Approaches to Accountability in the Medical Laboratory Sector in Ontario

By

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Abstract

Purpose: Greater accountability within the Ontario medical laboratory sector is a high priority and desirable. This sector provides approximately 80% of the objective data for diagnosis, monitoring and treatment. The goal of this study is to determine how accountability is defined, and the advantages and challenges of the approaches used in this sector.

Methodology: A case study design based on a mix methods approach incorporating quantitative (i.e., scoping review of documents) and qualitative data (i.e., 20 semi-structured interviews) to examine the approaches to accountability in the medical laboratory sector and the implication of core independent variables on the approaches used. Key stakeholders in the medical laboratory sector were interviewed to determine views on the advantages and challenges of the possible approaches.

Results

The four approaches to accountability used in the medical laboratory sector are: financial incentives, regulations, information directed towards potential users, reliance on professionalism and stewardship. Regulation is the main approach to accountability in the medical laboratory sector. Ontario Laboratory Accreditation and licensing by the Ontario government is mandatory in all laboratories except those found in physicians' offices.

There were variations in the approaches to accountability based on core independent factors such as: policy goal being pursed, the governance /ownership structures and the goods and services being delivered and their production characteristics. Laboratory services are delivered by public health, hospitals, large community based laboratories and small laboratories often found in physicians' offices.

Key informants identified quality and safety as top priorities regardless of the approach that is used. Concern for costs and resources exists within the sector as a whole. Laboratory results gain much of their value by being embedded within a system of care, in which providers order tests appropriately and are aided in interpreting and acting upon their results. The pre/post analytical stages are just as important as the analytical stage in measuring performance and ensuring validity, reliability and accountability.

Conclusion:

While the medical laboratory sector is highly regulated, the implementation of additional mechanisms to enhance accountability in the pre/post analytical phases is needed. The importance of this is further highlighted by the advancement of point of care testing at the bedside, the pharmacy and at home which is not fully captured by the accountability mechanisms currently in place. Advances in new technologies such as molecular and genetic testing will also impact future accountability in the medical laboratory sector.

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Table of Contents

LIST OF TABLES

LIST OF APPENDICES

LIST OF ABBREVIATIONS

AABB	American Association of Blood Bankers
CADTH	Canadian Agency for Drugs and Technologies in Health
CAP	College of American Pathologists
CHA	Canada Health Act
CHA	Canadian Healthcare Association
CBC	Canadian Broadcasting Corporation
CBS	Canadian Blood Services
CDC	Centers for Disease Control and Prevention (United States)
CIHR	Canadian Institutes of Health Research
CHST	Canada Health and Social Transfer
CIHI	Canadian Institute for Health Information
CLMA	Clinical Laboratory Management Association
CMA	Canadian Medical Association
CMLTO	College of Medical Laboratory Technologists of Ontario
CNA	Canadian Nuclear Association
CNSC	Canada Nuclear Safety Commission
CPSO	College of Physicians and Surgeons of Ontario
CSMLS	Canadian Society of Medical Laboratory Sciences
CPHA	Canadian Public Health Association
EQA	External Quality Assessment
HAAS	Health Advisory and Assessment Services

HPRAC	Health Professional Regulated Advisory Council
HSAA	Hospital Service Accountability Agreement
HSRC	Health Services Restructuring Commission
ISO	International Organization for Standardization
LCDC	Laboratory Centre for Disease Control
LIS	Laboratory Information System
LPTP	Laboratory Proficiency Testing Program
LHIN	Local Health Integration Networks
LSRS	Laboratory Services Restructuring Secretariat
ML sector	Medical Laboratory Sector
MLT	Medical Laboratory Technologist
MOHLTC	Ministry of Health and Long-Term Care (Ontario)
NUPGE	National Union of Public and General Employees
OAML	Ontario Association of Medical Laboratories
OHIP	Ontario Health Insurance Plan
OHSA	Occupational Health and Safety Agency
OAHPP	Ontario Agency for Health Protection and Promotion
OHC	Ontario Health Coalition
OLA	Ontario Laboratory Accreditation
OMA	Ontario Medical Association
OSMT	Ontario Society of Medical Technologist
P4P	Pay For Performance
PUC	Public Utilities Commission

PHAC	Public Health Agency of Canada
PHSI	Partnership for Health System Improvement
POCT	Point-of-care testing
QA	Quality Assurance
QMP-LS	Quality Management Program – Laboratory Services
RHA	Regional Health Authorities
RHPA	Registered Health Professional Act
SOP	Standard Operating Procedure
UOIT	University of Ontario Institute of Technology
WHO	World Health Organization

Definition of Key Terms and Concepts

As this research will address major approaches to accountability currently being used in the health sector in Canada and internationally, one must recognize the context in which these concepts are employed. All terms are defined by the Merriam-Webster Dictionary

Accountability: the quality or state of being accountable; *especially* an obligation or willingness to accept responsibility or to account for one's actions.

Incentives: something that incites or has a tendency to incite to determination or action.

Regulations: an authoritative rule dealing with details or procedure e.g. safety *regulations* or a rule or order issued by an executive authority or regulatory agency of a government and having the force of law.

Professionalism: the conduct, aims, or qualities that characterize or mark a profession or a professional person.

Stewardship: the conducting, supervising, or managing of something; the careful and responsible management of something entrusted to one's care.

Chapter 1

Introduction

1.1 Statement of the problem

Accountability in health care has become a topic of great interest. Governments, researchers and the tax-paying public are paying closer attention to quality indicators such as patient outcomes, decreased wait times, cost containment, and quality of care (Deber, 2010). Canadian citizens themselves issued a strong challenge for greater accountability within the healthcare sector (The Romanow Inquiry, 2002). The recent Nanos poll shows that Canadians ranked keeping our health care system strong as the number one priority. (IRPP Nanos Survey, 2012). In 2001, Listening for Direction: A National Consultation on Health Services and Policy Issues, identified governance and accountability as a major research theme (Listening for Directions, 2012).

Strengthening accountability is central to the recommendations made in all recent studies on the future of health care (Brown, 2004). The *Excellent Care for All Act, 2010* highlights the commitment of the government of Ontario to accountability in healthcare by stating that it will *"*put patients first by improving the quality and value of the patient experience through the application of evidence-based health care" (The *Excellent Care for All Act, 2010).*

Demand for greater accountability within the medical laboratory sector became a priority following a number of recently publicised cases. The Krever's Commission of Inquiry in 1994 examine issues of accountability relating to the transmission of HIV and Hepatitis C through contaminated blood from the Canadian Red Cross. It was estimated that close to 30,000 Canadians were exposed to the Hepatitis C virus through transfusion of contaminated blood or

blood products (Krever commission, 1994). Further, there was the Walkerton Inquiry in 2000, in which seven persons died and over two thousand more became ill after drinking water contaminated with *E. coli* bacteria in Walkerton, Ontario. The investigations revealed that the laboratory tests conducted were accurate and valid. The errors occurred in the pre and post analytical phases of testing due mainly to operator negligence. The Cameron Commission of Inquiry on Hormone Receptor Testing (2009) undertaken by the Government of Newfoundland and Labrador examined accountability for laboratory test results for breast cancer patients. It was determined that between 1997 and 2005, 383 patients received wrong results which impacted the treatment program for their breast cancer (Commission of Inquiry on Hormone Receptor Testing, 2009). The more recent example occurred in a number of Alberta hospitals in December 2011. Systematic errors in testing negatively impacted the diagnosis and treatment of cancer patients in that province (Komarnicki, 2012; Canadian Association of Pathologist, 2012).

In the past, it was believed that accountability processes in the medical laboratory sector were simple and easy to monitor, but the recent Cameron Inquiry noted, "there was a failure of both accountability and oversight at all levels" (Commission of Inquiry on Hormone Receptor Testing, 2009). Many stakeholders, including the Ontario Ministry of Health and Long Term Care (MOHLTC), have indicated that accountability is an area of great importance to them and highlight the need for more empirical and theoretical evidence to guide the approaches to accountability measures that are used (MOHLTC, 2012).

1.2 What is Accountability?

Accountability, simply defined means having to answer to someone for meeting defined objectives (Emanuel & Emanuel, 1996; Marmor & Morone, 1980; Fooks & Maslove, 2004). The result of the literature review indicated that many scholarly papers have been written on

accountability (Fooks & Maslove, 2004; Abelson & Gauvin, 2004; Minkler, 2004). However, much of this work did not focus on accountability in healthcare and more specifically in the medical laboratory sector. The literature indicates that accountability has financial, performance and political/democratic implications, (Binkerhoff, 2004) and can be ex ante or ex post (Klein, 1993). Within healthcare, this may translate into fiscal accountability to payers, clinical accountability for quality of care, (Binkerhoff, 2004) and accountability to the public. The players involved may include various combinations of providers, patients, payers, and regulators who are connected in various ways (Fooks & Maslove, 2004; Binkerhoff, 2004; Klein, 1993). One of the ways that many healthcare organisations inform the public on accountability issues is through a variety of quality indicators such as hospital mortality rates, emergency department length of stay, and readmission rates. The medical laboratory sector uses a variety of performance indicators such as quality assurance and assessment to inform providers on accountability.

1.3 The novelty of this thesis

As indicated in the literature, there is need for more research on approaches to accountability and an increasing recognition that variation exists between healthcare sectors and within sectors (e.g., medical laboratory sector- ML sector). A more nuanced understanding necessarily begins with clarifying what is meant by accountability, including specifying for what, by whom, to whom and how (Deber, 2010). One conceptual innovation of this thesis is that it will draw upon several theoretical frameworks, which, although highly relevant, have existed in silos, and have not necessarily been applied to issues of accountability within the healthcare sector in general and the medical laboratory sector specifically.

This thesis is part of a large Partnership for Health System Improvement (PHSI) study funded by the Canadian Institutes for Health Research (CIHR). The purpose of this PHSI study was to examine and compare the approaches to accountability across eleven different healthcare sectors. The importance of this issue was endorsed by the government and various community partners. The MOHLTC stated that "accountability is a vitally important area to the MOHLTC and the proposed work is particularly timely." Strong letter of support for research of this kind was also received from the Quality Management Program-Laboratory Services (QMP-LS), an organization operated by the Ontario Medical Association (OMA) with special responsibilities for quality assurance in Ontario's medical laboratories. The ML sector provides approximately 80% of data used by physicians in the diagnosis, treatment and monitoring of patients, as well as disease surveillance. The majority of laboratory testing in this province is publicly funded and therefore this sector should be held accountable for its use of tax-payers money. The lack of significant research in this field was a motivating factor for the researcher to choose medical laboratories as the study sample. Working on an interdisciplinary team will provide an opportunity to compare and contrast approaches to accountability across healthcare sectors to clarify what is known about best practices.

