinicalConnect portal.
This has created rich opportunities to intricately explore the state of the local environment and the
capability of this particular solution to provide results to family physicians.

Kulikowski (2002) noted that, "a major challenge for medical informatics is to uncover principles of
information and knowledge organization and application that span this wide range of health-related
disciplines, while developing specific systems that best suit the radically different problems that arise at
the different levels of scale." This is especially applicable to information sharing between stakeholders
across the acute/primary continuum of care.

The focus of this study pulls together various aspects of the Health Informatics realm. The development
and adoption of electronic health record solutions, and messaging and content standards are a critical
feature of this research. The engagement, communication, and value to clinical, health care service and
system providers is essential to allow for growth and improvement across the continuum of care.
Appendix B: Interviews and Ethics Approval

As per the University of Victoria Research Ethics Board approval and consent form, all interviewees provided signed consent to be identified by name and credited in the results of the study, and to have their responses attributed to them by name in the results. Nine interviews were completed between March 2010 and May 2010:

- Dr. Jennifer Caspers (JC) – April 1, 2010.
- Dr. Stella Pasion (SP) – March 11, 2010.
- Dr. David Schieck (DS) – March 4, 2010.
- Dr. Chris Stemerdink (CS) – March 9, 2010.
- Dr. Shira Thomas (STh) – March 30, 2010.
- Dr. Tom Tobin (TT) – March 4, 2010.
- Dr. Steve Traplin (ST) – March 1, 2010.
The following application form is an institutional protocol based on the Tri-Council Policy Statement on the Ethical Conduct for Research Involving Humans.

Instructions:
1. Download this application and complete it on your computer. Hand-written applications will not be accepted. The ethical review process takes 4-6 weeks.
2. Use the Human Research Ethics Board Guidelines to complete this application: http://www.research.uvic.ca/Forms/. Note: This form is linked to the guidelines. Access links in blue text by hitting CTRL and clicking on the blue text.
3. Submit one (1) original and two (2) copies of this completed signed application with all attachments to Human Research Ethics Administrative Services Building (ASB), Room 8202, University of Victoria, PO Box 1700 STN CSC, Victoria BC, V8W 2Y2 Canada.
4. If you need assistance, contact the Human Research Ethics Assistant at (250) 472-4646 or ethics@uvic.ca.
5. Please note that applications are screened and will be returned to the applicant if incomplete (e.g., missing required attachments, signatures, documents).
6. Once approved, a Request for Renewal must be completed annually for on-going projects for continuing Ethics approval.

A. Principal Investigator
If there is more than one Principal Investigator, provide their name(s) and contact information below in Section B.

Last Name: Mitchell
First Name: Doug
Department/Faculty: Health Informatics
Email: damitch@uvic.ca
Phone: 519-341-4113
Fax: n/a
Mailing Address including Postal Code: 292 Watson Pkwy N, Guelph ON N1E 7J5
(if different from Dept/Faculty)

Title/Position:
☐ Faculty
☐ Undergraduate
☐ Ph.D. Student
☐ Staff
☐ Master’s Student
☐ Post-Doctoral

Students: Provide your Supervisor’s:

Name: Denis Protti
Email: dprotti@uvic.ca
Department/Faculty: Health Informatics
Phone: 250-721-814
Graduate Students: Provide your Graduate Secretary’s email address: hisgrad@uvic.ca

FOR HUMAN RESEARCH ETHICS' USE ONLY

HREB Chair Approval Signature: Protocol No.

Start Date: Annual Renewal Due:

Approval Expiry:

Figure 15: Ethics Application - Page 1
B. Project Information

Project Title: Interoperability of Lab Results for Family Physicians

Anticipated Start Date: February, 15, 2010  Anticipated End Date: April 30, 2010

Geographic location(s) of study: Waterloo-Wellington region, Ontario

Keywords: 1. Informatics  2. Interoperability  3. Physician  4. Laboratory

Is this application connected/associated/link ed to one that has been recently submitted? □ Yes  □ No

If yes, provide further information:

Other investigator(s) and Research Team:
(Include co-investigators, students, employees, volunteers, community organizations. The form will expand.)

<table>
<thead>
<tr>
<th>Contact Name</th>
<th>Role in Research Project</th>
<th>Institutional Affiliation</th>
<th>Email or Phone</th>
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For Faculty Only: Graduate Student/Research Assistant who will use this data to fulfill UVic thesis/ dissertation/ academic requirements.

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<tr>
<th>Student/Research Assistant</th>
<th>Email or Phone</th>
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C. Agreement and Signatures

Principal investigator and Student Supervisor affirm that:
- I have read this application and it is complete and accurate.
- The research will be conducted in accordance with the University of Victoria regulations, policies and procedures governing the ethical conduct of research involving human participants.
- The conduct of the research will not commence until Ethics approval has been granted.
- The researcher(s) will seek further HREC review if the research protocol is modified.
- Adequate supervision will be provided for students and/or staff.

Principal Investigator

Student’s Supervisor

_ Signature

_ Signature

Print Name

Print Name

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<td>Approval Expiry:</td>
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D. **Project Funding**

| Have you applied for funding for this project? | □ Yes | ☒ No |
| Has notice of award been received? | □ Yes | ☒ No |

If yes, please complete the following:

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<tr>
<th>Source(s) of Project Funding</th>
<th>Project Title used in Funding Application(s)</th>
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Will this project receive funding from US Funders (e.g. NIH)?

| □ Yes | ☒ No |

If yes, provide further information.

---

E. **Level of Risk**

The Tri-Council Policy Statement (TCPS) definition of "minimal risk" is as follows:

*The research can be regarded as within the range of minimal risk if potential participants can reasonably be expected to regard the probability and magnitude of possible harms implied by participation in the research to be no greater than those encountered by the participant in those aspects of his or her everyday life that relate to the research. The designation of minimal or non-minimal risk affects the way the application is reviewed not the substance of the ethical review."

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Figure 17: Ethics Application - Page 3
Based on this definition, do you believe your research qualifies as “minimal risk” research?

☐ Yes  ☐ No

Explain your answer by referring to the level of risk stated in the TCPS definition:

The involvement of human participants (physicians, physician office staff, and hospital lab management) is limited to providing information about their respective organizations, services or processes, and information systems. No possible harms are expected.

F. Scholarly Review

What type of scholarly review has this research project undergone?

☐ External Peer Review (e.g., grant review)

☒ Supervisory Committee or Supervisor—required for all student research projects

☐ None

☐ Other, please explain:

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G. Other Approvals and Consultations

Do you need to seek approval from other agencies, community groups, First Nations, local governments, etc.?

☐ Yes  ☐ No

(Attach proof of having made request for permission or approval letter. Please forward approval upon receiving them. Be assured that ethics approval may be granted prior to receipt of external approvals.)

If Yes, what types of other approval will you need?

☐ School District, Superintendent, Principal, Teacher

☐ VIHA or other regional government authority. If you are planning to conduct research (including recruitment via poster placement), in a VIHA facility you must use the Joint UVic/VIHA application form on the ORS website. Above minimal risk applications, please contact the Ethics Office.

☐ Community Group (e.g., formal organization, informal collective)

☐ Indigenous Organization (e.g., Treaty Group, Tribal Council)

☐ Indigenous Community

Approval from an Indigenous community or organization may be required when the research involves Indigenous people in relation to their community or organizational affiliation (whether residing in urban or reserve areas), the cultural knowledge and/or resources of Indigenous people, or where individuals speak on behalf of an Indigenous community or nation.

a. Does your research specifically involve or include in the study’s population sample individuals from an Indigenous community or organization?

☐ Yes  ☐ No

b. Will a particular Indigenous community, group of communities, or organization be a central focus of the research?

☐ Yes  ☐ No

c. Will the cultural knowledge, resources or heritage of an Indigenous community be a central focus of the research?

☐ Yes  ☐ No

d. If you answered “yes” to questions a), b), or c) have you consulted with the Indigenous community or communities for this study?

☐ Yes  ☐ No

e. If you answered “yes” to question d), describe the process that you have followed or will follow. Include any documentation of consultations and the role or position of those consulted, including their names if appropriate.

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f. If you answered "no" to question c), briefly justify your decision not to seek Indigenous community approval.

☐ UVic Biosafety Committee Approval. Please attach Biosafety Human Materials Form to this application. Note that Ethics Approval is contingent on Biosafety Approval.

☐ Other Approval, please explain

The hospital organizations (Guelph General Hospital, and Wellington Health Care Alliance) have an ethics review process that is contingent upon the approval of the research institution, in this case, University of Victoria. Once the approval is received from University of Victoria, the hospitals will include that approval in their local approval processes.

A request has also been made of the local family health team administrators to determine whether they have any specific approval processes. Consultation with the hospital ethics representative has identified no known formal processes/requirements for family physician involvement.

H. Description of Research Project

1. Purpose and Rationale of Research

Briefly describe in non-technical language:
Please use 150 words or less. The form will expand to the length of your answers.

1a. The research objective(s) and question(s)

The purpose of this research is to define requirements and identify solutions and a proposed roadmap for hospitals and private labs to improve the way lab results are shared electronically with family physicians. The research question is stated: "In the current environment of southwestern Ontario, how can lab service providers best provide electronic laboratory results to physician offices, such that the data can be efficiently and effectively received, integrated, and interpreted?"

1b. The importance and contributions of the research

Research of this nature is important as advances in information sharing have the potential to improve business process efficiency, enhance physician understanding and planning of patients' health care, and support enhanced adoption and usability of physician electronic medical records and other information systems. This may be accomplished through the building of partnerships and cooperative processes, and the application of standards for software systems.

1c. If applicable, provide background information or details that will enable the HREB to understand the context of the study when reviewing the application.

Access to information enables clinical services by physicians, and when information is integrated through the clinical process and in a consistent and accessible format, the utilization of that information to support the clinical practice is enhanced. Preliminary investigation into the current state of lab result sharing, and the potential solutions has revealed a number of opportunities and different mechanisms to exchange information

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between information systems. This study will link the opportunities identified in the preliminary investigation to the requirements, capacity, and value for the direct participants as defined by the study's stakeholder interviews.

I. Recruitment

2. Recruitment and Selection of Participants

2a. Briefly describe the target population(s) for recruitment. Ensure that all participant groups are identified (e.g. group 1 - teachers, group 2 - administrators, group 3 - parents).

Group 1 - Physicians and their office staff
Group 2 - Lab service providers (i.e. hospitals)

2b. Why is this population of interest?

Group 1 - Physicians are the ultimate recipients and beneficiaries of the services, and have responsibility for acknowledging/interpreting the lab results. Group 2 - Lab service providers are the source of the lab results being delivered, and have responsibility for ensuring the delivery is completed.

2c. What is the desired number of participants?

Approximately 10 physicians and/or office staff (Group 1), and lab directors of each of the involved lab service provider organizations (Group 2).

2d. What are the salient characteristics of the participants (e.g. age, gender, race, ethnicity, class, position, etc.).

The identifying characteristics of the study subjects will be the positions they hold - whether physician office staff responsible for managing results and information, physicians who provide direction for office initiatives and directly utilize the results in their information system, or the lab service directors who are responsible for the results that are provided to physicians from the lab service organizations.