1.4 Research Hypothesis

The impact of the approaches to accountability present in the ML sector is a function of three independent core variables: policy goal being pursed, the governance /ownership structures and the goods and services being delivered and their production characteristics.

1.5 Research Objectives

1. To classify various approaches to accountability using policy/ governing instruments.
2. To describe the ML sector.

3. To ascertain which approaches to accountability is being used in the ML sector.

4. To describe core independent variable present in the ML sector.

5. To analyze the views of key informants on the advantages and disadvantages of approaches to accountability in the ML sector.

1.6 Research Goals

The goals of this study are to determine:

1. To identify the approaches to accountability in Ontario's ML sector.
2. To determine the implications of the core independent variables on:

   a) The policy goal being pursed

   b) The governance/ownership structures and relationship in place, which in turn affects who will be accountable, and to whom

   c) The goods and services being delivered, and their production characteristics

3. To ascertain key informants views on the advantages and disadvantages of the approaches used.

The investigation of accountability in the Ontario medical laboratory sector will be based on a multistage analysis guided by the following research questions:

1) Description of the Ontario medical laboratory sector
   a. Who is involved in the funding and delivery of medical laboratory services in Ontario?
   b. What are the goods and services being delivered, and their production characteristics?
   c. What are the ownership and governance structures in place?
   d. What are the policy goals in the medical laboratory sector?

e. How is quality defined in the medical laboratory sector?

Stage 1 will provide an overview of the Ontario medical laboratory sector within the framework of the three main independent core variables: a) policy goals being pursued; b) governance/ownership structure and c) the goods and services being delivered. The overview will also provide information on the funding models for medical laboratory services in Ontario. **Stage II** will present and describe the approaches to accountability in Ontario's medical laboratory sector. This will include identifying variations, if any, within the ML sector. (i.e., hospital versus community laboratories). **Stage III** will present the views of key stakeholders on the potential barriers for the implementation of accountability measures in the ML sector. It will examine the advantages, disadvantages and benefits, if any, of accountability approaches that are being used, noting variations.

1.7 Overview of Thesis Chapters

The following overview illustrates how the remaining chapters of the thesis address the research questions identified above.

Chapter two provides a review of the relevant literature and the conceptual framework upon which this thesis is based. This will include the conceptualization of accountability in healthcare, the description of the core independent variables, an examination of the role of the public and private sector in health care, and a description of the governing instruments used to ensure accountability.

Chapter three provides an overview of the Canadian healthcare system, a description of the Ontario ML sector, and the approaches to accountability that are used in this sector.

Chapter four details the methodological approaches used for this study. This thesis is based on a mixed methods case study approach. Data collection is based on document review and semi-structured interviews. A discussion on data sources and analytical techniques used is presented. Included in this chapter is a discussion of the limitations of this study.

Chapter five presents the results of data collected from the documents reviewed and the semi-structured interviews.

Chapter six provides a discussion of the research findings within the analytical framework presented in Chapter three. The chapter ends with the lessons learned and suggestions for future research.

Chapter seven consist of a conclusion to the thesis. It returns to the core issue of approaches to accountability and articulates that although all four approaches are present, regulation is the main approach to accountability in the ML sector.

Chapter 2

Conceptual Framework and Literature Review

This chapter examines the concept of accountability and how it applies to the healthcare sector. The chapter will start with the conceptual framework used for this thesis. A number of concepts will be discussed under the headings: 1) A general overview of accountability 2) Governing instruments used to influence behaviour to achieve accountability in the Canadian health care context with special emphasis on the Ontario ML sector, and 3) a description of the independent variables.

2.1 Conceptual Framework

This thesis is a part of a lager study on Approaches to Accountability that is funded by Partnership for Health System Improvement (PHSI). It is collaboration among an accomplished interdisciplinary team, working in partnership with senior policy makers across multiple health care sub-sectors. The conceptual framework used in this thesis was adopted (with slight modifications to respond to the ML sector) from existing conceptual framework used by Dr. Raisa Deber, the principal investigator.

Political scientists have noted that decision makers are able to use a number of "policy instruments" or "governing instruments," to guide them in their choice of policy directions (Howlett & Ramesh, 2003). These instruments vary considerably in their degree of coercion (Doern & Phidd, 1992) or intrusiveness (Baxter-Moore, 1987). According to Doern et al., at the extreme non-intrusive end of the scale, they may choose not to act. The next level that they can choose is symbolic responses. Doern et al. called this level of intervention "exhortation." Government may choose to discreetly intervene by using incentives for action. The kind of incentives used can vary. Government may try to secure voluntary compliance with its objectives

without accompanying threats or inducements. Another strategy that they may choose to use is 'expenditure' and/or 'taxation' policies. A still more intrusive set of instruments may be termed "directives" or what Doern et al. call "regulation." These often shift compliance costs from the regulators to those being regulated (Doern & Phidd, 1992).

Most writings on policy instruments theorize them as the extent to which government directly intrudes on private decision making. This analysis can be extended to examining the potential intrusiveness of one level of decision makers upon others (Deber, 1991). The policy instrument framework also includes the literatures on ways of enforcing these agreements, including information, licensure/accreditation, payment, and legal sanctions. This literature has been linked to the literature on the new public management (Hood, 2000). Before selecting a policy instrument, special attention should be paid to the interaction between public and private forces, as well as the implications of the type of policy network for selection of policy instrument (Bresser, 1998).

Policy instrument models have been widely applied to the field of environmental regulation, particularly in the European Union (Zito, 2003; Jordan, 2005). There are few examples of them been used in primary healthcare in Switzerland (Braun & Etienne, 2004) and social services such as child health policy in Australia (Leggat, 2004). However the literature review indicated that there was no record of any efforts to apply them to accountability.

This thesis examines the following four major approaches to accountability currently being employed in the health sector in Canada and internationally. The research goal was to be able to identify which of these approaches to accountability has been used in the ML sector. It is hypothesized that these approaches will have differing success when applied to various categories of services within the ML sector, with the likely outcome depending upon the policy

goal being pursed, the governance/ownership structures and relationship in place, which in turn affects who will be accountable, and to whom and the goods and services being delivered, and their production characteristics.

Approaches to Accountability

1. **Financial incentives:** are approaches which modify payments to encourage providers to behave in the desired manner (Robinson, 2001; Evans, 1984). To achieve this they use the 'expenditure' governing instrument. One example, which was reviewed in detail, is the family of Pay for Performance (P4P) experiments for physician services underway in such jurisdictions as the UK, US, Australia, and Ontario (Epstein, 2007; Pink et al., 2006; Doran et al., 2006; Donaldson et al., 2005). The use of financial incentives and purchasing for hospitals and other sub-sectors, including laboratory services was also highlighted in the literature (Baranek, Deber & Williams, 2004). For example, Ontario's hospital accountability agreements contain financial incentives for balanced budgets.

2. **Regulations:** which employ the 'regulation' governing instrument (Walshe, 2003) play a major role in health care. These also require providers to behave in a certain way. Regulations may be supported through the signing of binding agreements. They may also rely on agency theory, and be enforced using professional regulatory bodies (Eisenhardt, 1989). This thesis will examine the accountability agreements being used in the medical laboratory sub-sector. The literature notes the ongoing tension of balancing market forces and regulation, and the implications of regulatory and medico-legal barriers for achieving such goals as inter-professional practice (Lahey & Currie, 2004). Regulation plays an important role in the delivery of laboratory services in Ontario.

3. Information: directed towards potential users (patients, public and private payers) within a context of allowing market forces to work more effectively by encouraging rational choice of the 'best' care (Howells, 2005; Morris & Zelmer, 2005). Examples of the use of this approach include ongoing activities in performance measurement and improvement (Bansley et al., 2005). One challenge that was highlighted in the literature was the issue of establishing and enforcing these guidelines. Particular attention will be paid to the use of report cards, audit reports, publicly-available inspection reports (e.g., lab accreditation reports) and quality indicators, including adverse events (Saltman & Ferroussier- Davis, 2000). The use of this instrument may work indirectly and produce some unintended consequences. For example, providing information to interest groups and media may affect the reputation of various providers, which in turn affect the willingness of patients and payers to purchase their services.

4. Reliance on professionalism/stewardship: This approach employs a second variant of the exhortation governing instrument, but directs the information to providers rather than to payers or consumers (Abelson & Guavin, 2004). It relies on high trust and the expectation that providers, as a group, wish to do the right thing. One barrier detected in the literature is the need for support in clarifying what are best practices. Best practice is "adopting a method or technique that has consistently produced results that are better than those obtained by using other means" (Bogan & English, 1994). Clinical guidelines and other forms of evidence-based practice are currently being used in such sub-sectors as: hospitals, medical laboratories (inspections), and primary health care. Under some circumstances, report cards may also fall into this category of approach, depending upon the indicators used and the way the information is shared. In this thesis, particular emphasis will be placed on the applications to clinical accountability. Whenever the professionalism/stewardship approach is used, it is often backed up by self-

regulation through professional colleges. Many of the professionals who work in the laboratory sector are members of a regulated college in the province.

An additional nuance is the extent to which blended approach model of policy instruments may be used. This is particularly evident in the use of additional policy instruments for enforcement. A government policy aimed at enforcing a piece of legislation may include various combinations of exhortation (e.g., efforts to evaluate and improve the quality of information, citizen engagement to widen the scope of inputs); expenditure (e.g., fiscal penalties); taxation (e.g., tax breaks to encourage desired activities), and regulation (e.g., audit, accreditation, professional self -regulation, and legal sanctions) (Deber, 2011).

The enforcement of desired policy instruments at the strongest level is backed by government legislation. An example is the country of Norway that has a "Patient's Bills of Rights" as a part of its formal appeal mechanism for patients. The objective of the Act is "to help ensure that all citizens have equal access to good quality health care by granting patients' rights in their relations with the health service and promote a relationship of trust between the patient and the health service and safeguard respect for the life, integrity and human dignity of each patient." (Legislation Norway, 2013). This law gives the citizens of Norway the legal rights to quality health care.

In Ontario, there are a number of initiatives aimed at enforcing government policy. One initiative is a review procedure for getting out-of-province coverage for medically insured services. Out-of-province service is usually provided as emergency or non-emergency care to Ontarian outside of the province but within Canada. There are legislations and regulations for the administration of compensation by Ontario Health Insurance Plan (OHIP). Another initiative is to examine the public complaints process for nursing homes. There is also an initiative to have a

patient's "Bill of Rights" that would provide guarantees to patients such acceptable wait time for surgeries. Other enforcement mechanisms may rely upon litigation (e.g., malpractice, human rights). The office of the Ontario Ombudsman provides service to persons who maybe having difficulty accessing the healthcare services that they need. The Auditor General reports fall within the information category. The report released in 2007 provided detailed assessment and recommendation for the laboratory sector in Ontario and will be discussed in Chapter 4 of this thesis.

2.2 **An Overview of Accountability**

Healthcare is a top priority for both citizens and governments of Canada (Deber, 2010; McGregor, 2012). Opinion polls show that Canadians continue to support a publicly funded healthcare system (National Union of Public and General Employees, 2012; Nanos research, 2012). However the delivery of universal medicare is not without cost. In 2012 total government spending on healthcare nationwide was expected to reach C$ 207 billion (CIHI, 2012). The province of Ontario was expected to spend $47.6 billion on healthcare in 2012 (CIHI, 2012). It is essential that individuals and organizations that are spending taxpayers' dollars be held accountable for their use of resources in the provision of quality service within the healthcare sector.

Accountability is an important issue in healthcare as evident by recent healthcare reports identifying accountability as a major issue for Canadians (McGregor, 2012; Brown, 2006; The Romanow Inquiry, 2002; McIntosh, Forest & Marchildon, 2004). There are many advantages to having better accountability such as better leadership and governance, stronger operational and clinical management, improved access to care and greater worker and customer satisfaction

(Relman, 1988). The challenge is to define exactly what high-quality accountability entails because the healthcare system in Canada is complex and there is an increasing recognition that one size does not fit all (Deber, 2010).

Accountability is defined as "the obligation to answer to an authority that conferred a responsibility, by an agent who accepted it, with the resources and delegated authority necessary to achieve it, and with the understanding that inadequate performance will result in an intervention"(Shortt & MacDonald, 2002). The accountability process requires establishing relationships among a number of different stakeholders. For example, medical laboratories receive funding from the Ontario provincial government to perform laboratory testing for other health providers (e.g., physicians) to assist in the diagnosis and treatment of patients. As a result the medical laboratories are accountable to: the government who is responsible for funding and regulation, to the tax payers who pay though taxation, to providers who order the tests, and ultimately to the patient who is the recipient of care.

The Royal Commission on Financial Management and Accountability stated that "accountability, like electricity, is difficult to define, but possesses qualities that make its presence in a system immediately detectable" (Hartle, 1979). This definition is captured in the total management system recommended by the Quality Management Program-Laboratory Services (QMP-LS). It is based on the philosophy that similar to electricity, "quality is not inspected but rather built into every phase of laboratory test" (QMP-LS, 2012).

According to Fooks and Maslove, there are five components on which accountability is built: 1) define roles and responsibility 2) delegation of authority to take action 3) being answerable to the decisions and actions taken 4) evaluation of performance and 5) the use of sanctions and corrective solutions (Fooks & Maslove, 2004). The Ontario Laboratory

Accreditation (OLA) program requires that all laboratories have proper documentation to demonstrate compliance within all five components. Failure to meet the requirements of OLA will result in warnings and/or suspension of the laboratories licence to operate.

Accountability is very important to the healthcare sector and there is growing demand for greater accountability at all levels (Canadian Healthcare Association, 2006; Marchildon, 2011; Flood & Archibald, 2005). However there is little scientific evidence regarding what to measure or how and when measurement should take place. Policy analysts usually look to policy instruments or governing instruments to influence behaviour in the selection of preferred policy directions (Howlett & Ramesh, 1993). The next section will examine the governing instruments that have been used in healthcare based on the typology of Deber et al. (Deber, 2010).

2.3 Governing or policy instruments used to achieve accountability in the Canadian health care context with special emphasis on the Ontario medical laboratory sector

The literature review indicated that accountability has multiple definitions and therefore may mean different things to different people. In its simplest form, accountability is being answerable to someone for meeting specific goals and objectives (Emanuel & Emanuel, 1996). An accountability framework is an important tool that is used to provide information about an organization. It is the medium though which information about the mission, vision, values, and goals are shared with stakeholders such as the public, patients and payers (Brinkerhoff, 2003). Accountability framework provides transparency as to what an organization is accountable for and who in the organization is being held accountable (Ableson & Gauvin, 2006). The tools for establishing, monitoring and enforcing accountability are different depending on what, whom, why and how it is being measured. This next section will examine five types of accountability: 1) Vertical and horizontal, 2) Financial, 3) Managerial, 4) Political, and 5) Professional. The

purpose of this is to demonstrate the types of relationships that exist between government and its citizens. In a democracy like Canada, accountability ensures that those who govern (individual or organization) are answerable to those whom they govern (Day & Klein, 1986).

Vertical and Horizontal Accountability

In describing accountability relationships between actors (e.g., government, medical laboratories, physicians, patients, etc.), the literature identified two types: *vertical* accountability and *horizontal* accountability (Schedler, 1999; Schacter, 2000). Vertical accountability mechanisms include electoral processes, strong civic organizations and an independent news media (Schedler, 1999). Horizontal accountability mechanisms include the arms-length public institutions, judiciary, legislatures, auditor generals, public ombudsmen, offices of the privacy commissioner; human rights commissions (Schacter 2000). Elements of both horizontal and vertical accountability are easily identified in Ontario's healthcare system. An example of vertical accountability in the laboratory would be the hierarchical relationship between the laboratory manager, director and the hospital's administration for clinical practice and patient safety. An example of horizontal accountability is the relationship with the College of Medical Laboratory Technologists of Ontario (CMLTO) which acts as a monitor or watchdog to protect the public interest.

Financial Accountability

The majority of healthcare services in Canada are publicly funded (CIHI, 2012). The total amount that Canada was expected to spend on health care in 2012 was $207 billion. This is an average of $5,948 per person (CIHI, 2012). As previously mentioned, healthcare spending in Ontario was expected to reach $47.6 billion in 2012 representing approximately 42% of the Ontario provincial budget (CIHI, 2012). Considering that financial resources are finite and are

provided by tax payers, healthcare providers are responsible for demonstrating the judicious use of these resources (Fenn, 2006).

Managerial Accountability

Managers are responsible for the coordination and organization of work (Robbins, Coulter & Stauart-Kotze, 2003). This involves more than financial accountability as managers are responsibility for demonstrating effective and efficient management of services or systems. The focus tends to be on performance as well as the use of resources. For example, in the public health laboratories, mangers are accountable to "support health care providers, the public health system and partner ministries in making informed decisions and taking informed action to improve the health and security of all Ontarians"(OAHPP, 2012).

Political Accountability

This is the responsibility for demonstrating responsiveness to citizens and delivering on commitments (Fooks & Maslove). The MOHLTC represented by elected officials and members of the civil service are morally responsible to the citizens of Ontario for the decisions made and actions implemented. For example, the inappropriate practices by the Walkerton's Public Utilities Commission (PUC) operators resulted in the deaths of seven individuals who drank contaminated water that was deemed safe by the PUC (Walkerton Inquiry, 2000). The Minister of Health had to take responsibility of the actions of the PUC and provide answers to the residents of Ontario during question period in the Parliament.

Professional Accountability

Healthcare professionals are expected to follow standards that ensure the delivery of safe and quality services. In Ontario, the *Regulated Health Professions Act* provides guidelines which

Regulatory Colleges are to use to protect the public (RHPA, 2012). The College of Physicians and Surgeons of Ontario (CPSO) and The College of Medical Laboratory Technologists of Ontario (CMLTO) are responsible for the regulation of doctors and medical laboratory technologists who work in Ontario medical laboratories. The Colleges "protects the public's right to safe, competent, and ethical healthcare" (CMLTO, 2012).

Many decision makers in healthcare rely on a number of policy or governing instruments to help them achieve their desired goals. The following section will expand on the four major policy instruments mentioned in the conceptual framework that are being used in the healthcare sector.

2.3.1 Policy Instruments

There are important reasons why the Canadian public should be concerned with approaches to accountability in healthcare. Maintaining a sustainable healthcare system is a most pressing problem for our time. As the life expectancy of Canadians continue to increase (Marchildon, 2012) there is concern as to whether our present system will be able to meet the needs of an aging population. There is also concern regarding the increase in chronic diseases and the burden that they will place on the healthcare system (CIHI, 2012). The rising cost of healthcare (Marchildon, 2012) and the concerns about inefficiencies, duplication, waste and wait times are all driving forces. It is the responsibility of governments to respond to these concerns by implementing policies that will frame the future of healthcare. Typically, governments in Canada tend to use regulatory or economic policy instruments to influence different actors in order to achieve a desired goal (Deber, 2010).

This thesis will use the analytical framework created by Deber et al. One dimension of the framework classified potential approaches to accountability in terms of the political science

concept often referred to as 'policy instruments' or 'governing instruments.' The second dimension looks at the independent variable that affects the impact of these instruments on accountability approaches. The thesis will focus on four policy or governing instruments: 1) financial incentives, 2) regulations, 3) information to taxpayers, and 4) professionalism/stewardship. These were chosen in order to be able to compare the findings from this research (which is a part of a larger study) with that of other researchers working in different healthcare sub-sectors.

1) Financial Incentives

Financial incentive is the adjustment of payment in order to influence providers of healthcare to behave in a certain way. One example is the family of Pay for Performance (P4P) that is been used in this province to reward physicians for meeting certain pre-determined performance measures for quality of service (Devlin, Sarma & Hogg, 2006). Another example is government providing a tax incentive to industry to locate in a specific area to provide jobs and/or service. Government has also chosen to offer financial incentives for balanced budget, as a way of influencing the actions of hospitals boards in Ontario (Abelson & Gauvin, 2004).