2e. Provide a detailed description of your exact recruitment process. Explain:

Who will recruit/contact participants (e.g. researcher, assistant, third party)

As per dialogue with the hospital ethics board, it will be acceptable for the researcher to contact interview subjects directly so long as signed consent forms are obtained.

In the hospitals, the researcher will contact the Group 2 individuals. In the physician practices of Group 1, the researcher will contact the office/practice administrator.

ii) List and explain any relationship between the investigator(s) and participant(s) (e.g. acquaintances, colleagues). Complete item 3 if there is a power over relationship (e.g. instructor-student, manager-employee).

Group 1 - The researcher is currently involved in the technical aspects of providing results to the recipient physicians.

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Group 2 - The researcher is employed by a hospital that is providing lab services, and involved in supporting, in part, the Information services for the hospital lab services.

iii) Describe how recruitment will be done (e.g. in person, by telephone, letter, snowball sampling, word of mouth, advertisement) and from what source(s) will the participants be recruited. If applicable, include how contact information for participants will be obtained.

In both groups, relationships with the stakeholders already exist as the researcher is currently providing services to these groups. Contact information is available for group 2 via internal contact listings, and group 1 phone numbers and email addresses are available through existing provision of results to the family physicians.

iv) Describe the steps in the recruitment process.

Existing interactions have identified physician offices (group 1) who have expressed interest in lab result sharing. These offices, and lab service provider lab directors will be contacted by phone or email.

v) Indicate whether the permission of other bodies is required for recruitment (e.g. school boards).

There is no other body that requires permission for recruitment, beyond that of the hospital ethics board, as mentioned above. An inquiry has been made to the family physician team/group administration, with acknowledgement and approval of the research study participation.

3. Power-Over

If you are completing this section, please refer to the:
Guidelines For Ethics in Dual-Role Research for Teachers and Other Practitioners

Are you or any of your co-researchers in any way in a position of authority or power over participants?
Examples of a "power-over" situation include teachers-students, therapists-clients, supervisors-employees and possibly researcher-relative or researcher-close friend.

☐ Yes  ☒ No  ☐ Varies

If yes or varies, describe below:

i) The nature of the relationship.

ii) Why it is necessary to conduct research with participants over whom you have power.

iii) What safeguards (steps) will be taken to minimize inducement, coercion or potential harm.

iv) How the dual-role relationship and the safeguards will be explained to potential participants.

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Figure 22: Ethics Application - Page 8
Recruitment Materials Checklist:
Attach all documents referenced in this section (check those that are appended):
- Script(s) – in-person, telephone, 3rd party, e-mail, etc.
- Invitation to participate (e.g. Psychology Research Participation System Posting)
- Advertisement, Poster, Flyer
- None; please explain why (e.g. consent form used as invitation/recruitment guide)

J. Data Collection Methods
4. Data Collection
   For community-based research, autobiographical or observational research, please see Appendix III of the Guidelines.

4a. Which of the following methods will be used to collect data? Check all that apply.

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<td><strong>Interviewing participants:</strong></td>
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<td>- in-person</td>
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<td>- by telephone</td>
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<tr>
<td>- conducting group interviews or discussions (including focus groups)</td>
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<tr>
<td><strong>Administering a questionnaire or survey:</strong></td>
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<tr>
<td>- in person</td>
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<td>- by telephone</td>
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<td>- mail back</td>
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<td>- email</td>
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<td>- web-based</td>
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<tr>
<td>- Other, describe:</td>
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<tr>
<td><strong>Administering a computerized task:</strong></td>
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<tr>
<td>(describe in 4b)</td>
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<tr>
<td><strong>Observing participants</strong></td>
</tr>
<tr>
<td>(In 4b, describe who and what will be observed. Include where observations will take place.)</td>
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<td><strong>Recording of participants using:</strong></td>
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<tr>
<td>- audio</td>
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<tr>
<td>- video</td>
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<td>- photos or slides</td>
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<td><strong>Analyzing secondary data or secondary use of data:</strong> (Refers to information/data that was originally gathered for a purpose other than the proposed research and is now being considered for use in research, e.g. patient or school records, personal writings, lesson plans.)</td>
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Figure 23: Ethics Application - Page 9
Secondary data involving anonymized information (Information/data is stripped of identifiers by another researcher or institution before being shared with the applicant). May be eligible for Application for a Waiver from Full Ethical Review.

Secondary data with identifying information (Data contains names and other information that can be linked to individuals, e.g., student name, employment records, medical history, personal opinions).

In item 4b describe the source of the data, and explain whether and how consent was obtained from the individuals for use of their data.

- Using human samples (e.g., saliva, urine, blood, hair)

Ensure that you apply to the Biosafety Committee for the storage and use of biological materials. Also, complete the Human Materials Form, if it applies, and attach it to your application. If using human tissue only, skip to 7g-8, 11-end.

- Other. Specify: The research will gather information about the nature of use of lab result information, and the information systems and processes that support the exchange of information.

4b. Provide a sequential description of the procedures/methods to be used in your research study.

List all of the research instruments and interview/discussion questions, and in an appendix provide copies of all instruments. If not yet available, provide drafts or sample items/questions.

For multi-method or other complex research, use the following sections in ways best suited to explain your project. If you have more than one participant group, be sure to explain which participant group(s) will be involved in which activity/activities.

Interview topics will encompass value, scope, methods, requirements, vision, and strategies to develop, implement, or use solutions that support interoperability of lab results. Interviews will be qualitative, and directed by the specific nature of the involvement of the interviewed individual and their organization.

4c. Where will participation take place? (Provide specific location, e.g., UVic classroom, private residence, participant’s workplace)

Participation will occur virtually at the researcher’s private residence (participants will not appear in person, rather you dialogue with the researcher by phone or email) or in the participants workplace (i.e., physician office) or public location.

4d. How much time will be required of participants?

Interviews are expected to be not more than 60 minutes each, with 1 interview per individual, with possible email lead-up/follow-up (limited to a few minutes).

4e. Will participation take place during participants’ office hours or instructional time? If so, indicate whether other permission (e.g., from workplace supervisor) is required.

Participation will occur during participants’ office hours, or when most convenient. No permission beyond the hospital ethics approval is required of the hospital (group 2), and permission will be obtained via consent from the physician or their office staff (group 1).

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Data Collection Methods Checklist:
Attach all documents referenced in this section (check those that are appended):
☐ Standardized Instrument(s)
☐ Survey(s), Questionnaire(s)
☒ Interview and/or Focus Group Questions
☐ Observation Tools

K. Possible Inconveniences, Benefits, Risks and Harms to Participants

5. Benefits
Identify any potential or known benefits associated with participation and explain below.
Keep in mind that the anticipated benefits should outweigh any potential risks:
☒ To the participant    ☒ To society    ☒ To state of knowledge

Participation will facilitate improved understanding of the requirements and capabilities of the participants, including recipients (physicians), service providers (private/public labs), or solution providers. The solutions that are identified will ultimately have the potential to improve the business processes of family physicians (including the participants of group 1) and the lab service providers (including the participants of group 2). There will also be benefits to the health care services provided to patients in the community, and the results of the study will guide future interoperability efforts (i.e. expanding scope beyond lab result sharing, to other hospital reports such as diagnostic imaging reports).

6. Inconveniences
Identify and describe any known or potential inconveniences to participants:
Consider all potential inconveniences, including time devoted to the research.

Participants' time commitment may be perceived as an inconvenience, particularly of physicians and their office staff as short-term reduced productivity, but offset by the collaborative and mutually beneficial value of the discussion.

7. Estimate of Risks
Could this study involve the following? Please answer each question by putting an X in the appropriate boxes:
7a. Could a participant feel demeaned or embarrassed during their participation in the research?
☒ Very unlikely   ☐ Possibly   ☒ Likely
7b. Could a participant feel fatigued or stressed due to the research?
☒ Very unlikely   ☒ Possibly   ☐ Likely
7c. Could a participant experience any other emotional or psychological discomfort as a consequence of participation?
☒ Very unlikely   ☒ Possibly   ☐ Likely

FOR HUMAN RESEARCH ETHICS' USE ONLY

HREB Chair Approval Signature: ____________ Protocol No. ____________
Date: ____________

Start Date: ____________ Annual Renewal Due: ____________ Approval Expiry: ____________
7d. Is there any social risk, possible stigmatization, loss of status, privacy and/or reputation?
   - Very unlikely □ Possibly □ Likely

7e. Are there any physical risks?
   - Very unlikely □ Possibly □ Likely

7f. Could a participant experience any economic risk? (e.g. job security, job loss)
   - Very unlikely □ Possibly □ Likely

7g. Do you see any chance that participants may be harmed in any other way? (e.g. risk to community)
   - Very unlikely □ Possibly □ Likely

8. Possible Risks
   If you indicated in Item 7 (a) to (g) that any risks are possible or likely, please explain below:

8a. What are the risks?

8b. What will you do to try to minimize or prevent the risks?

8c. How will you respond if the risk of harm occurs? (e.g. what is your plan?)

9. Deception
   Will participants be fully informed of everything that will be required of them prior to the start of the research session?
   - Yes □ No (If no, complete the Request to Use Deception form on the ORS website.)

L. Compensation

10. Compensation

10a. Is there any compensation for participating in the research (e.g. gifts, honorarium, bonus points, reimbursement for transportation, parking, childcare, etc.)?
   - Yes □ No

If yes, explain the nature of the compensation and why you consider it to be necessary. Also consider if the amount of compensation could be considered to be a form of inducement.

10b. Explain what will happen to compensation if participants withdraw during or anytime after data collection (e.g. compensation will be pro-rated, full compensation will be given, etc.).
M. Free and Informed Consent

The following questions address the competence of participants to give consent, the process used in your research to obtain consent, ongoing consent, and the participants’ right to withdraw. Consult Appendix V of the Guidelines for further information.

11. Participant’s Capacity (Competence) to Provide Free and Informed Consent

Identify your prospective participants: (Check all that apply)

<table>
<thead>
<tr>
<th>Competent</th>
<th>Non-Competent</th>
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<tbody>
<tr>
<td>☑ Competent adults</td>
<td>☑ Non-competent adults:</td>
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<tr>
<td>☑ A protected or vulnerable population (e.g., inmates, patients)</td>
<td>☑ Consent of family/authorized representative will be obtained</td>
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<td>☑ Assent of the participant will be obtained</td>
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<tr>
<td>☑ Competent youth</td>
<td>☑ Non-competent youth:</td>
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<td></td>
<td>☑ Consent of parent/guardian</td>
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<tr>
<td></td>
<td>☑ Assent of the youth will be obtained</td>
</tr>
<tr>
<td></td>
<td>☑ Youth 13 to 18: consent of youth will be obtained, and parental consent is required due to institutional requirements (e.g., school district)</td>
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<td>☑ Youth 13 to 16: consent of youth will be obtained, parents will be informed</td>
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<tr>
<td></td>
<td>☑ Youth 13 to 16: consent of youth will be obtained, parents will NOT be informed</td>
</tr>
<tr>
<td></td>
<td>☑ Youth 17 to 18: consent of youth will be obtained, parents will not be informed</td>
</tr>
<tr>
<td></td>
<td>☑ Competent children</td>
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<td></td>
<td>☑ Children under 13: consent of parent/guardian will be obtained, and child consent will be obtained</td>
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<td>☑ Other, explain:</td>
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12. Means of Obtaining Consent:

(Check all that apply, attach copies of all consent materials, complete item 13)

☑ Signed consent (Attach consent script(s) and consent form(s) - see Compliance available on ORS Website)

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Figure 28: Ethics Application - Page 14

☐ Verbal consent. (Attach information letter(s). Explain below why written consent is not appropriate and how verbal consent will be documented.)