Financial Incentives and the Ontario medical laboratory sector

The majority of the medical laboratory sector is publicly funded and privately delivered as for-profit or not-for-profit entities. In the Canadian healthcare context, public usually means government owned and private means owned by the people (Deber, 2010). Publicly funded implies that the service is paid for using tax payers' dollars under universal medicare. Since laboratories are users of public funds, they are accountable to their stakeholders. The main methods of delivery for laboratory services are: public-not-for-profit, private-not-for-profit and

private-for-profit. A full description on the medical laboratory sector will be presented in Chapter Four of this thesis. The literature review indicated that financial incentives differ according to the sub-sector within the medical laboratory sector. The following section will present the results of financial incentives based on sub-sector groupings.

Public health laboratories

The 11 Public Health Laboratories that operate in Ontario are publicly funded and delivered. They have their funds transferred directly from the Ministry of Health and Long Term Care (Deber, 2010). The financial incentive is prudent use of allocated resources to ensure continued government funding. The employees are civil servants.

Hospital laboratories

Laboratories that are situated in hospitals are categorized as publicly funded, privately delivered. They operate as not-for-profit entities and provide service for hospital-based inpatients and outpatients. Laboratory tests done in hospitals are funded by the hospitals' global budget through what is termed a "public-contract model," in which public payers (the government) contract with private health- services care providers such as hospitals (Deber, 2010). The expense for the medical laboratory services is a part of the total budget submissions made to Local Health Integration Networks (Deber, 2010). In hospital laboratories, the main financial incentive is operating within the budget allocated by the hospital board (MOHLTC, 2012).

Community Laboratories

Laboratories that are situated in the community are categorized as publicly funded, privately delivered. They operate as for-profit entities and are reimbursed by the Ontario Health Insurance Plan (OHIP) on a per-test basis. In 1996 the Ministry of Health and Long Term Care (MOHLTC) and the Ontario Association of Medical Laboratories (OAML) introduced the

corporate cap payment for for-profit laboratories (Sutherland, 2011). A corporate cap is the maximum total amount that a particular laboratory could be paid by OHIP in a fiscal year. The amount paid is decided on through direct negotiation with the government and the Ontario Association of Medical Laboratories (OAML). The amount a laboratory bills over its corporate cap is not funded by OHIP and is therefore absorbed by the laboratory (Information and Privacy Commissioner of Ontario, 2013). Within the for-profit community laboratories sub-sector, the financial incentive is on making profit for their shareholders (Gamble & Deber, 2004; Deber, 2010).

2) Regulations

Regulation is the most commonly used policy instrument in Canadian healthcare (Deber et al., 2010) Regulations influence how actors or providers behave. According to Deber, "regulation is the extent to which government directly intrudes on private decision making" (Deber, 1991). The regulatory policy instrument when applied usually shift compliance cost from the regulators to those that are being regulated. There are several organizations involved in the regulation of the medical laboratory sector. The major ones will now be discussed.

Government Regulations through the Ministry of Health and Long Term Care (MOHLTC)

The MOHLTC is responsible for the licensing, inspection and accreditation of all medical laboratories in Ontario. The duties are divided between two departments. The Laboratory Branch of the MOHLTC is responsible for the licensing and inspection of the medical laboratories. The Ontario Medical Association (OMA) working through the QMP-LS, is responsible for accreditation and assessment of all medical laboratories in Ontario.

Licensing and Inspection

The licensing and inspection of medical laboratories falls under the jurisdiction of the Ministry of Health and Long Term Care. *The Laboratory and Specimen Collection Center Licensing Act* sets out the guidelines that are used to determine who owns, operate and licenses a specimen collection center or a laboratory in Ontario. The Act outlines the type of license that may be issued which in turn determines the type of tests that can be performed. A laboratory that is issued a series 4000 license will be paid from public funds for testing done on specimens from patients who are admitted to a hospital. A laboratory that is issued with a 5000 series license will be reimbursed for laboratory test done on both in-patient and out-patient specimens. *The Laboratory and Specimen Collection Center Licensing Act* sets out the time for inspection, the fees for inspection and the consequences for non-compliance (The Laboratory and Specimen Collection Center Licensing Act, 2012)

Accreditation and Assessment

The Quality Management Program—Laboratory Services (QMP-LS) is a mandatory program for all medical laboratories in Ontario. The work of QMP–LS is conducted under two umbrellas: 1) External Quality Assessment (EQA), 2) Ontario Laboratory Accreditation (OLA). Laboratories are accredited based on the OLA 15189Plus^{TM} standards. The EQA division is responsible for performing proficiency testing that evaluates the medical laboratory based on pre-analytical, analytical and post-analytical criteria.

The Regulated Health Professional Act (RHPA)

RHPA provides the framework for the regulation of Ontario's 23 health professions under their respective colleges. This legislation was enacted in 1991. It includes a general Act, a Procedural Code for all the regulated health professions and profession-specific Acts (RPHA,

2012). The Act allows for the self- regulation of Ontario's Medical Laboratory Technologists (MLTs) under their respective college, The College of Medical Laboratory Technologists of Ontario (CMLTO). Pathologists and other medical doctors who work in the laboratory sector are regulated by their college, The College of Physicians and Surgeons of Ontario (CPSO). Regulatory colleges are responsible for: a) regulating the practice of a health profession, b) developing and maintaining standards of qualification for those who apply for certificates of registration, c) developing and maintaining standards of professional practice, knowledge, and skill for its members and, d) have statutory committees such as a complaints committee that deals with complaints against a health professional (RHPA, 2012). *The Medical Laboratory Technology Act,1991* falls under the umbrella of the RHPA and provide information on the scope of practice and controlled act that MLTs are licensed to perform. The Medical Laboratory Technology Act specifies the conditions under which MLTs may perform the controlled act "to take blood samples from veins or by skin pricking" (CMLTO, 2012). The purpose of the colleges is to protect the public by ensuring that only qualified persons are licensed to practice a particular profession. Members of the college are expected to maintain the professional competencies.

3**) Information provided to payers and patients**

Information provided to private payers, public, and patients can take the form of report cards, annual reports, and performance measurement (Baker et al., 2004). Information sharing requires providers to report publicly and be responsible for their actions and decisions. While the transparency involved in information sharing is generally regarded as good for accountability it may lead to some unintended consequences. The sharing of "bad reports" can affect the willingness of patient and payers to continue to use the services of a particular provider. On the other side of the coin it may drive a provider to make sweeping changes to improve the quality of

the service that it provides. This thesis will examine the most common ways that the medical laboratory sector shares information with the stakeholders through quality indicators, financial reports, annual or quarterly reports, audit reports, and accreditation reports.

4) Professionalism/Stewardship

Professionalism/stewardship is an instrument for achieving accountability. It directs the information to providers rather than to payers and patients. It is based on the high trust that professionals as a group or as an individual intend to do the right thing to benefit the patient. Health professionals rely on evidence-based practice and best-practice guidelines to help them make the best decisions for their patients. In the medical laboratory sector, medical laboratory technologists (MLT) and physicians rely on their regulated college, the CMLTO and CPSO to set the standards for professional, legal, and ethical scope of practice. Many MLT and doctors also belong to other voluntary professional organization such as the Canadian Society of Medical Laboratory Science (CSMLS) and the Ontario Society of Medical Technologist (OSMT). Professional associations represent the voice of their members and are able to lobby for their best interest collectively. They provide best practice information to their members and work to raise the public profile of their profession.

2.4 Independent variables

A number of independent variables directly or indirectly influence the approaches to accountability that is used by an organization. This thesis will focus on three: a) the policy goals being pursued e.g., access, quality, cost control and effectiveness, and customer satisfaction, b) the governance/ownership structures e.g., public versus private, c) the goods and services being delivered e.g., contestability, measurability, and complexity. This thesis chose to focus on these variables because it hypothesized that they will have a greater influence on the approaches to

accountability that will be used and set the stage to determine who will be accountable, and to whom, and for what. This framework is also easily adapted to other researchers working across different sub-sectors of healthcare in the large study. At the conclusion of the larger study it will be relatively easy to compare and contrast across a series of related sub-studies, and examine the impact of the similarities and differences in their governance/ownership, and the production characteristics of the services they deliver.

a) Policy goals

Policy goals may include elements such as: the delivery of quality care in a safe environment, the delivery of care in a cost effective manner, greater transparency, and improved stakeholders (patients, payers, customers) satisfaction (Myers & Lacey, 2012). In the literature, Behn highlighted improved performance, fairness, and financial stewardship as key objectives in achieving accountability (Behn, 2001).

The Ontario medical laboratory sector is not homogenous. The literature review indicated that there are variations in policy goals based on the sub-sector. For example, private for-profit laboratories have a policy of goal making a profit for their shareholders, while the private not-for-profit laboratories are not concerned with making a profit but maintaining a balance budget (Deber, 2010).

Another policy goal is greater transparency. Transparency in healthcare refers to an open communication of information to all stakeholders including patients, consumers, providers, employers, and policy makers (Behn, 2001). All organizations that use public money have a responsibility to be as open and transparent at all levels to ensure proper accountability. Financial transparency ensures that tax payer money is being spent in a cost effective, cost

efficient manner. The literature found that private not-for-profit (hospital) laboratories tend to be more transparent in providing information to stakeholders about how services are delivered and at what cost (Sutherland, 2011). Private for-profit (community) laboratories are concerned that providing sensitive business information could be used by a competitor and generally tend to be less transparent (Sutherland, 2011).

The policy goal of delivering laboratory services in a cost effective manner was found in the literature. Cost effectiveness is a way of comparing cost and health effects of an intervention of two or more outcomes (Preker & Harding, 2000). The information obtained can then be used to make a decision as to where the best place is to allocate healthcare resources. According to Culhane, cost effectiveness is a tool that can be used to achieve accountability (Culhane, 2013). Because laboratory services are paid for with taxpayers' money, every effort should be taken to ensure that the procedures are done at the lowest cost to the taxpayers.

In the literature, Sutherland made some comparisons between the cost of delivering laboratory services in the for-profit and not-for-profit laboratory sector (Sutherland, 2011). The problems that are associated with any attempt to measure cost within the ML sector is that there are multiple meanings of cost, how and what should be measured. For example, a laboratory seeking to reduce cost may decide to contract out a specific test to another laboratory. While this action may reduce the unit cost of doing the test, there could be potential adverse effects such as a longer turn-around time, which could translate into longer a hospital stay for the patient. In this scenario the laboratory may have saved money but the overall cost to the healthcare system may have actually increased, while patient outcome and satisfaction may have also decreased. According to Deber at el., it is possible that within an organization, policy goals may clash

(Deber, 2012,). The challenge is to ensure that conflicting goals are achieved without sacrificing quality patient care (Deber, Topp & Zakus, 2004).