☐ Implied consent (e.g. anonymous, mail back or web-based survey. Attach information letter, see template)

☐ Other means. (Explain below and provide justification.)

☐ Consent will not be obtained. (Please see TCPS Article 2.1c and explain below)

Explain consent procedure if "verbal consent," "other" or "consent will not be obtained".

13. Informed Consent

Describe the exact steps you will follow in the process of explaining and obtaining informed consent.

14. Ongoing Consent

Ongoing consent is required for research that occurs over multiple occasions and/or extended periods of time (e.g., more than one point of contact, including second interviews, review of transcripts, etc.)

14a. Will your research occur over multiple occasions or an extended period of time?

☐ Yes ☒ No

14b. If yes, describe how you will obtain and document ongoing consent:

15. Participant's Right to Withdraw

Free and informed consent requires that participants have the right to withdraw at any time without consequence or explanation.

Describe what participants will be told about their right to withdraw from the research at any time.

The consent form will describe that they have the right to withdraw from the research before, during, or after participation in the interview. If the individual withdraws during or after the interview, discussion will occur about what may be included in the research and what must be omitted.

16. What will happen to a participant's data if the study withdraws part way through the study or after the data has been collected/Submitted? If applicable, include information about visual data such as photos or videos.

☐ It will not be used in the analysis and will be destroyed.

☐ It is logistically impossible to remove individual participant data (e.g. anonymously submitted data).

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When linked to group data (e.g. focus group discussions), it will be used in summarized form with no identifying information. Include this agreement in the consent form.

☑️ It will be used in the analysis if the participant agrees to this. Describe how this agreement will be obtained.

If a participant requests that part of their contribution be excluded from the research, the content provided by the individual will be reviewed and verbal approval to include content will be obtained and documented.

Free and Informed Consent Checklist:
Attach all documents referenced in this section (check those that are appended):
☐ Consent Form(s) – Include forms for all participant groups and data gathering methods
☐ Letter(s) of Information for Implied Consent
☐ Verbal Consent Script

17. Anonymity
Anonymity means that no one, including the principal investigator, is able to associate responses or other data with individual participants.

17a. Will the participants be anonymous in the data gathering phase of research?
☐ Yes  ☑️ No

17b. Will the participants be anonymous in the dissemination of results (be sure to consider use of video, photos)?
☐ Yes  ☑️ No

18. Confidentiality
Confidentiality means the protection of the person’s identity (anonymity) and the protection, access, control and security of his or her data and personal information during the recruitment, data collection, reporting of findings, dissemination of data (if relevant) and after the study is completed (e.g., storage).

18a. Will the confidentiality of the participants and their data be protected?

☑️ No - If confidentiality will not be protected, explain why. If you are asking the participants to waive their right to confidentiality (you plan to identify them with their data), explain what steps will be taken to respect their privacy, if any.

Information obtained is not about the individual, but rather about the organizational processes and practices. The individual is providing information about their organization on behalf of the organization. If individuals indicate they do not want to be referenced to their information, their identity will be anonymized in the dissemination of data.

☐ Yes, completely

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Date:

Start Date:

Annual Renewal Due:

Approval Expiry:

Figure 29: Ethics Application - Page 15
Yes. with limits (Check relevant boxes below.)

☐ Limits due to the nature of group activities (e.g. focus groups) the researcher can not guarantee confidentiality
☐ Limits due to context: The nature or size of the sample from which participants are drawn makes it possible to identify individual participants (e.g. school principals in a small town)
☐ Limits due to selection: The procedures for recruiting or selecting participants may compromise the confidentiality of participants (e.g. participants are identified or referred to the study by a person outside the research team)
☐ Limits due to legal requirements for reporting
☐ Other:

18b. If confidentiality will be protected, describe the procedures to be used to ensure the anonymity of participants and for preserving the confidentiality of their data (e.g. pseudonyms, changing identifying information and features, coding sheet, etc).

18c. If there are limits to confidentiality due to the methods (e.g. group interviews), sample size or legal requirements (e.g. reporting child abuse) so that you cannot guarantee confidentiality, explain what the limits are and how you will address them with the participants.

O. Use and Disposal of Data

19. Use(s) of Data

19a. What use(s) will be made of all forms of data collected (field notes, photos, videos, audiotapes, transcripts, etc.)?

Data will be documented, aggregated, analyzed, and described.

19b. Will your research data be analyzed, now or in future, by yourself for purposes other than this research project?

☐ Yes ☐ No ☐ Possibly

19c. If yes or possibly, how will you obtain consent for future data analysis from the participants (e.g. request future use in current consent form)?

19d. Will your research data be analyzed, now or in future, by other persons for purposes other than explained in this application?

☐ Yes ☐ No ☐ Possibly

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HREB Chair Approval Signature: ____________________________ Date: ____________________________

Start Date: ____________________________ Annual Renewal Due: ____________________________ Approval Expiry: ____________________________

Figure 30: Ethics Application - Page 16
19e. If yes or possibly, by whom and how will you obtain consent from the participants for future data analysis by other researchers (e.g. request future use in current consent form)?

20. Commercial Purposes

20a. Do you anticipate that this research will be used for a commercial purpose?

☒ Yes ☐ No

20b. If yes, explain how the data will be used for a commercial purpose:

The data in the research project will be used to define a recommended strategic path to provide interoperable IaA results to physicians. It is conceivable that this path will be followed, including utilization of the thesis as supporting documentation for solution evaluation and/or request for proposals, and engagement of vendors/solution providers to implement a solution.

20c. If yes, indicate if and how participants will benefit from commercialization.

Participants will not personally benefit, but they will be a beneficiary as a recipient/user of the solution that may be ultimately provided.

21. Maintenance and Disposal of Data

Describe your plans for protecting data during the project, and for preserving, archiving, or destroying all the types of data associated with the research (e.g. paper records, audio or visual recordings, electronic recordings, coded data) after the research is completed:

21a. means of storing data (e.g., a locked filing cabinet, password protected computer files):

Locked computer and password protected electronic files.

21b. location of storing data:

Personal computer, with secure archiving.

21c. duration of data storage (if data will be kept indefinitely, explain):

Research materials will be maintained for posterity, and for use only by the primary investigator.

21d. methods of destroying or archiving data:

Data (non-personal information) will be archived on a local device, and in a secure online repository for backup.

22. Dissemination

How do you anticipate disseminating the research results? (Check all that apply)

☒ Thesis/Dissertation/Class presentation

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HREB Chair Approval Signature: ____________________________

Protocol No. ____________________________

Date: ____________________________

Start Date: ____________________________

Annual Renewal Due: ____________________________

Approval Expiry: ____________________________

Figure 31: Ethics Application - Page 17
Presentations at scholarly meetings  □ Published article, chapter or book
□ Internet  □ Media (e.g. newspaper, radio, TV)
□ Directly to participants and/or groups involved. Indicate how (e.g., report, executive summary, newsletter, information session):

☐ Other, explain:

If the strategic plan to implement interoperable lab result sharing is adopted, it is anticipated that the research findings may be presented within the jurisdiction, and possibly published or presented into other jurisdictions.

P. Researchers

23. Conflict of Interest

23a. Apart from a declared dual-role relationship (Section I, item 3), are you or any of the research team members in a perceived actual or potential conflict of interest regarding this research project (e.g., partners in research, private interests in companies or other entities)? □ Yes  □ No

23b. If yes, please provide details of the conflict and how you will manage it:

24. Researcher(s) Qualifications

In light of your research methods, the nature of the research and the characteristics of the participants, what training or qualifications do you and your research team have (e.g. research methods course, language proficiency, committee experience)?

The researcher has academic training in standards, electronic records, research methods, and strategic planning, and non-academic experience in the health care environment (hospital based, including providing information technology/systems services to community physicians), engaging physicians and other service/solution providers in information system initiatives and strategic planning.

25. Risk to Researcher(s)

25a. Does this research study pose any risks to the researchers, assistants and data collectors?

No.

25b. If there are any risks, explain the nature of the risks, how they will be minimized, and how they will be responded to if they occur.

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Q. Further or Special Questions

26. Multiple Site Research

26a. Does this project involve collection of data at multiple sites within Canada requiring the approval of other sites, bodies or organizations (e.g., other ethics board(s))?
   ☒ Yes   ☐ No

26b. If you responded Yes to 26a. above, list the sites, bodies or organizations:

   Research Ethics Board of Guelph General Hospital, Research Ethics Board of Wellington Health Care Alliance

27. International Research

27a. Will this study be conducted in a country other than Canada?
   ☐ Yes   ☒ No

27b. If yes, describe how the laws, customs and regulations of the host country will be addressed:

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HREB Chair Approval Signature: ____________________________ Date: _____________

Start Date: _____________ Annual Renewal Due: _____________ Approval Expiry: _____________

Protocol No. ____________________________
Attachments*

*Ensure that all applicable attachments are included with all copies of your application. Incomplete applications will not be processed and will be returned to the applicant.

**Information for Submission**

- Applications may be printed and submitted double-sided
- Do not staple the original application with original signatures
- The two photocopies may be individually stapled or clipped
- Do not staple or clip the individual appendices
Title and label attachments as Appendix 1, 2, 3 etc. and attach the following documents (check those that are appended):

**Section I - Recruitment Materials:**

- [ ] Script(s) – in-person, telephone, 3rd party, e-mail, etc.
- [x] Invitation to participate
- [ ] Advertisement, Poster, Flyer

**Section J - Data Collection Methods:**

- [ ] Standardized Instrument(s)
- [ ] Survey(s), Questionnaire(s)
- [x] Interview and/or Focus Group Questions
- [ ] Observation Tools

**Section M - Free and Informed Consent:**

- [x] Consent Form(s) – Include forms for all participant groups and data gathering methods
- [ ] Letter(s) of Information for implied Consent
- [ ] Verbal Consent Script

- [ ] Approval from external organizations (or proof of having made a request for permission)

- [ ] Permission to gain access to confidential documents or materials

- [ ] Request to Use Deception form

- [ ] Human Materials Form

- [ ] Other, please describe:

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Subject: Invitation to Participate in 'Lab Result Sharing' Research Study
Date: February 15, 2010

Hello;

My name is Doug Mitchell. I am a graduate student at the School of Health Information Science at the University of Victoria. I am completing a study in partial fulfillment of my masters degree on how lab results are shared with family physicians.

The purpose of this research is to define requirements and identify solutions and a proposed roadmap for hospitals and private labs to improve the way lab results are shared electronically with family physicians. Research of this nature is important as advances in information sharing have the potential to improve business process efficiency, enhance physician understanding and planning of patients’ health care, and support enhanced adoption and usability of physician electronic medical records and other information systems.

I would like to invite you to participate in this study because you are a key stakeholder in the process of sharing lab results, and because of your direct involvement, experience, and/or communicated interest in lab result sharing.