Providing quality care in a safe environment is a policy goal that is shared across healthcare and the ML sector. The recent report from the National Consultation on Health Services and Policy Issues: Listening for Directions 111, identified quality and safety as priority themes for research in healthcare (National Consultation on Health Services and Policy Issues: Listening for Directions 111, 2012). However, the definition and measurement of quality within healthcare is difficult because it is based on both the perception of the user and provider of the service and each one may have a different perspective as to what comprises quality service. Despite these challenges, providing quality service in healthcare should remain an important policy goal. According to Donabedian, measuring quality should involve looking at structure (e.g., is there a lab policy in place for sample collection), process (e.g., is there a system for recording and reporting critical results in a timely manner) and outcome (e.g., does prompt reporting lead to improved patient outcome) (Donabedian, 2005). In the ML sector, quality is broadly defined to include technical (e.g., performing daily QC) and clinical proficiency (e.g., reporting critical reports), and the suitability of testing performed (Shahangian, & Snyder, 2009).

The quality of laboratory services can be assessed using quality indicators or performance measures found in a total quality management system. Quality management is an active and continuous process that validates, monitors, resolves, and documents every step of a procedure. In a laboratory that practices quality management, quality is not inspected but built into the job of every worker (Harmening, 2012). The literature indicated that quality in a medical laboratory should extend beyond the analytical phase to include pre and post analytical phase (Harmening,

2012). For example, the quality of results obtained for a throat swab cultured in the microbiology laboratory depends on the quality of swab taken by the doctor (i.e. throat and not mouth).

The ordering of appropriate tests is another area of concern in pre-analytical testing. The literature indicated that there were a number of provincial inquiries across Canada directly related to the quality of laboratory testing (Krever's Inquiry, Cameron Inquiry, and Walkerton Inquiry). The following sub-headings provide a summary account of each one of the inquiries conducted.

The Krever's Commission of Inquiry

The Krever's Commission of Inquiry in 1994 looked at issues of accountability relating to the contamination of the blood system with the HIV and Hepatitis C viruses from the Canadian Red Cross (Krever's Commission of Inquiry, 1994). The Commission's report concluded that the relationship between the Red Cross and the federal and provincial governments was poorly defined and often dysfunctional. It stated that:

> "The Red Cross, coupled with the federal and provincial governments, failed to create a national blood policy. As a result, no one authority was clearly in charge of, or accountable for, the safety of the blood supply" (Krever's Commission of Inquiry, 1994).

In response to the lack of accountability identified, the report made several essential recommendations concerning how Canada's blood supply system should be organized, as well as the need to compensate those who were infected by the tainted blood supply. These included the need for a "national operator" that would manage the blood system, implementation of national standards, and compensation for those affected. The Government took action to implement the recommendations of the Inquiry. Two of the actions taken that are very relevant to this thesis were: 1) the establishment of the Canadian Blood Services (CBS) in 1998. The CBS has instituted many of the recommendations of the Krever's Inquiry, including stronger

accountability and safety mechanisms, as well as remaining at arm's length from the government in its daily operations (Krever Inquiry, 1980), 2) Implementing National Standards. In 2004, federal, provincial, and territorial governments announced the first national standards for the quality and safety of the blood system. This included guidelines for the handling of blood from "vein-to-vein," as well as the collection, storage, distribution and labeling of blood (CBS, 2012). The newly formed organization named the Canadian Blood Services (CBS) adopted two guiding principles: the safety of the blood system is paramount, and accountability and transparency in the operation of the blood system must be clear (CBS, 2012).

The Walkerton Inquiry

In May 2000, seven persons died and over two thousand more became ill after drinking water contaminated with *E. coli* bacteria in Walkerton, Ontario. The Walkerton Inquiry was convened and headed by Justice Dennis O'Connor, to examine the circumstances that lead to the outbreak and to look into the future safety of the water supply in Ontario (Walkerton Inquiry, 2000). There were 93 recommendation made in the second report of the Inquiry. The one that is of interest in this thesis is the role of laboratory testing services in municipalities. In 1996, the testing of water was transferred from the public health laboratories to the private for profit laboratory sector. In this thesis, it is hypothesized that the type of governance/ownership structures and relationships in place, will affect who will be accountable, and to whom, and the goods and services being delivered, and their production characteristics. In his report Justice O'Connor stated that:

> "When water testing was privatized in 1996, private sector laboratories were not regulated by the provincial government. There were no established criteria governing quality of testing, no requirements regarding the qualifications or experience of laboratory personnel, and no provisions for the licensing, inspection, or auditing of such laboratories by the government" (Walkerton Inquiry, 2000).

It was determined by the Walkerton inquiry that the errors in laboratory test results were due to more than analytical procedures, but included errors in pre-analytical and post- analytical stages. The inquiry report recommends that accreditation be just one element in an oversight regime that also includes licensing and possibly inspection by the provincial environment ministry. The report calls for the results of laboratory audits to be available to the public (Walkerton Inquiry, 2000; Waterprotection.com, 2011).

The Cameron Commission

The Cameron Commission of Inquiry on Hormone Receptor Testing (2009) established by the Government of Newfoundland and Labrador examined accountability for laboratory test results for breast cancer patients (Cameron Commission of Inquiry, 2009). As noted by Justice Cameron "...had proper quality assurance and control policies been put in place and had been followed, the problem with ER/PR [estrogen and progesterone receptors in breast cancer] testing would certainly have been discovered much earlier" (Cameron Commission of Inquiry, 2009). In the past, it was the belief that accountability processes in the medical laboratory sector were simple and easy to monitor, but the Cameron Inquiry determined that "there was a failure of both accountability and oversight at all levels" (Cameron Commission of Inquiry, 2009).

Alberta Hospitals

As recent as December 2011, there was another report after a series of misdiagnoses and misread laboratory tests at hospitals in Drumheller, Edmonton, and Calgary, Alberta. These systematic testing errors negatively impacted the treatment of cancer patients and resulted in a provincial review of testing in that province (Komarnicki, 2012).

All of these cases clearly show that there is a need to examine the approaches to accountability that have been used across the laboratory sector in Ontario. Doctors and other

healthcare professionals rely on laboratory services for diagnosis, monitoring, and treatment of their patient, (CSMLS, 2012) therefore providing high quality laboratory services should translate into better quality patient care.

b) Governance/Ownership

According to Denis et al. "Governance deals principally with the adaptation of organizations to new contingencies and deals with the roles of all regulatory, administrative, professional, and clinical authorities in the pursuit of collective goals" (Denis, 2005). There are two ownership models for laboratories in Ontario: public (government) and private (hospital and community). There are 11 public health laboratories that are owned by the government. Public health laboratories are directly funded by the government and operate in a non-partisan manner.

There are about 200 accredited laboratories that are privately owned (QMP-LS, 2012) as well as laboratories that are situated in physicians' offices. Deber et al. describes the funding arrangements between government and the rest of the laboratory sector as a "public-contract model" in which there is third party accountability arrangements between government and owners (Deber, 2012). Medical laboratories located in hospitals are owned by the hospital and usually operate as a private not-for-profit organization. Each laboratory has a hierarchical organizational structure of governance that includes: a director, manager, department supervisor, medical laboratory technologist, and laboratory technicians. Each member of the team plays a very distinct yet important role. For example, laboratory technicians are often employed in the pre-analytical phase of sample collection and processing. The quality of their work has direct implications on the role that medical laboratory technologists play in the analytical phase of testing of the patient's sample.

Private for-profit community laboratories increased in numbers with the implementation of the *Medical Care Insurance Act* (1966) which provided universal insurance coverage for laboratory services (Sutherland, 2011). Community laboratories operate as a business and are funded on fee-for-service basis by Ontario Health Insurance Plan (Sutherland, 2011). As for-profit organizations they are expected to provide a return on investment to their shareholders. For-profit organizations are able to access capital by issuing equity and are able to use this money to make investments in equipment such as fully automated laboratories and buildings. Even though they may have the same goal of quality services for their patients, they often use a different model from the not-for hospital laboratories to accomplish this. This is reflected in ownership/governance models found in many community laboratories. In order to remain viable, for-profit laboratories have to offer services at rates and quality that are comparable to that offered in the public health or hospital laboratories (Deber, 2002). Some of the ways that they do this by having better management, freedom from labour agreement, sacrifice of difficult to measure intangibles and risk/cream skimming i.e. offer only tests that are deemed to be profitable (Deber, 2002). For example, community laboratories usually make money by performing high volume, routine, easily automated laboratory tests.

The literature review indicated that the private community laboratory sector in Ontario is controlled by three multinational corporations: Life Labs (formerly MDS), Gamma-Dynacare and CML Health Care (Sutherland, 2011). The Ontario Health Coalition (OHC), report stated that "as of 2006, these three corporations controlled 93% of Ontario's $564 million community laboratory market, up from 43% in 1985" (Ontario Health Coalition, 2012). The remaining community laboratories are medium to small investor owned and operated. The number of

community laboratories in Ontario fell from 17 to 11 between 1999 and 2006"(Ontario Health Coalition, 2012).

c) Production Characteristics and the Goods and Services Delivered.

According to the literature, it is important to examine the production characteristics of goods and services because it affects how performance can be measured and managed ((Vining & Globerman, 1999; Preker et al., 2000; Deber, 2004; Rico & Puig-Junoy, 2002). This thesis will focus on the three production characteristics that influence accountability approaches: contestability, measurability, and complexity.

Contestability

The concept of contestability as defined by Preker and Harding states that:

> "*Contestable* goods are characterized by low barriers to entry and exit from the market, whereas non-contestable goods have high barriers such as sunk cost, monopoly market power, geographic advantages, and "asset specificity" (Preker and Harding 2000)."

In the delivery of medical laboratory services, an important question to ask is: how easy is it for a new provider to enter the market, set up a laboratory, and begin to provide services? The ML sector is categorised in the literature has non-contestable because there are many barriers to entry (Deber, 2012). Some of these are: licensing requirements, regulations, monopoly market power (e.g., more than 90% of the for-profit market is controlled by three companies), geographic location, trust, high sunk costs (e.g., the cost of laboratory equipment), and asset specificity (e.g., laboratory equipment can only be used in a laboratory) (Deber, 2002). In Ontario, anyone wishing to open a laboratory must obtain permission from the government and fulfill the conditions set out in the *Laboratory and Specimen Collecting Center Licensing Act 1984*. Only licensed laboratories are allowed to bill OHIP. The fact that since 1973, no new

laboratories have been opened in Ontario (Sutherland, 2011) suggests that laboratory services are non-contestable goods.

Nearly all medical laboratories operating in Ontario must be accredited by Ontario Laboratory Accreditation (OLA). The exception is the unregulated laboratories that operate out of physicians' offices. Other organizations (e.g., Accreditation Canada) are involved in the accreditation of laboratory services. Accreditation requirements present as a barrier to entry making laboratory service non-contestable. The high capital investment and licensing requirement need to start up a laboratory (especially community for-profit) serves a barrier to entry and make laboratory services non-contestable.

The existence of market monopoly and specialty testing also make laboratory service non-contestable. The majority of the large teaching hospitals in Ontario have fully functional laboratories that offer service in all five disciplines (microbiology, chemistry, histology, hematology, and transfusion science) as well as specialized testing such as flow cytometry and molecular technology. Most hospitals, even in rural areas, have at least a rapid response (core) laboratory that provides stat testing (CIHI, 2012). There are 11 public health laboratories that provide specialized tests and assistance in disease surveillance and monitoring. There is an extensive network of community laboratories across the province (Sutherland, 2011). Therefore finding a niche in the market to open a new laboratory is not going to be very easy. Likewise finding the right location and building trust of stakeholders (payers and patient) is something that will take considerable time and effort.

Another barrier to entry in the medical laboratory sector is the high cost of purchasing laboratory equipment and reagents. In addition, laboratory assets have high specificity, which

means it is difficult to transfer their use to another service. Another barrier to contestability that was found in the literature is the fact that some customers/patients may choose to remain with a certain provider even if they were able to find the same service elsewhere cheaper (Deber, 2002). In a highly competitive market there are usually few barriers to entry and exit (Deber, 2002). However, laboratory services have numerous barriers to entry and exit and therefore non-contestable. As Preker and Harding concluded:

> "Once incumbents have invested in activities that result in expertise or generate trust, they enjoy a significant barrier to entry for other potential suppliers, thereby lowering the degree of contestability." (Preker and Harding, 2000).

Measurability

Measurability is the term used to describe "the precision with which inputs, processes, outputs, and outcomes of a good or service can be measured" (Preker & Harding 2000). It is important in performance monitoring that we are able to account for inputs and outcomes. The challenge that the healthcare sector faces it how and what should be measured. As Einstein said:

> "Not everything that can be counted counts and not everything that counts can be counted" (Einstein, attributed).

It is easier to monitor performance when measurability is high. This observation was confirmed by the findings of Bendick who compared private sector organization with public sector organizations. Bendick concluded that private for-profit organizations tended to be efficient at jobs where goals were measurable, easily monitored, and evaluated, while private not-for-profit organizations tend to better at providing service (Bendick, 1989). Based on his observation, complex organizations like healthcare that are service orientated are better suited for private not-for-profit delivery although some sectors within healthcare (e.g., laundry services) may be well suited for private for-profit delivery. In the healthcare environment, there are

variations as to how to precisely measure performance. Some sector such as medical laboratories, have a high degree of measurability. For example, when performing a specific laboratory test, it is easy to set performance criteria such as reference range, accuracy, precision and turn-around time. On the other hand it is more difficult to itemize the activities to be expected from a visit to your family doctor, and therefore more difficult to monitor performance and ensure quality.

Complexity

In the literature, complexity is defined as "whether the goods and services stand alone or require coordination with other providers" (Deber, 2002). Another term used to describe this same concept is "embeddedness". Many of the services provided in healthcare gain their value by being embedded. For example, the food services of a hospital may not be easily contracted to a regular outside food provider because of the special dietary needs of the patients. Similarly, most hospitals need in-house laboratory services in order to diagnose and treat patients in a timely manner. It is this idea of "embeddedness" that has been at the heart of resistance to any initiatives to amalgamate or centralize laboratory testing especially in the private not-for-profit hospital laboratories.

2.5 Summary

Accountability in health care has been identified as an area of interest in efforts to reform healthcare (Deber, 2011). However, in the literature review, there were few definitions of accountability that were specifically related to healthcare. Most of the definitions found were all borrowed from general definitions of accountability that have been used in many other sectors. There is need for more empirical evidence to guide the development of accountability mechanisms in public healthcare (Deber, 2011; Minkler, 2004; Health Professions Regulatory

Advisory Council, 2009). The traditional vertical and horizontal relationships between government and its citizens are also present in the health care sector but there are additional relationships created by the presence of health care providers and health care-specific public institutions (Schedler 1999 & Schacter 2000; Deber, 2011).

Recent discussions on accountability in healthcare in Ontario have been centered on the LHINs, healthcare facilities, and healthcare professionals. Canadians are demanding greater vertical and horizontal accountability from government and healthcare providers (Schacter, 2000; Flood & Choudhry, 2001; Kirby, 2001; Maxwell, 2002). According to Stein, two main themes that have emerged from a number of commissions examining the Canadian healthcare system are: a) financial and managerial accountability, which is a desire to know more about money, and performance and b) political accountability which is an increased capacity to classify rights and an increased desire to involve citizens more actively in policy reforms (Stein, 2001).

CHAPTER 3

An Overview of the Canadian Healthcare and the Ontario Medical Laboratory Sector

3.1: Introduction

Canada's healthcare model is largely referred to as a publicly funded and privately delivered system of care (Marchildon, 2012; Deber et al. 2010; Deber, Gamble & Mah, 2010). Financing addresses how healthcare is paid for while delivery addresses how healthcare is organized, managed, and provided (Organisation for Economic Co-operation and Development 1987; Donahue 1989; Deber, Narine, Baranek et al., 1998). In Canada, the majority of healthcare (approximately 70%) is publicly financed through money collected from taxation (CIHI, 2012). The remaining 30% is private financed mainly through private insurance, employee benefit packages, or out of pocket payment (CIHI, 2012). In 2012, a forecasted total of C$ 207 billion was spent on healthcare (CIHI, 2012). Understanding the role of the public and private sectors in terms of funding and delivery is important to ensure accountability for the use of public money (Deber, 2002). Therefore the next section will discuss the role of the public and private sectors in the financing and delivery of healthcare in Ontario.

Private and Public

A first step is to define public and private. According to Starr, the terms "public" and "private" are usually paired to represent such opposites as open and closed, government and markets, or the whole versus part (Starr, 1989). The term "public" is synonymous with government or the state, while "private" refers to that which lies outside of the scope of government, which usually is the market or family (Deber, 2002). Deber et al. classified the public sector into four levels of government:

- Federal (national government)
- Provincial (state, province or territory)
- Regional (e.g., regional health authority)
- Local (e.g., municipal)

This is the typology that will be used in this thesis to define the public sector.

The private sector includes both for-profit and not-for-profit organizations. Deber et al. classifies the private sector into four groups:

- For-profit corporations (e.g., LifeLabs)
- For-profit small business/entrepreneurial (e.g., labs located in physician's office)
- Not-for-profit organizations (e.g., hospitasl in Ontario)
- Friends, family and individuals (e.g., at home point of care testing).

While it is helpful to distinguish public from private, in reality the boundaries between the two can be blurred, especially in private organization that performs some public sector functions. For example The College of Medical Laboratory Technologist of Ontario (CMLTO) uses private money (i.e., member's registration fees) to carry out a public function (i.e., protecting the public).

The public sector and the private sector are both involved in the Canadian healthcare model (Deber, 2010). As noted above, the majority of services are publicly funded and privately delivered. This thesis will focus on the delivery of publicly funded laboratory services by the public sector (e.g., Public Health Laboratories), the private not-for-profit sector (e.g., laboratories in hospitals), and the private for-profit sector (e.g., corporations). This thesis does not describe and examine the for-profit laboratories in physician offices. This sector does not come under the

same licensing and regulations, as do the laboratories indicated above. Using the typology found in the literature (Donahue, 1989; Deber, Narine & Baranek et al. 1998), the following table provides an overview of the relationship between public/private sectors and the financing/delivery dimensions in the Canadian healthcare model.

Table 3.1 The relationship between public/private sectors and the financing/delivery dimensions

Delivery	**Financing**	
	Public	**Private**
Public	The public sector both funds and delivers services (e.g., communicable disease testing done by public health units).	The public sector delivers services (public ownership) but private insurance, employer sponsored benefits or individuals pay for care (e.g., prostate-specific antigen (PSA) screening test for prostate cancer).
Private	The public sector pays for services that are privately delivered (Hospital-based laboratories, Canadian Blood Services (CBS), Community (large corporation, small to medium sized owned and operated labs and small labs in doctor's offices).	Private insurance, employer sponsored benefits or individuals pay for care delivered by the private sector (e.g., speciality testing at laboratories in private fertility clinic).

Private not-for-profit (NFP) delivery

Private not-for-profit organizations vary in size from small (e.g., women's auxiliary gift shop) to large multi-million dollar establishments with many workers (e.g., hospital). In order to be classified as NFP, an organization must have the some or all of the following features: not part of the government, do not pay profit to individuals, receive charitable contributions, use

voluntary help, receive tax exemptions, can go bankrupt and have multiple objectives (Deber, 2002). Private not-for-profit organization are often said to do a better job at representing the interest of the public (Bendick, 1989).

Private for-profit (FP) delivery

Private for-profit organizations also vary in size from small (e.g., laboratory in a physician's office) to large multi-partner corporations with shareholders (e.g., LifeLabs). The characteristics of for-profit organizations are: making a profit for shareholders, able to access capital through issuing equity, cannot attract charitable donations or volunteer labour, and they have to pay taxes (Deber, 2002). Private for-profit organizations have as their incentive to maximize profit by minimizing cost. The dilemma that they often face is how to achieve this without compromising patient care (Cutler, 2000; Fuller, 2006).