If you agree to voluntarily participate in this research, your participation will include an interview to discuss questions related to the clinical value and use of lab results, mechanisms of managing lab results, and possible models of lab result sharing. The interviews may occur by phone, email, or in person at your workplace. It is anticipated that the interview will require not more than 60 minutes of time. A signed consent form (see attached) will be required before we may begin.

Please let me know by March 5th if you would be willing to participate in this study.

Thank you.

Doug Mitchell
damitch@uvic.ca
519-837-6440x2179

Figure 36: Invitation Letter
Participant Consent Form

You are invited to participate in a study entitled “Interoperability of Lab Results for Family Physicians” that is being conducted by Doug Mitchell.

I, Doug Mitchell, am a Graduate student in the School of Health Information Science at the University of Victoria and you may contact me if you have further questions by phone at 519-837-6440x2179, or by email at damitch@uvic.ca.

As a Graduate student, I am required to conduct research as part of the requirements for a degree in Health Information Science. It is being conducted under the supervision of Denis Protti. You may contact my supervisor by phone at 250-721-8814, or by email at dprotti@uvic.ca.

Purpose and Objectives
The purpose of this research is to define requirements and identify solutions and a proposed roadmap for hospitals and private labs to improve the way lab results are shared electronically with family physicians. The research question is stated: “In the current environment of southwestern Ontario, how can lab service providers best provide electronic laboratory results to physician offices, such that the data can be efficiently and effectively received, integrated, and interpreted?”

Importance of this Research
Research of this nature is important as advances in information sharing have the potential to improve business process efficiency, enhance physician understanding and planning of patients’ health care, and support enhanced adoption and usability of physician electronic medical records and other information systems. This may be accomplished through the building of partnerships and cooperative processes, and the application of standards for software systems.

Participants Selection
You are being asked to participate in this study because you are a key stakeholder in the process of sharing lab results. You were selected because of your direct involvement, experience, and/or communicated interest in lab result sharing.

What is involved
If you agree to voluntarily participate in this research, your participation will include an interview to discuss questions related to the clinical value and use of lab results, mechanisms of managing lab results, and possible models of lab result sharing. The interviews may occur by phone, email, or in person at your workplace. It is anticipated that the interview will require not more than 60 minutes of time.

Inconvenience
Participation in this study may cause some inconvenience to you in terms of time commitment.

Risks
There are no known or anticipated risks to you by participating in this research.

Benefits
The potential benefits of your participation in this research include contribution to the understanding of solution requirements, and identification of solutions that will directly benefit the processes surrounding electronic lab result sharing. The information you provide will also benefit the knowledge of the current state, and development of future states, of lab result sharing in other jurisdictions, including across the province of Ontario.

Interoperability of Lab Results for Family Physicians – Consent Form
Voluntary Participation
Your participation in this research must be completely voluntary. If you do decide to participate, you may withdraw at any time without any consequences or any explanation. If you do withdraw from the study, we will discuss what data you may already have contributed, and how you permit this to be used.

Anonymity
In terms of protecting your anonymity, your information may be specifically tied to you, but the data collected from multiple interviews will be aggregated. Unless you specifically request otherwise, you may be quoted in the thesis.

Confidentiality
Your confidentiality and the confidentiality of the data will be protected by secure storage of collected information, including password-protected storage in an online file repository.

Dissemination of Results
It is intended that the results of this study and the resulting thesis be presented to a thesis advisory committee. It is anticipated that there may be a request to share the results in the hospitals or jurisdictions that would be directly involved in lab result sharing initiatives.

Commercial Use of Results
This research may lead to identification of requirements and a roadmap to implement one or more commercial products or services, to electronically distribute lab results to physicians from hospitals and/or private labs.

Disposal of Data
Data from this study will be archived only for the researcher's own use. It will be stored electronically on the researcher's own computer system, and for backup on a secure online file repository.

Contacts
Individuals that may be contacted regarding this study include the researcher and supervisor (see above for contact information). In addition, you may verify the ethical approval of this study, or raise any concerns you might have, by contacting the Human Research Ethics Office at the University of Victoria (250-472-4545 or ethics@uvic.ca), the Research Ethics Board of Guelph General Hospital at 519-837-5440x2831 or mbott@gghorg.ca (Michelle Bott), or the Research Ethics Board of Wellington Health Care Alliance at 519-824-1010x2118 or abdostev@homewood.org (Dr Steve Abdool).

WAIVING CONFIDENTIALITY
I agree to be identified by name / credited in the results of the study. __________ (participant initials)
I agree to have my responses attributed to me by name in the results. __________ (participant initials)

Your signature below indicates that you understand the above conditions of participation in this study, that you have permission to participate, and have had the opportunity to have your questions answered by the researcher.

Name of Participant: ____________________________ Signature: ____________________________ Date: ____________________________

A copy of this consent will be left with you, and a copy will be taken by the researcher.

Interoperability of Lab Results for Family Physicians – Consent Form
Page 2 of 2
Interview Questions

• What is your specific role and responsibilities in the family physician practice?
• From which hospitals and private labs do you receive results? What proportion/type of results come from the hospitals?
• What is the clinical use of laboratory results provided by hospitals, and how does this compare to results provided by private labs?
• Are there results you do not need/want to receive (i.e. interim results, specific tests)?
• In what format/manner do you receive these results (i.e. by fax, email, etc.)?
• What challenges do you encounter with receiving results?
• What are your requirements for lab results?
• Do you insert the results into your electronic medical record? If so, what is the process?
• How is the physician notified that new results are available?
• How do you process revised or interim results?
• How are the results displayed in the electronic medical record? Describe how clinical decisions and overall patient care is influenced by the display of results?
• Describe the ideal future state for lab result sharing.

Frameworks

• Please comment on these models of lab result sharing.
• How does result sharing extend to other types of reports (i.e. medical transcribed reports, diagnostic imaging reports)?
• How will HealtheConnections and the Medseek ClinicalConnect portal change the way you access results from the hospitals?
Human Research Ethics Board  
Certificate of Approval  

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<th>Department/School</th>
<th>Supervisor</th>
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<tr>
<td>Doug Mitchell</td>
<td>HEIS</td>
<td>Denis Protti</td>
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<td>Master's Student</td>
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<td>Co-Investigator(s):</td>
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**Project Title:** Interoperability of Lab Results for Family Physicians

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**Certification**

This certifies that the UVic Human Research Ethics Board has examined this research protocol and concluded that, in all respects, the proposed research meets the appropriate standards of ethics as outlined by the University of Victoria Research Regulations Involving Human Participants.

This Certificate of Approval is valid for the above term provided there is no change in the protocol. Extensions and/or amendments may be approved with the submission of a "Request for Annual Renewal or Modification" form.

Dr. Afzal Suleman  
Associate Vice-President, Research

Figure 39: Ethics Approval
Thanks for the update Doug, I'll put this information in your file for our records.

cheers,

Shannon McCallum
Human Research Ethics Assistant | Office of Research Services | University of Victoria
Administrative Services Building B231 | PO Box 1700 STN CSC | Victoria BC  V8W 2Y2
Tel: (250) 472-4545 | Fax: (250) 721-8960 | Email: ethics@uvic.ca | Web: www.research.uvic.ca

This email message may contain confidential information and is intended only for the individuals named. If you have received this email by mistake, please notify the sender immediately and delete the email from your system.

Hello Shannon;
My approval requested that I forward approval from the research ethics boards of the Guelph General Hospital and the Wellington Health Care Alliance to be included in my file. I made a formal request, but they have collectively not been responsive. I have discussed it with my thesis advisor, and have received approval to omit the hospital interviews (group 2) and focus on the physician interviews (group 1) which are the primary emphasis, and covered through UVic’s approval.
Let me know if you have any questions. Thank you,
Doug

On Thu, Feb 11, 2010 at 8:32 PM, Human Research Ethics Review <hrerevu@uvic.ca> wrote:

Dear Doug Mitchell:

Your Application for Ethics Approval entitled 'Interoperability of Lab Results for Family Physicians' has been approved and assigned Protocol Number 10-081.

Beginning January 2, 2008, as per federal regulations, ethics protocols are approved for a one-year period. All
Principal Investigators are required to submit a Request for Annual Renewal form prior to the certificate End Date to maintain ethics approval. You will be contacted via email with a prompt for your renewal submission or project completion details approximately six weeks prior to the end date on your Certificate of Approval.

You may begin your research and will receive your Certificate of Approval via regular mail.

Good luck with your study.

Shannon McCallum
Human Research Ethics | University of Victoria | Administrative Services Building B202 | Victoria, BC | Canada
Tel: 250-472-4545 | Fax: 250-721-8960 | http://www.research.uvic.ca | E-mail: ethics@uvic.ca
Appendix C: Requirements

Requirements reflect the most significant opportunities to realize value, and the prerequisites in order to achieve those opportunities.

Regulatory Requirements
The Ontario Laboratory Accreditation (OLA) process sets out a series of mandatory requirements for licensed Ontario medical laboratories, primarily to help laboratories “deliver high-quality, efficient laboratory services.” (HICL, 2007) OLA Version 4.1 (released July 2008) spells out a number of requirements specifically related to the post-analytic reporting of results. These include:

- that results include proper identification, including the name and address of the laboratory; patient’s full name and identification number; type of specimen and source; comments on the quality of the specimen; date and time of specimen collection, laboratory receipt, and release of the report; identification of the examination, results, units of measurement; quantitative examination results accompanied by reference intervals; detection limits/limitations; and, interpretation of results. (Requirements VIII.2).

- that the results be made to persons authorized by law to receive and use medical information. (Requirement VIII.2.10)

- that reported results must be retained as required by regulation, and that copies or files of reported results shall be retained in a manner that permits prompt retrieval. (Requirement VIII.4)

- that there must be documented procedures for the release of examination results (Requirement VIII.9), and specifically for the release of results by telephone or electronic means (Requirement VIII.9.1).

- that “corrected” or altered results indicate that the new result is replacing a previously reported incorrect result – “this applies to all paper reports, as well as data that are displayed on Laboratory Information System (LIS) video terminals or terminals of other systems receiving patient data from the LIS” (Requirement VIII.11)

(OLA Requirements and Guidance Information, 2008)
Appendix D: Case Study

Current State

The following scenario illustrates the requirements related to result sharing between providers, organizations, and systems:

Carl Heath is an average, middle-aged male, who recently moved to a small town in Wellington County, Ontario. Shortly after moving, Carl registers with a family physician, Dr. Fuller, in his hometown. Dr. Fuller is a member of one of the local Family Health Teams (FHTs), Wellington FHT. Dr. Fuller's office, Community Medical Center (CMC), uses the typical Practice Solutions Suite CMS/EMR. Upon registration, Carl's electronic record is created in his physician's EMR. Carl has a complete physical where his baseline measures are established and initial problem list is identified. Dr. Fuller enters a note, and orders lab tests. Once the lab work has been collected and analyzed, the results are received by CMC, and are entered into the EMR. Dr. Fuller reviews the results, and calls Carl with the findings.