An understanding of the concept of public and private is important to this thesis as it relates to the way laboratory services are financed and delivered in this province. The distinction between financing (who pays for services) and delivery (who owns and operate them), was described in the literature by Gamble (Gamble, 2002). The majority of medical laboratory services in Ontario are publicly financed. The methods of delivery are: public-not-for-profit, private-not-for-profit and private-for-profit.

4.2 An overview of the Ontario Medical Laboratory Sector

The delivery of quality laboratory services plays an integral part in the quality of care that a patient receives (CMLTO, 2013). The medical laboratory sector provides approximately 80% of the objective data for diagnosis, monitoring, and treatment of patients (CSMLS, 2013). Laboratories also produce results that are useful in public health for disease control and surveillance. High quality laboratory services produce additional benefits to the healthcare such

as infection control, reduction in length of stay or re-admission, fewer public inquiries, and fewer mal-practice law suits (CMLTO, 2013).

Medical laboratory providers are a diverse group that incorporate the public, private not-for profit and private for profit sectors. As well, a wide range of professionals contribute to the delivery of medical laboratory services: medical doctors/pathologists, laboratory managers, scientist/researchers, owners, medical laboratory technologist (MLTs) and medical laboratory technicians (CMLTO, 2013). The members of each of these groups have different interests and expertise and work through inter-professional collaboration to ensure cohesiveness with the medical laboratory sector (CMLTO, 2013). The responsibility of managing and performing laboratory testing is largely the responsibility of medical laboratory technologists. Medical laboratory technologists are the third largest group of regulated healthcare professionals in Ontario. The College of Medical Laboratory Technologists of Ontario is the regulatory College for this profession with 7711 members (CMLTO, 2013).

The majority of medical laboratory services in Ontario are publicly funded and are delivered as public-not-for-profit (public health laboratories), private-not-for-profit (hospitals-based laboratories, CBS) or private-for-profit (community-based laboratories). This thesis will focus on public health laboratories, hospital-based laboratories and community-based laboratories. As stated earlier, the privately funded and privately delivered laboratories as well as laboratories in physician offices will not be covered in this thesis. The reason for this is because they have a different licensing and regulatory bodies. Note that Canadian Blood Services is a not-for-profit entity. However, it is not accredited by the Ontario Laboratory Accreditation (OLA) but by Health Canada through Accreditation Canada.

Financing of Medical Laboratory Services

For the 2005/06 fiscal year (based on the most recent publicly available data), the Ministry of Health and Long Term Care spent $1.4 billion on laboratory services (Auditor General Report, 2007). Hospital-based laboratory expenditures accounted for $824 million; $572 million was paid to community-based laboratories, with three companies receiving over 90% of these payments. $4.4 million was paid to the OMA to operate its quality-management program for laboratory services on the Ontario Ministry of Health and Long-Term Care's behalf (Auditor General Report, 2007).

Delivery of Medical Laboratory Service

There are two delivery methods: 1) public and 2) private. Delivery can be further sub-divided into for-profit and not-for-profit as shown in Table 4.2. The term not-for-profit (NFP) covers most of the medical laboratories operating in hospitals and the public health laboratories.

Table 3.2 Delivery of Laboratory Services

Sector		Examples
Private	For-profit	Community-based laboratories 1. Large commercial labs 2. Small to medium owner operated labs. 3. Labs in physicians' offices
	Not-for-profit	Hospital-based laboratories (Note that hospital-based laboratories vary in size and services delivered)
Public		Public health laboratories

In the literature, private for-profit organizations are broken down into two categories: 1) Private for-profit small business (FP/s). This includes small business/entrepreneurs which are privately owned (often by the health professionals delivering the service), but need not answer to shareholders (Deber, 2002). Private small businesses tend to closely resemble the private-not-for-profit in the way they are structured and operated. The main difference is that their surplus is considered a profit. Many small laboratories that operate out of physicians' offices are usually categorized as small for-profit. As indicated earlier, laboratories located in physician's offices were not a main focus of this thesis. 2) Private for-profit Corporate (FP/c). This includes the community-based laboratories that are privately owned and return a profit to shareholders. The three mains providers in terms of market share are LifeLabs, Gamma-Dynacare, and CML Healthcare.

The type of services delivered will vary from one laboratory to another depending of the license issued by the MOHLTC and the accreditation awarded by the Ontario Laboratory Accreditation (OLA) team.

What are the approaches to accountability in the medical laboratory sector?

Based on the typology of Deber et.al, approaches in the Ontario ML sector will be discussed using four major approaches to accountability: 1) financial incentives, 2) regulations, 3) information, and 4) professionalism/stewardship.

1) Financial Incentives

Deber et. al., defines financial incentives as an approach to accountability, which adjusts payments to induce providers to behave in the desired manner. As noted in Chapter 2, an understanding of the role of the public and private sector in the financing and delivery of medical laboratory services is important in this study. The majority of medical laboratory services in

Ontario are publicly financed (Deber, 2010). Some services which are not deemed medically necessary are privately funded. For example blood testing for insurance policies and drug testing for truck drivers are not covered under the publicly insured system. Financial incentives vary across the different sub-sector with the ML sector.

Public not-for-profit laboratories

Publicly delivered laboratory services include the 11 public health laboratories that operate in Ontario. Public health laboratories (PHL) receive funding directly from the provincial government. The Ontario Agency for Health Promotion and Protection (OAHPP) responsiveness to fiscal responsibility is found in its commitment to the citizens of Ontario to "apply wisdom in managing and allocating these resources to ensure the best possible outcomes" (OAHPP, 2013).

Private not-for-profit laboratories

Private-not-for-profit (e.g., hospital-based) laboratories are usually funded under what is refers to as a "public-contract model," in which public payers contract with private health-care providers (Deber, 2010). This means that there is an accountability arrangements are between government and the "third sector" (e.g., hospital), and the laboratory, which presents an additional layer of complexity (Schwartz 2003). This in turn affects who will be accountable, to whom, and for what. For example, the hospital-based laboratory is accountable to the hospital administration and the physicians who order laboratory test for patients. The hospital is accountable to the provincial government who provides the funding.

Hospital-based inpatient and outpatient laboratory testing is funded through the hospitals' global budget. Hospitals control expenditures for their laboratories, which are a part of the budget submissions to the Ontario Ministry of Health and Long-term Care (MOHLTC). All laboratories are required to submit the number of reportable tests conducted each year to the

MOHLTC. In addition, hospital laboratories are required to calculate and submit workload unit reports to the MOHLTC (CADTH, 2013).

Private for-profit laboratories

Private community-based laboratories submit claims to OHIP on a per-test basis. There is a cap to funding for private laboratories (CADTH, 2013). In 1993 the MOHLTC, recognizing that it needed to allocate a finite amount of health care dollars effectively, introduced a ceiling ("industry cap") on the total amount payable by OHIP for community-based laboratory services carried out in a particular fiscal year. In 1996-7 the MOHLTC and the Ontario Association of Medical Laboratories (OAML) introduced the corporate cap payment to address the issue of fairness in funding distribution on a geographic basis. Under the corporate cap model, the Ministry only pays each individual laboratory up to its threshold amount ("corporate cap"). A corporate cap is the maximum total amount that a particular laboratory could be paid by OHIP in a fiscal year. This means that the amount a laboratory bills over its corporate cap is not funded by OHIP and is therefore absorbed by the laboratory (Information and Privacy Commissioner of Ontario, 2013).

Every two years the government negotiates a new agreement with the OAML. Under this new policy of corporate cap there has been guaranteed market share for community labs. This has resulted in lack of financial incentives for competition for market share. Corporate capping is an incentive to for-profit laboratories to take on mainly high volume, low unit cost testing. Therefore they do not offer the range of services that a laboratory situated in an academic hospital would. The challenges to the hospital-based laboratories, as noted in the British Columbia laboratory review (BC Laboratory Services Review, 2003) is that most hospitals perform low volume, complex, high unit cost tests. If hospital laboratories are able to generate

revenue based on fee-for-service billing for low cost outpatient services, this would offset the cost of the high unit cost tests that they perform (BC Laboratory Services Review, 2003).

2) Regulation, Licensing, Inspection and Legislations that governs the practice of Medical Laboratories in Ontario.

Regulation

The use of regulation as a policy instrument is deeply entrenched in the Ontario ML sector. The ML sector relies heavily on regulation. Most laboratories in Ontario are directed by a medical doctor with specialized training in laboratory medicine (MOHLTC, 2012). Doctors are members of the College of Physicians and Surgeons of Ontario (CPSO). As noted, medical laboratory technologists are members of the College of Medical Laboratory Technologist of Ontario (CMLTO). Regulatory Colleges exist to protect the public interest and ensure the highest standards of medical care through regulation of the professions (CMLTO, 2010). Both the CMLTO and CPSO have accountability to the public as part of their mandate.

The Ministry of Health and Long Term Care works through its appointed agency, the Ontario Medical Association (OMA), to provide accreditation for medical laboratories. The OMA was founded in 1880 as a voluntary association of the province's physicians. One of the roles of the OMA is to provide guidance in the development and promotion of healthcare in Ontario. The organization has professionals in a number of fields, including laboratory proficiency testing, and was legislated by the MOHLTC to carry out a quality management program (OMA, 2013). This program is called the Quality Management Program–Laboratory Services (QMP–LS). The Ontario Laboratory Accreditation (OLA) is part of the total quality management program operated by QMP-LS. OLA provides information about the accreditation

program and describes the rights and duties of accredited laboratories (QMP-LS, 2010). A discussion on the role of QMP-LS as a provider of information will be presented later in this chapter.

The medical laboratory sector is also regulated by numerous other organizations such as: Accreditation Canada, Industry Canada, Revenue Canada, Canada Nuclear Safety Commission, Office of the Fairness Commissioner and the College of American Pathologists (CAP). CAP is a medical society serving doctors, patients, and laboratory communities all over the world since 1947. One of its goals is to "promote quality in the practice of pathology" (CAP, 2013). One of the ways that it does this is by offering ISO 15189 accreditation to participating laboratories. In Ontario, CAP accreditation is not mandatory but many laboratories chose to participate on a voluntary basis. A further discussion of the role of Accreditation Canada as it relates to the delivery of laboratory services will be presented below. The other organizations are not discussed in this thesis as they are not mandatory and are only used by some laboratories depending on their licensing agreement and accreditation submission.