One day, Carl experiences a health care event and presents to the ER at Wellington General Hospital (WGH). An electronic patient record (EPR) is created in the hospital's information system, Meditech. Carl is assessed, and various lab tests are ordered, then collected, and resulted, and Dr. Fuller is cc'd on the results. Similarly, diagnostic imaging tests are ordered, completed, and Dr. Fuller is cc'd on the results. Finally, a copy of the emergency record is sent to Dr. Fuller. Carl requires further assessment and testing and is admitted to WGH under the attending hospitalist, Dr. Hammond who dictates a history and physical, orders additional labwork, and consults the specialist, Dr. Singh. Dr. Singh orders some further bloodwork, dictates a Consultation, which are each cc'd to Dr. Fuller. Dr. Hammond continues the care, ultimately discharging Carl, dictating a Discharge Summary to be sent to Dr. Fuller for post-hospitalization follow-up.

Through this case, Dr. Fuller received at least four sets of lab results (including from a private lab, and ordered by an emergency physician, hospitalist, and specialist), an emergency report, diagnostic imaging results, a history and physical, consultation, and a discharge summary. Each report needs to be imported into Dr. Fuller's EMR, with only the private lab results possibly doing so automatically. There is no accessibility of the results from the private lab or Dr. Fuller's office to the hospital physicians.
Future State

The following scenario illustrates the requirements related to result sharing between providers, organizations, and systems in the future state models:

Carl Heath is an average, middle-aged male, who recently moved to a small town in Wellington County, Ontario. Shortly after moving, Carl registers with a family physician, Dr. Fuller, in his hometown. Dr. Fuller is a member of one of the local Family Health Teams (FHTs), Wellington FHT. Dr. Fuller's office, Community Medical Center (CMC), uses the typical Practice Solutions Suite CMS/EMR. Upon registration, Carl's electronic record is created in his physician's EMR, and by connection with the EHR, creates a longitudinal health record, available in Ontario and across Canada. Carl has a complete physical where his baseline measures are established and initial problem list is identified. Dr. Fuller enters a note, and orders lab tests electronically. The problem list is available through the EHR, and the lab test orders are transmitted to OLIS.

Carl presents to his choice of lab, where the electronic referral is accepted, and the bloodwork is collected. Once the lab work has been analyzed, the results are transmitted by the private lab to OLIS where they are available in the iEHR for viewing, and by transmission to or query from the CMC EMR. A notification is automatically generated, and within hours of the test being ordered and within seconds of the specimens being collected and analyzed, Dr. Fuller reviews the results. The results are also viewable by Carl in his personal health record and depending on the result, a notification is manually or automatically triggered to Carl that results are available.

One day, Carl experiences a health care event and presents to the ER at Wellington General Hospital (WGH). An electronic patient record (EPR) is created in the hospital's information system, Meditech. A query to the EHR patient registry finds a match and makes Carl's records available to the ER physician, from the family physician office, the private lab (via OLIS), and Carl's personal health record. Carl is assessed, and various lab tests are ordered and resulted, diagnostic imaging tests are ordered and interpreted, and the emergency record is completed. Carl requires further assessment and testing and is admitted to WGH under the attending hospitalist, Dr. Hammond who dictates a history and physical, orders additional labwork, and consults the specialist, Dr. Singh, who orders some further bloodwork, and dictates a consultation. Ultimately, Dr. Hammond discharges Carl, dictating a Discharge Summary. The ER labwork, diagnostic imaging exams, emergency record, inpatient history and physical, labwork, consultation, and discharge summary are sent in real-time to the EHR, triggering notifications to Carl. Between the time of Carl's discharge and his presentation to Dr. Fuller for post-hospitalization follow-up, Dr. Fuller is able to review each of these normalized and trended results, with annotation by each of the responsible physicians (ER physician, hospitalist, and specialist).

Through this revised case, Dr. Fuller received notification for those results he was expected to follow-up on, and received on-demand access to the remaining of the four sets of lab results and diagnostic imaging reports, as well as notification of the emergency visit and subsequent admission, along with the corresponding notes/reports for each of the ER physician, hospitalist, and specialist.
Appendix E: Processes

The usual process to integrate the fax into an electronic medical record is as follows:

1. Report is generated.
2. Report is faxed to office.
3. Faxed report is scanned.
4. Scanned report is converted to text (via OCR).
5. OCR text is copied to clipboard.
6. Patient record is opened in EMR.
7. New report is created in EMR.
8. Clipboard is copied to EMR.
9. Patient record in EMR is filed.

An alternative process has evolved in recent years as a result of computerized fax integration with office EMRs, replacing steps 3 thru 9 with two computer-based steps:

1. Report is generated.
2. Report is faxed to office.
3. A sub-application of the EMR electronically receives the faxed report.
4. Report is classified and added to the patient record

Digital Reports

The process steps are:

1. Reports are generated from the EPR applications
2. The reports for specific enrolled physicians are sent electronically to a report distribution solution.
3. The electronic report is created as a PDF.
4. The PDF is 'read' electronically to identify the recipient and name the PDF file with key identifiers (ie. report type and date, patient name and date of birth)
5. The PDF is delivered to an FTP folder, specific to the physician's office.
6. An office staff person (usually clerical, occasionally nursing, sometimes even the physician themselves) logs in to the remote access portal via SSL-VPN.
7. The PDF files are downloaded from the FTP folder to the local PC/server.
8. The PDF files may be viewed, printed, or directly or indirectly attached to the patient record in the EMR.

Direct attachment of the report is often supported by drag’n’drop functionality, whereas the indirect attachment method is similar to the Push: Fax option described earlier:
1. Patient record is opened in EMR.
2. New report is created in EMR.
3. Clipboard is copied to EMR.
4. Patient record in EMR is filed.

Print on Demand

The process is as follows:
1. Login to the remote access portal
2. Login to the EPR
3. Identify the patient and report to be retrieved.
4. ‘Print’ the report.
5. This generates a PDF of the report into the Digital Reports folder.
7. Download the PDF report.
8. View, print, or import the report, as previously described.
Appendix F: Regional Elements

Primary Care/Family Physicians
The following Family Health organizations/teams exist within the WWLHIN:

- Center for Family Medicine FHT (Kitchener)
- East Wellington FHT (Erin)
- Grandview FHT (Cambridge)
- Guelph FHT (Guelph)
- Minto-Mapleton FHT (Palmerston)
- Mount Forest FHT (Mount Forest)
- New Vision FHN (Kitchener)
- Phoenix FHO (Guelph)
- Two Rivers FHT (Cambridge)
- Upper Grand FHT (Fergus)

Regional Lab Services
In 1996, Ho published a review of hospital lab services in Ontario. Ho (1996) identified that provincial funding is the primary and often sole source of revenue for the 200 hospital laboratories in Ontario. These hospitals, unlike their US counterparts, are prohibited from billing the provincial health insurance system (OHIP) since the annual global budget for hospitals is intended to cover the costs of outpatient services. When a pilot project between a hospital and a private lab in Parry Sound was discontinued, the hospital was not approved to continue providing the outpatient services independently as there is no mechanism for separate funding for hospitals when performing community based lab services, only when provided by private labs (Dash, 2008). In fact, outpatient specimens received by a hospital obligates the hospital to assume costs for the specimen – even if sent out to an outside lab (Ho, 1996).

The Ontario Regional Laboratory Services Planning (ORLSP) initiative developed a coordinated regional laboratory services system across 9 regions, primarily emphasizing the integration of lab information systems across service providers (particularly hospitals) in a region. (OHA, 2006). These 9 regional projects continue to exist, and often span LHIN boundaries. All hospitals utilize Ontario Public Health Laboratories for specialized testing, but:

- GGH also sends out specimens for testing to Laboratory Reference Center (LRC) in Hamilton, and to Children's Hospital of Eastern Ontario (CHEO), Kingston General Hospital (KGH), St. Michael's Hospital in Toronto, and McMaster University Medical Center (MUMC) in Hamilton.
• GMCH also sends out specimens for testing to GGH, and Lifelabs, and secondarily to MUMC and LRC.

• NWHC also sends out specimens for testing to Lifelabs and Stratford, and secondarily to Hospitals in Common Laboratories (HICL) and London Health Sciences Center (LHSC).

These relationships create complexity as results often do not interface from the receiving lab to the sending lab.

“Conglomerates of regional hospital laboratories as well as numerous partnerships and alliances between hospitals and private laboratories are the probable patterns of the future. Although hospital laboratory services may not be better, they will be far more cost effective and, in the eyes of the provincial politicians in power, affordable.” (Ho, 1996)

• In addition, hospital labs may form purchasing groups to “negotiate as a larger entity with vendors for supplies, service contracts, capital equipment, and software at reduced rates.” (Ho, 1996).

The Interhospital Laboratory Partnership of Southwest Ontario (IHLP) is an example of this form of partnership, formed out of the ORLSP. IHLP is a pan-LHIN partnership, spanning 3 LHINS and 11 hospitals (540 acute beds) in 6 member organizations in southwestern Ontario, including the two hospitals of NWHC. IHLP supports laboratory services between host hospitals, with referral to the regional lab center (Stratford General Hospital, including all pathology and microbiology testing), a private lab (Lifelabs), Ontario Public Health Labs, or to tertiary hospital labs in London or Toronto.

• To improve efficiencies, and accommodate funding constraints, hospitals have contracted out services or established formal partnerships with private laboratories, leveraging a legal loophole that allows billing of OHIP for outpatient work (Ho, 1996). An example of this existed in the WWLHIN. One of the hospitals of WHIN, Groves Memorial Community Hospital was providing community lab testing as part of a provincial pilot project under a fixed funding amount. Without funding increases, and increasing demand due to population growth and increased primary care demand, the situation became unsustainable. In 2007, the estimated costs were $200,000 in excess of the amount provided by the ministry. By transitioning community lab services to a private lab service provider, the hospital could focus on lab services for emergency, ambulatory, and admitted patients. (Lifelabs, Collaboration)

Private Labs

• CML HealthCare: provides a range of medical imaging services across Canada and the USA, and laboratory testing services, including a 30.6% market share, in Ontario. Ontario's lab testing services include one licensed medical diagnostic laboratory and 124 licensed patient service
centres, over the past 30 years acquiring 13 laboratory service businesses, from single facilities thru large multi-facility corporations. (CML)

- **LifeLabs**: Founded 15 years ago as MDS by five individuals from IBM (N. Berner, verbal communication, October 21, 2009), LifeLabs is now Canada's largest independent network of clinical laboratories, and is responsible for 31.6 percent of community laboratory services in Ontario. (Lifelabs, Funding Agreement). In addition to lab testing and results delivery, Lifelabs delivers supplies for specimen collection, and performs electrocardiograms (Lifelabs, Collaboration). N. Berner of LifeLabs stated, “In Ontario,... we deliver 35 million test results to over 6.5 million patients and 6,000 physicians annually.” (Lifelabs, Collaboration) LifeLabs' patient volumes each year are greater than all emergency room volumes in the province combined. (Lifelabs, Collaboration)

- **Gamma-Dynacare**: “formed in a dynamic partnership of three of Ontario's most prominent medical diagnostic laboratories. Its parent company LabCorp is the second largest laboratory in North America. LabCorp has the largest genetic focus of any laboratory in the world and in combination; Gamma-Dynacare now brings to Canada the largest testing menu of any laboratory as well as the very latest in laboratory technology. Gamma-Dynacare Medical Laboratories is one of the largest medical laboratory by volume in Ontario. Its 2,000 employees at its 130 collection sites and 10 Main and STAT laboratories perform millions of patient tests every year for more than 10,000 physicians and other clientele across the country.” (Gamma Dynacare, 2008) Gamma Dynacare also offers Holter monitoring and electrocardiograms. Gamma Dynacare does not have lab locations in the Guelph area. Gamma Dynacare previously offered results electronically by modem connection, but they are transitioning to a webportal solution (either manually or automatically by web service calls) (A. Chan, email communication, August 9, 2009).

In 1996, Ho found that private laboratories are able to bill OHIP for each test performed, and the more tests performed, the more revenue is generated (Ho, 1996). But private labs now function under a capped ‘fee-for-service’ funding model that limits the amount of funding that can be received, thereby limiting the testing that will be performed. This translates to a limitation on the family physician orders that may be fulfilled, and also supports the tendency for labs to maximize the performance of high efficiency tests (such as routine bloodwork), and send out the more complex and lower efficiency tests (such as genetics) to reference labs, often in hospitals. When volumes increase (in particular, for less intensive testing), the relative costs decrease, translating to greater profit for each test (Ho, 1996). Private laboratories have also tended to adopt the efficiencies associated with regionalization – that is, trading off regions with other private labs in which they have a lower market presence in order to more completely dominate a market. Private labs have also formed partnerships with hospitals and/or larger family physician practices to utilize their phlebotomy services and electronic order entry, allowing the private
laboratories to focus on lab testing. Intermediate lab services (such as Hospitals-in-Common-Laboratories (HICL)) that provide lab specimen and transport services, have also been gaining prevalence (N. Berner, verbal communication, October 21, 2009).
Appendix G: Stakeholders and Solutions

Infoway

Within the EHRS, the Health Information Access Layer (HIAL) that is described functions as the gateway connecting solutions to the rest of the EHRi and to other solutions. The HIAL consists of service components, service roles, information models and messaging standards required for the exchange of EHR Data and interoperability between EHR Services. There are common services in the HIAL, with a focus on integration, privacy and security, system configuration, management and monitoring functions. These functions are shared and reusable across EHR components. There are also 'communication bus services' that pertain specifically to enabling communication capabilities, such as receiving and sending of messages – whether between components of the EHR or with other EHRs (Canada Health Infoway, Blueprint).

The blueprint states that "several modes of communication have to be supported in order to cover the different types of interactions that are needed. Most of the communications rely on a service oriented
messaging framework for the purposes of reading and writing clinical information in and out of the EHRI. Some communications rely on streaming protocols (e.g. diagnostic imaging). Pan-Canadian EHRI communication standards are based on industry standards such as HL7, DICOM, EBXML, SOAP, SHTTP and TCP/IP. (Canada Health Infoway, Blueprint) Components of the HIAL and the EHRI exist, but as a cohesive and integrated strategy there are a number of disconnects.

**eHealthOntario**

The three priorities of eHO include diabetes, medication, and wait time management. Lab result sharing is absent in an explicit form from the three priorities, though it directly relates to functionality and utilization of many of the supporting systems defined for these priorities, that is – Physician eHealth, Hospital Information Systems, Portals, OLIS, eCHN, Registries, and the HIAL.

**eHealth Portal**

The eHealth Portal is not specifically a lab result exchange solution, but rather a framework to include access to lab result exchange. In partnership with other component solutions (such as OLIS or the OntarioMD Report Manager), the Portal could provide a consolidated and standardized single point of access, for physicians locally and across the province. eHealth's position is that the portal is “a key enabler of the eHealth Strategy” (eHealth Newsletter, 2008), and as such, it’s potential to meet requirements related to lab result sharing cannot be overlooked.

**OntarioMD Report Manager**

The OntarioMD Report Manager receives HL7 messages from hospitals, and performs real-time mapping to the CMS 'core data set' messaging specifications. These specifications were defined to permit exchange of patient records between CMS.

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![OntarioMD Report Manager Diagram](image-url)
products (i.e. in the event a patient transfers to a new family physician), and are leveraged for this additional purpose in order to support CMS non-specificity. There is no normalization of test or report names (neither LOINC nor SNOMED CT) but can accommodate ‘coding at the source’, that is, the tests will be LOINC encoded if the hospital transmits that information in the HL7 message. This solution requires local offices, dependent upon CMS functionality, to create mappings ‘on-the-fly’ that are remembered for messages/reports received in the future. Patient matching is performed in the CMS based on name, sex, date of birth, and health card number, with unmatched records being manually reconciled by the physician office. Reports are not retained in the OntarioMD Report Manager for repository-type viewing (as with OLIS, eCHN, and Medseek) but rather merely passes the reports on, logging all activity. There has been interest expressed to OntarioMD from various LHINs, not including WWLHIN. (H. Rodin, verbal communication, October 16, 2009). OntarioMD is looking to expand the reach of the Report Manager by building a Consult Case Manager solution on the same technology, to enable consult requests from family physicians to specialists (B. Forster, email communication, September 14, 2009).

OLIS

OLIS demonstrates conformance to standards (OLIS has interface specifications based on HL7 v2.3.1, and plans to support a version between 2.4 and 2.7. OLIS standardizes test names according to LOINC terminology), privacy and consent management and user registration and enrollment processes, and the
consistent and validated identification of patients, practitioners, and facilities (Waterloo Smarter Health Seminar Series, 2006).

OLIS faces some key challenges as a pioneer of eHealth initiatives in Ontario – broad, simultaneous, and varied environments for deployment, iterative development based on stakeholder input, a changing healthcare and eHealth environment forcing change in the midst of development activities, and Infoway funding and involvement. The scope of the project with limited resources continues to be a challenge, in addition to an eHealthOntario driven administration that challenges stakeholder engagement, change management, and deployment planning (“making OLIS real to stakeholders”). The development of business models and alteration of business practices in the context of a new solution such as OLIS, requires extensive engagement of vendors and lab service partners in the midst of overlapping and conflicting initiatives. Critical success factors include governance, stakeholder commitment, alignment with the political agenda, enforced standardization, consensus, and dedicated resources. Lack of message format and content standardization, closed systems, and hybrid paper/electronic environments were three challenges to be addressed by OLIS. (Waterloo Smarter Health Seminar Series, 2006).

Lakeridge Health is a foundation adopter of OLIS. Lakeridge Health, the pioneer contributing hospital corporation for OLIS, has been submitting results to OLIS since April 2007, and has recently begun using OLIS as a reference center hub to send orders and receive results electronically with LifeLabs. (N. Berner, verbal communication, October 21, 2009). Hoskins reports that the OLIS functionality is “completely embedded within our HIS” and is seamless to users. Although capability exists to query OLIS for historical results for viewing of OLIS results via the hospital's Meditech PCI results viewer application and soon Lakeridge's provider portal, this integrated view is not occurring anywhere in the province, due to ongoing OLIS privacy reviews. Hoskins states that it is a long term goal to enable CMS or portal vendors to query OLIS for historical results and return the results to the user. This may, depending on the CMS vendor, likely also include a means to import results into the physician CMS. OLIS has a “very rudimentary view portal”, but it is not endorsed to be integrated with systems, but rather intended as a standalone solution for physician offices without EMRs. (M. Hoskins, email communication, October 14, 2009)

eCHN

52 hospitals are currently contributing to eCHN, and over 100 hospitals have access to view eCHN. WHIN hospitals are currently participating in interfacing reports to eCHN. These reports are currently limited to radiology reports, with medical transcription reports and lab results scheduled for summer/fall 2010.
Access is restricted to individuals and organizations that provide care to paediatric patients – including health care providers in hospitals, Community Care Access Centres (CCAC’s), Children’s Treatment Centres (CTC’s) and family practice clinics. (eCHN Professionals, eCHN About eCHN; eCHN Membership)

Issues:

• eCHN is limited to pediatric records.
• eCHN offers no download/import functionality.
• eCHN has no integration with private lab results.
• There is no large-scale rollout of eCHN to family physicians.

Unfortunately for the purposes of this study, eCHN’s scope limitation to paediatric patients, with no indication of near-future expansion to include adults nor result delivery to physician EMRs. As a result, there is low viability that eCHN could independently serve report delivery requirements, but a partnership, for example with OntarioMD for result delivery and OLIS for private lab results, could create new potential.

**HealtheConnections and Medseek’s ClinicalConnect Portal**

The Medseek ClinicalConnect portal is perceived by some to have the highest potential for information exchange across local health care providers. This provider portal utilizes live queries to presents clinical results from various hospital information systems, making the results available for consolidated viewing via a web-based user interface. A second proposed function of the Medseek portal is to enable download of reports, based on a distinct repository structure. This functionality is under development at this time. It is intended to allow recent results for subscribed patients to be encoded in an HL7v2 formatted message, to be manually downloaded in a single packaged file (generally on a daily basis). This formatting is compatible with one EMR solution (Practice Solutions), and once downloaded to a specific local folder monitored by the EMR, the reports are available for the physician to review and automatically encode and import into the EMR.

Current Issues:

• Medseek depends upon the hospital's identification of a patient-provider relationship (i.e. where the physician is specified for the particular account as the patient's family, attending, ER, or other physician), or the physician's manual identification of a patient, to enable subscriptions to a patient.
  • If the hospital fails to define the physician relationship (i.e. if the family physician is merely entered as an “Out of Town” or free-text doctor, then the relationship will not be established
and the family physician is provided no indication that their patient is not included in their EMR subscription and the subsequent download.

- These relationships expire in the Medseek portal's EMR subscription routine 30 days after the patient is discharged. Therefore, no reports that are created or revised after 30 days post-discharge will be downloaded to the EMR.

- If a physician is not identified as having a formal relationship with a patient, but has been specified as an add-on recipient of a report, that physician will not receive the reports by download that they would otherwise receive by fax or mail.

- Medseek excludes patients, visits, or reports classified as 'confidential'. Patients may make requests for confidentiality in a number of ways - for example, a patient may request that their results be made available to providers in their circle of care (such as their family physician) but not to others (such as other care providers that may have access to the EPR or EHR). By nature of making a unique request, these patients will not be added to the EMR subscription list, and their reports will not be delivered to their family physician. There will be no indication that these results existed but were not included. Furthermore, if a patient has one visit marked as confidential, all of the patient's visits - past, present, and future - will be treated as confidential in Medseek. So, if a patient has a single confidential visit, all other visits will be restricted from having results delivered to any recipient.

- Auditing of accesses within the view portal is available, but does not provide granularity to the level of the report (rather it indicates that transcribed reports in general were accessed). A patient that requests an audit of who has accessed a particular report, or a physician office who indicates that a report was not delivered to them can not be supported with the Medseek auditing tool. There is also no auditing of downloads, and no acknowledgement that the downloading/import has been successful.

- Medseek offers no mapping to LOINC codes, so reconciliation of results across sites will be manual.

The Medseek portal is an obvious locally preferred candidate, due to the efforts and resources that have already been allocated to take advantage of funding for the solution. Unfortunately, in addition to the above issues, the following factors limit the ability of this solution to meet the requirements in the short-term:

- The download functionality is limited to only users of a single EMR solution. Almost all family physicians in WWLHIN with EMRs use PSS, but very few specialists use PSS as their EMR.

- The initial implementation is limited to only users within the family health teams, and excludes family physicians who belong to a local FHO but not to the involved FHTs.
• The download functionality is a new feature of the Medseek portal. The implementation is generally considered to be ‘pre-beta’. This has resulted in a very high number of issues that caused significant delays to the implementation targets.
• The Medseek portal currently only includes Medical Transcription reports (such as History and Physicals, Consults, and Discharge Summaries). Lab results are a future phase, with no scheduled timeline for implementation.

HeC has indicated that existing hospital peer-to-peer processes to deliver reports to physicians must continue in spite of the availability of a Medseek-based download solution. The above download process may in the long-term replace current solutions, but likely not until/unless the above issues are addressed.

Peer-to-peer

Practice Solutions (the most prevalent EMR in WWLHIN), has worked with several hospitals to arrange peer-to-peer delivery of results to physician EMRs, using SFTP for communications, and HL7 for message structure (A. Chan, email communication, March 23, 2009).
<table>
<thead>
<tr>
<th>Ownership</th>
<th>Advantages</th>
<th>Disadvantages</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>National Ownership</td>
<td>National, centralized data management</td>
<td>Costly to implement; does not take advantage of existing system investments</td>
<td>UK NHS (no Canadian equivalent)</td>
</tr>
<tr>
<td></td>
<td>High degree of standardization</td>
<td></td>
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<tr>
<td></td>
<td>Easier technical integration</td>
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<td></td>
<td>Stored data allows greater outcomes analysis</td>
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</tr>
<tr>
<td>Provincial Ownership</td>
<td>Regionalized data standards or data collection, with record locator service/registry.</td>
<td>Requires master patient index to provide a high-level of accuracy</td>
<td>OLIS eCHN OntarioMD eHealth Portal</td>
</tr>
<tr>
<td>Regional (LHIN) Ownership</td>
<td>Data accessed through portal or EHR</td>
<td>Data is not stored nationally, limiting long-term outcomes analysis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Regionalized data standards or data collection, with record locator service/registry, utilizing existing lab systems, clinical data repositories, and patient IDs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Regional (LHIN) Ownership</td>
<td>Data accessed through portal or EHR</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Regional (LHIN) Ownership</td>
<td>Single standard for data transmission/ receipt</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Regional (LHIN) Ownership</td>
<td>Leverages existing RHIO investments by permitting RHIO to RHIO exchange.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Regional (LHIN) Ownership</td>
<td>Leverages strength of current patient &gt; physician &gt; hospital relationships</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Individual Ownership</td>
<td>Data stored at the provider/ entity level, utilizing existing lab systems, EMRs, EPRs, and patient IDs</td>
<td></td>
<td>Multi-LHIN Medseek Portal (HeC)</td>
</tr>
<tr>
<td>Individual Ownership</td>
<td>Data accessed through portal or EHR</td>
<td></td>
<td></td>
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<tr>
<td>Individual Ownership</td>
<td>Single standard for data transmission/ receipt</td>
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<tr>
<td>Individual Ownership</td>
<td>Leverages strength of current patient &gt; physician &gt; hospital relationships</td>
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<tr>
<td>Individual Ownership</td>
<td>Takes into account existing system investments (at provider or entity level)</td>
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<tr>
<td>Individual Ownership</td>
<td>Precedent set with private lab result interfacing to EMRs</td>
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<tr>
<td>Individual Ownership</td>
<td>Recognizes value of push-technology</td>
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<td>Hospital-specific Portal</td>
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<tr>
<td>Individual Ownership</td>
<td></td>
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<td>Private lab feeds</td>
</tr>
</tbody>
</table>

Table 8: Model Comparison (based on HHS Models of Ownership, 2006)
Appendix I: Standards

HL7
HL7 is an organization that supports the development of a framework and related standards/specifications.

HL7v2
HL7v2 is supported by every major health information system vendor in the US, and most US laboratory and diagnostic systems deliver their results electronically via HL7v2 (McDonald, 2003). HL7v2.3 was the most commonly used standard in the OHA survey (OHA, 2006).

HL7v3 CDA
HL7v3 is a specification developed by Health Level Seven (HL7) and certified by the American National Standards Institute (ANSI).

A CDA document consists of a header that, using XML-encoded metadata elements, identifies and classifies the document and provides additional details on the authentication, encounter, patient, and involved providers, and a body that contains the actual clinical report. The body may be organized into sections, with capacity to encode using standard vocabularies. Attributes unique to the RIM exist to support key clinical concepts using these vocabularies, including, for example, a data type to support post-coordination of SNOMED CT terms. (Dolin, 2006) A clinical document is defined as having longevity (as compared to the transiency of ‘messages’), stewardship by an organization, the ability to be legally authenticated, a specific context (ie. a patient visit), completeness (not being split), and human readability (CDA R2 Normative webedition). These attributes are supported through the CDA.

Flexibility is revealed in the the XML structure that is able to accommodate varying degrees of encoding, while maintaining full compliance. For example, a CDA document body may reference an external document (whether it be PDF, Word document, or image), may include a block of un-encoded text, or, unique to CDA R2, the body may capture discrete data elements in individually coded sections. This permitted range of complexity within the specification is referred to as “incremental semantic interoperability”, where the standard allows the user to implement at one level of compliance, with the possibility to define further markup beyond the CDA schema, and in some cases, use coded values that are not defined in the code sets (Dolin, 2006; HL7 Library; HL7 FAQ). A particular strength of CDA is the readability. The natural design of XML messages enables electronic processing, parsing, and formatting of documents (machine readability), but the human readability is what distinguishes the CDA from
messaging standards such as HL7 V2 and V3. Through simple and configurable XML rendering, the documents can be formatted to be displayed in a clear and usable format at the point of care, using basic technology such as browsers or smart phones. (HL7 FAQ; HL7 Library)

In Canada, the Dalhousie Discharge Summary System has resulted in prototyping of structured CDA R1-based documents to exchange reports from hospitals to community-based family practice (HL7 CDA Brief). In Victoria BC, MedEmed is a research initiative to develop a CDA-driven middleware solution facilitating information flow across networks of integrated information systems (HL7 CDA Brief). Furthermore, CDA is endorsed by Canada Health Infoway through support of HL7 V3 models (HL7 CDA Brief). The current state of adoption, though, is a barrier to short-term standardization. CDA may be monitored into the future as a potential long-term solution, particularly for narrative documents.

Integration Frameworks/Profiles
Integrating the Healthcare Enterprise (IHE) develops Integration Profiles as specific guides to the implementation of existing standards to address specific clinical information management use cases, and solve interoperability problems. (IHE 2009) IHE Laboratory is an IHE Domain that addresses information sharing and workflow related to diagnostic testing in clinical laboratories and at the point of care. Sharing Laboratory Reports (XD-LAB) is a Content Integration Profile that describes the sharing between systems of a clinical laboratory report. This report is described as an electronic document containing a set of results produced by a clinical laboratory, that is both human readable and importable into the target system. The scope of this profile excludes anatomic pathology, while including all other laboratory specialties. The profile describes the role of Content Creator (such as a lab service provider) who defines a stylesheet to render the report content readable by the Content Consumer (the Care provider). The Content Consumer also may have the option of importing the entire report, a section of the report, or the discrete data elements within sections of the report, to become part of the patient record. (IHE, 2007) The benefits include continuity of care through access to laboratory reports, reduced lab test ordering and collection by expanding the sharing of results from previous tests, and enablement of the consolidation of the patient’s lab history into the family physician’s office electronic medical record. Six major use cases are defined for the XD-LAB Integration Profile, including specific sharing of summary or cumulative results from the hospital information system to the family physician. (IHE, 2008). This profile is specifically built upon the HL7 CDA Release 2 standard for structure and content, and LOINC for terminology, and depends upon three other profiles, including XDS (Cross Enterprise Document Sharing) and XDM (Cross-Enterprise Document Media Interchange) which describes the transfer of documents as email attachments. XD-LAB has a status of “Trial Implementation” (IHE, 2008), and XD-LAB Profile implementations exist in Italy, US, Japan, and France. (IHE, 2007)
Communication Standards

Communication standards allow systems to connect to each other, and provide a means to exchange information. These standards may include the protocols to form a connection, as well as the means to exchange and secure information (the channel).

A Point-to-Point (P2P) Interface is a dedicated mechanism to exchange messages (usually HL7) between the sender and the recipient. P2P interfaces often use the Internet Protocol Security (IPSec), a framework of open standards. Ideally, both the sender and receiver would employ an interface engine bound to a static IP address to transmit acknowledgement responses for any received message. Point-to-point enables typically one sender to connect directly to one recipient, with replicability for many recipients. Each recipient must setup and maintain a connection to each sender that uses this approach – for example, to each of a private lab and one or more hospitals. This mechanism also depends upon constant connection between the sender and receiver, which is challenging for a small physician office potentially connecting to more than one hospital or private lab, and challenging to maintain and troubleshoot for individual hospitals and lab providers interacting with numerous physician offices.

Alternatively, a portal provides a more open-ended mechanism to connect one or more providers of information to many recipients. This enables a single sender, such as a hospital, to develop a single integration for all physician offices. It may also enable a single physician office to receive information from several participating hospitals. A portal is commonly installed on an infrastructure that consists minimally of a physical server, webserver installation to provide HTTP services, and security mechanisms including a firewall, secure communications (such as VPN) and authentication. A suite of services provides access to applications designed for this infrastructure to enable the access and exchange of interactive information. Portals are developed for a broad range of functions, including remote access over the internet to one or more components of the information systems for a hospital, lab, or regional solution. Portal technology is the foundation behind some existing local hospital based remote access solutions, and regional projects such as eCHN and Medseek/CCV. In the broker sense of a portal, OLIS and the OntarioMD report manager may be included.

Within the scope of Portals, Secure Socket Layer Virtual Private Network (SSL-VPN) may be used to connect individuals securely to a central data source or private network. SSL requires users to be authenticated, and uses cryptographic algorithms to encrypt data that is shared over the insecure Internet, most commonly as a web-based application using the Secure HTTP (HTTPS) standard. As of 2006, SSL VPN was not itself a standard, but rather was made up of standards-based components (such as SSL and HTTP) from the Internet Engineering Task Force (IETF) (Steinberg, 2006). In practice, VPNs
do have a tendency to disconnect fairly often, which is difficult for hospital information technology staff to troubleshoot for physicians. (A. Chan, email communication, March 23, 2009). Currently, standard unencrypted file transfer protocols (FTP) over SSL-VPN is used in WHIN to exchange reports with community physicians with a commonly accepted degree of security and familiar method of access. Secure Shell (SSH) is an alternative means of facilitating the secure and encrypted exchange or transfer of files over the Internet. The value of SFTP is that there is no requirement for a direct connection to the hospital which may depend upon unreliable surrounding Internet connections. Using SFTP has been found to significantly reduce support costs (A. Chan, email communication, March 23, 2009).
## Appendix J: Glossary and Abbreviations

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Definition</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>BCMA</td>
<td>British Columbia Medical Association</td>
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<tr>
<td>CCAC</td>
<td>Community Care and Access Center</td>
<td>Home care</td>
</tr>
<tr>
<td>CCV</td>
<td>Common Clinical Viewer</td>
<td></td>
</tr>
<tr>
<td>CDA</td>
<td>Clinical Document Architecture</td>
<td>HL7's v3 standard</td>
</tr>
<tr>
<td>CHI</td>
<td>Canada Health Infoway</td>
<td></td>
</tr>
<tr>
<td>CMA</td>
<td>Canadian Medical Association</td>
<td></td>
</tr>
<tr>
<td>CMH</td>
<td>Cambridge Memorial Hospital</td>
<td>One of the hospitals of WWLHIN</td>
</tr>
<tr>
<td>CMH</td>
<td>Cambridge Memorial Hospital</td>
<td>One of the hospitals of WWLHIN</td>
</tr>
<tr>
<td>CML</td>
<td>Canadian Medical Laboratories</td>
<td>One of three private labs in Ontario</td>
</tr>
<tr>
<td>CMS</td>
<td>Clinical Management System</td>
<td>See also Electronic Medical Record (EMR)</td>
</tr>
<tr>
<td>CPDB</td>
<td>Corporate Provider Database</td>
<td>Owned by Provider Services Branch, Operated and maintained by Health Services Cluster in Kingston, Nightly transmission of updates to OLIS, Used to validate practitioners and laboratories authority to order tests [OLIS Fundamentals]</td>
</tr>
<tr>
<td>CPSO</td>
<td>College of Physicians and Surgeons of Ontario</td>
<td></td>
</tr>
<tr>
<td>CWLHIN</td>
<td>Central West Local Health Integration Network (LHIN 5)</td>
<td>A regional health organization that neighbours WWLHIN</td>
</tr>
<tr>
<td>DI-r</td>
<td>A regional diagnostic imaging repository, across multiple PACS solutions</td>
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<tr>
<td>ECG</td>
<td>Electrocardiogram</td>
<td></td>
</tr>
<tr>
<td>eCHN</td>
<td>Electronic Child Health Network</td>
<td>Ontario's pediatric EHR</td>
</tr>
<tr>
<td>EDI</td>
<td>Electronic Data Interchange</td>
<td></td>
</tr>
<tr>
<td>eHO</td>
<td>eHealthOntario</td>
<td></td>
</tr>
<tr>
<td>EHR</td>
<td>Electronic Health Record</td>
<td>Regional, trans-organization medical record</td>
</tr>
<tr>
<td>EMR</td>
<td>Electronic Medical Record</td>
<td>Physician office-based medical record. See also Clinical Management System (CMS)</td>
</tr>
<tr>
<td>EPR</td>
<td>Electronic Patient Record</td>
<td>Hospital-based medical record. See also Hospital Information System (HIS)</td>
</tr>
<tr>
<td>Exchange</td>
<td></td>
<td>Compilation, sending/transmission, receipt, and import</td>
</tr>
<tr>
<td>FHG</td>
<td>Family Health Group</td>
<td>A family practice model, with a primarily fee-for-service funding model</td>
</tr>
<tr>
<td>FHN</td>
<td>Family Health Network</td>
<td>A family practice model, with a blended capitation funding model</td>
</tr>
<tr>
<td>FHO</td>
<td>Family Health Organization</td>
<td>A family practice model consisting of multiple FHGs, with a blended capitation funding model</td>
</tr>
<tr>
<td>FHT</td>
<td>Family Health Team</td>
<td>A family practice model consisting of multiple FHOs, will a salary funding model</td>
</tr>
<tr>
<td>FTP</td>
<td>File Transfer Protocol</td>
<td></td>
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<tr>
<td>GGH</td>
<td>Guelph General Hospital</td>
<td>One of the hospitals of WHIN</td>
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<tr>
<td>GMCH</td>
<td>Groves Memorial Community Hospital</td>
<td>One of the hospitals of WHCA and WHIN</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Description</td>
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<tr>
<td>GP</td>
<td>General Practitioner/ Family Physician</td>
<td></td>
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<tr>
<td>GRH</td>
<td>Grand River Hospital/ One of the hospitals of WWLHIN</td>
<td></td>
</tr>
<tr>
<td>HC</td>
<td>HealtheConnections</td>
<td></td>
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<tr>
<td>HIAL</td>
<td>Health Information Access Layer</td>
<td></td>
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<tr>
<td>HIE</td>
<td>Health Information Exchange/ “The mobilization of health information electronically across organizations within a region or community” (eHI, 2005)</td>
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<tr>
<td>HIS</td>
<td>Hospital Information System/ See also Electronic Patient Record (EPR)</td>
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<tr>
<td>HL7</td>
<td>Health Level 7/ A messaging standard</td>
<td></td>
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<tr>
<td>HHNLHLHIN</td>
<td>Hamilton Niagara Haldimand Brant Local Health Integration Network (LHIN 4)/ A regional health organization that neighbours WWLHIN</td>
<td></td>
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<tr>
<td>HSC</td>
<td>Hospital for Sick Children</td>
<td></td>
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<tr>
<td>IHE</td>
<td>Integrating the Healthcare Enterprise</td>
<td></td>
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<tr>
<td>IHLP</td>
<td>Interhospital Laboratory Partnership of Southwest Ontario</td>
<td></td>
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<tr>
<td>IM</td>
<td>Information Management</td>
<td></td>
</tr>
<tr>
<td>Import</td>
<td>A function of the information system to accept and attach data (for viewing and interpretation/reference)</td>
<td></td>
</tr>
<tr>
<td>IT</td>
<td>Information Technology</td>
<td></td>
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<tr>
<td>ITIL</td>
<td>Information Technology Infrastructure Library</td>
<td></td>
</tr>
<tr>
<td>LHIN</td>
<td>Local Health Integration Network/ Ontario's regional health organizations</td>
<td></td>
</tr>
<tr>
<td>LILI</td>
<td>Laboratory Licence and Lab Inspection/ Owned by Laboratories Branch Operated and maintained by Health Services Cluster at CPHL – Resources Road Nightly transmission of updates to OLIS Used as a principle identifier for labs and collections Used to confirm a laboratory’s authority to perform tests(not confirmed if received after the fact) [OLIS Fundamentals]</td>
<td></td>
</tr>
<tr>
<td>LIS</td>
<td>Laboratory Information System/ In the hospitals, a component of the EPR/HIS; in the private labs, the lab's information system.</td>
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<tr>
<td>LMH</td>
<td>Louise Marshall Hospital/ One of the hospitals of NWHC, WHCA, and WHIN</td>
<td></td>
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<tr>
<td>LOINC</td>
<td>Logical Observation Identifiers Names and Codes/ A lab test meta data standard</td>
<td></td>
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<tr>
<td>LTC</td>
<td>Long-term Care/ Includes nursing homes</td>
<td></td>
</tr>
<tr>
<td>MOHLTC</td>
<td>Ministry of Health and Long Term Care</td>
<td></td>
</tr>
<tr>
<td>OAML</td>
<td>Ontario Association of Medical Laboratories</td>
<td></td>
</tr>
<tr>
<td>OHA</td>
<td>Ontario Hospital Association</td>
<td></td>
</tr>
<tr>
<td>OLA</td>
<td>Ontario Laboratory Accreditation</td>
<td></td>
</tr>
<tr>
<td>OLIS</td>
<td>Ontario Laboratory Information System</td>
<td></td>
</tr>
<tr>
<td>OMA</td>
<td>Ontario Medical Association</td>
<td></td>
</tr>
<tr>
<td>OMD</td>
<td>OntarioMD</td>
<td></td>
</tr>
<tr>
<td>ORLSP</td>
<td>Ontario Regional Laboratory Services Planning</td>
<td></td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Description</td>
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<tr>
<td>PACS</td>
<td>Picture and Archiving Communication System (Digital diagnostic imaging system)</td>
<td></td>
</tr>
<tr>
<td>pCLOCD</td>
<td>pan Canadian Laboratory Observation Code Database (See LOINC)</td>
<td></td>
</tr>
<tr>
<td>PDF</td>
<td>Portable Document Format (A document standard)</td>
<td></td>
</tr>
<tr>
<td>PDH</td>
<td>Palmerston and District Hospital (One of the hospitals of NWHC, WHCA, and WHIN)</td>
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<tr>
<td>PHIE</td>
<td>Provincial Health Information Exchange (Alberta’s provincially managed information ‘hub’)</td>
<td></td>
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<tr>
<td>PHR</td>
<td>Personal Health Record</td>
<td></td>
</tr>
<tr>
<td>PHRP</td>
<td>Personal Health Record Portal</td>
<td></td>
</tr>
<tr>
<td>PLIS</td>
<td>Provincial Laboratory Information Solution (BC’s equivalent to Ontario’s OLIS)</td>
<td></td>
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<tr>
<td>RHOIO</td>
<td>Regional Health Information Organization</td>
<td></td>
</tr>
<tr>
<td>ROI</td>
<td>Return on Investment</td>
<td></td>
</tr>
<tr>
<td>RPDB</td>
<td>Registered Persons Database (Owned by Registration and Claims Branch. Operated and maintained by Health Services Cluster in Kingston. Nightly transmission of updates to OLIS. Used to validate patient Health Numbers and to check OHIP eligibility [OLIS Fundamentals])</td>
<td></td>
</tr>
<tr>
<td>Secure FTP</td>
<td>Secure File Transfer Protocol (A normal FTP protocol session over SSH)</td>
<td></td>
</tr>
<tr>
<td>SFTP</td>
<td>SSH File Transfer Protocol (A special file transfer protocol developed specifically to run over SSH)</td>
<td></td>
</tr>
<tr>
<td>SLA</td>
<td>Service Level Agreement</td>
<td></td>
</tr>
<tr>
<td>SMGH</td>
<td>St. Mary’s General Hospital (One of the hospitals of WWLHIN)</td>
<td></td>
</tr>
<tr>
<td>SNOMED CT</td>
<td>Systematized Nomenclature of Medicine -- Clinical Terms</td>
<td></td>
</tr>
<tr>
<td>SSHA</td>
<td>Smart Systems for Health Agency (Now merged with eHealthOntario)</td>
<td></td>
</tr>
<tr>
<td>SSL VPN</td>
<td>Secure Socket Layer Virtual Private Network</td>
<td></td>
</tr>
<tr>
<td>SWLHIN</td>
<td>Southwestern LHIN (LHIN 2) (A regional health organization that neighbours WWLHIN.)</td>
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<tr>
<td>VIHA</td>
<td>Vancouver Island Health Authority (One of BC’s regional health authorities)</td>
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</tr>
<tr>
<td>WHCA</td>
<td>Wellington Health Care Alliance (A compilation of 3 hospitals (2 corporations) within Wellington county – North Wellington Health Care (consisting of Palmerston and District Hospital, and Louise Marshall Hospital) and Groves Memorial Community Hospital.)</td>
<td></td>
</tr>
<tr>
<td>WHIN</td>
<td>Wellington Hospitals Information Network (A compilation of 4 hospitals (3 corporations) within Wellington county – Wellington Health Care Alliance (including North Wellington Health Care (Palmerston and District Hospital, and Louise Marshall Hospital), and Groves Memorial Community Hospital) and Guelph General Hospital.)</td>
<td></td>
</tr>
<tr>
<td>WWLHIN</td>
<td>Waterloo-Wellington Local Health Integration Network (LHIN 3) (The regional health organization coordinating services and funding for the Waterloo-Wellington region)</td>
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</tbody>
</table>