Accreditation Canada

Accreditation Canada is an established organization responsible for accrediting Regional Health Authorities, hospitals, and community-based programs and services, from both private and public sectors, not only in Canada but around the world (Accreditation Canada, 2012). Patient safety is an integral part of the assessment. Accreditation Canada "employs standards that assess governance, risk management, leadership, infection prevention and control, and medication management, as well as services in over 30 sectors, including acute care, home care, rehabilitation, community and public health, laboratories and blood banks, and diagnostic imaging" (Accreditation Canada, 2012). Participating

organizations are surveyed once every three to four years. Many hospitals in Ontario chose to accredit by Accreditation Canada and the laboratories operating in these institution are usually a part of this exercise. Obtaining accreditation from Accreditation Canada provides the public with additional evidence that the laboratory is performing to industry standards.

Licensing

The licensing and inspection of medical laboratories falls under the jurisdiction of the Ontario Ministry of Health and Long Term Care. *The Laboratory and Specimen Collection Center Licensing Act* sets out the guidelines that are used to own, operate, and license a specimen collection center or a laboratory in Ontario. All hospital-based and community-based laboratories and specimen collecting centers must be licensed and the license must be renewed every year. The application process involves paying the appropriate fee and providing the MOHLTC with relevant information which should include details on a laboratory's staff number, staff qualifications, and laboratory equipment. The type of laboratory license determines what kind of tests the laboratory is licensed to perform. Laboratories can only bill for tests that it is licensed to perform. For example a hospital-based laboratory that is given a series 4000 license will only be allowed to bill for tests done on patients admitted to the hospital. With a series 5000 license, the hospital is allowed to bill for inpatient and outpatient tests.

The responsibility of licensing and inspection of licensed laboratories lies with the Director of Laboratory Branch in the MOHLTC. Under the Act, a license may be revoked or its renewal refused if specimen collections or laboratory tests are incompetently carried out, or the owner/operator does not comply with the Act and related regulations (The Laboratory and Specimen Collection Center Licensing Act, 2012) There has not been any new laboratory license issued since 1973 (Sutherland, 2011). There has been a reduction in the number of

community-based laboratories due to mergers and buying up of smaller laboratories. This practice has proven advantageous since buying a smaller laboratory also means acquiring their market share or corporate cap. The number of specimen collection centers has increased steadily from 1974 to 2008; while the number of community laboratories has steadily declined over the same time period. See Table 4.3.

Table 3.3 Number of Licensed Laboratory and Specimen Collection Centers in Ontario

Year	Hospital-based labs	Community labs	Public health labs	Specimen collection centers
1974	227	288	13	188
1993	216	159	13	273
2008	175	32	12	420

Source: Sutherland, 2011, Laboratory branch of MOHLTC

Physical Inspection

The laboratory branch of MOHLTC is also responsible for the physical inspection of all licensed laboratories. They are expected to conduct an on-site visit every 18 to 24 months. There is a standard inspection worksheet that is used to document findings. A written report is given and any laboratory found to be not compliant is required to take corrective action to rectify the deficiencies (MOHLTC, 2013).

Legislation

Tables 4.4 and 4.5 will provide a summary of the major legislations, reviews, and mandates that have directly impacted the medical laboratory sector.

Table 3.4 Summary of Legislations directly related to ML sector

Year	Legislation	Impact on the healthcare / ML sector
1958	Hospital Insurance and Diagnostic Services Act (HIDS Act)	Federal government provided matching funds to Provinces for healthcare. Laboratory services falls under the "comprehensive" clause which provided funding for diagnostic services.
1990	Public Hospitals Act	Provide the framework within which hospitals operate. Laboratory services were included under the clauses which relate to diagnostic services.
1990	Laboratory and Specimen Collection Centre Licensing Act	Provides the legislations governing the licensing of Laboratory and Specimen Collection Centres in Ontario
1991	Regulated Health Professions Act	It includes a general Act, a Procedural Code for all the regulated health professions, and profession-specific Acts. The ML sector was included as one of the 23 regulated health professions.
1991	The Medical Laboratory Technology Act	Provide the guidelines for the operation of the College of Medical Laboratory Technologists of Ontario(CMLTO)
1997	The corporate cap model is set out in Regulation 2/98.	The goal was to prescribe the industry-wide cap and set out the formula for the calculation of the corporate cap of for-profit community laboratories.

2001	Laboratory and Specimen Collection Centre Licensing Act	The OMA appointed the QMP-LS with special responsibilities to improve the quality of lab medicine through external quality assessment (EQA) and accreditation to the OLA 15189Plus™ standard.
2004	Commitment to the Future of Medicare Act	One component of the Act is Public Accountability. It states that the health system is governed and managed in a way that reflects the public interest and that promotes efficient delivery of high quality health services. This is area of interest in the ML sector.
2004	Quality of Care Information Protection Act	Designed to encourage health professionals to share information and hold open discussions to improve patient care, without fear that the information will be used against them.
2010	Excellent Care for All Act.	Recommends putting patients first by improving the quality and value of the patient experience through the application of evidence-based health care. This is in keeping with the goals of the ML sector to a total quality management with patient safety at its core.

The following section will provide a summary of the four latest pieces of legislation because they contain significant policy directives which focus on accountability.

The Laboratory and Specimen Collection Centre Licensing Act (2001).

The QMP-LS began operating in Ontario in 2000 under the O. Reg. 682 of the *Laboratory and Specimen Collection Centre Licensing Act*. It replaced the Laboratory Proficiency Testing Program (LPTP) (Gamble, 2005). The LPTP was established in 1974 by the OMA. Its role was to examine and evaluate the performance of publicly funded (hospital, public health and community) laboratories. In 2005, the LPTP was renamed QMP-LS. The Quality Management Program-Laboratory Services is a mandatory program operated by the Ontario Medical Association (OMA) and funded by Ontario's Ministry of Health and Long-Term Care (MOHLTC) in order to improve patient safety. QMP-LS achieves this by assessing the quality of laboratory test results and ensuring laboratories meet international and national standards of excellence through the OLA 15189Plus™ accreditation program (QMP-LS, 2013). The QMP-LS provides the following description of OLA 15189Plus™ International Organization for Standardization (ISO) guidelines:

> **"**ISO 15189 is an international accreditation standard for medical laboratories. Laboratories accredited to ISO 15189 demonstrate that they meet comprehensive international standards for quality and competence. Accreditation bodies around the world have signed an International Laboratory Accreditation Cooperation (ILAC) arrangement that fosters laboratory recognition of quality, competence and capability through ISO 15189 accreditation. These accreditation bodies are evaluated to ensure rigorous conformity assessment standards are met. Only those accreditation bodies that are part of the ILAC recognition arrangement may issue an ISO 15189 certificate. OLA's partnership with Standards Council of Canada (SCC) makes an ISO 15189 certificate from SCC possible for OLA accredited laboratories" (QMP-LS, 2013)

The work of QMP-LS is conducted under two umbrellas: 1) External Quality Assessment (EQA), and 2) Ontario Laboratory Accreditation (OLA).

1) External Quality Assessment (EQA)

The EQA program plays a critical role in the laboratory quality system. Quality in the medical laboratory sector is defined as a having technical and clinical proficiency and performing the correct test (Tulloc, 1998). It complements the laboratory quality control and quality assurance programs that ensure the test results physicians use to make a diagnosis and prognosis are accurate and reliable. Laboratory results are peer reviewed and examined for reliability. Appropriate steps are taken to address unsatisfactory performance in EQA. Laboratories that are not able to implement corrective action may be considered non-proficient and referred to the MOHLTC for further remedial action that may include suspension of testing. An important advantage of the EQA is that it evaluates not only analytical but pre and post analytical issues that can affect laboratory test results.

2) Ontario Laboratory Accreditation (OLA)

Mandatory OLA accreditation of the majority of medical laboratories that operate in the province guarantees that laboratories in the Ontario have a world-class quality management system. A laboratory's accreditation certificate provides recognition that the laboratory is competent and gives staff and the public confidence that its system will identify and correct mistakes before they affect patient care. To be considered for accreditation, a laboratory must undergo an assessment visit conducted by a team of trained assessors accompanied by an OLA staff technologist. If areas of non-conformance are cited, the laboratory is expected to take corrective action within 90 days of the visit. A panel then determines if the laboratory meets the criteria for an accreditation certificate. The OLA accreditation is a very rigorous exercise as laboratories are examined based on 509 OLA requirements. However the benefits of being OLA accredited far outweigh the drawbacks. Being OLA accredited increases the willingness of

patients and payers to purchase laboratory services. In Ontario, medical laboratories are accountable to provincial governments to ensure public protection.

Commitment to the Future of Medicare Act 2004

This Act was passed in 2004 in acknowledgement of the commitment of the government of Ontario to Medicare (the provinces system of publicly funded health services). The highlights of this legislation centered on patient care, delivery of services, and accountability as important issues in healthcare. These issues are also important for the medical laboratory sector because public funds should be used efficiently and effectively to provide the best quality of care possible for the patients. Laboratories must be held accountable for the quality of the results they produce. Some of the items covered in legislation were:

- Commitment to the principles of the Canada Health Act
- Support the prohibition of two-tier medicine, extra billing, and user fees
- A consumer-centered health system that ensures access is based on assessed need, not on an individual's ability to pay
- Recognition that pharmacare for catastrophic drug costs is important to the future of the health system
- Access to community based health care, including primary health care, home care based on assessed need and community mental health care are cornerstones of an effective health care system
- Public accountability to ensure that the health system is governed and managed in a way that reflects the public interest and that promotes efficient delivery of high quality health services
- Recognition that the promotion of health, and the prevention of and treatment of disease includes mental and physical illness
- Recognition of the importance of an Ontario Health Quality Council that would report to the people of Ontario on the performance of their health system to support continuous quality improvement
- Collaboration between the community, individuals, health service providers and governments, and a common vision of shared responsibility (Commitment to the Future of Medicare Act, 2004).

The Quality of Care Information Protection Act (QCIPA) 2004

This law came into effect November 1, 2004. As stated in the legislation "QCIPA will promote quality care and patient safety in Ontario by enabling hospitals and other health facilities to carry out a review of any incident or event with the assurance that the information generated by the review is protected from disclosure" (Ontario Hospital Association, 2013). This law does not "prevent legal action resulting from adverse outcome of care but rather provide a safe forum for healthcare professionals to discuss errors and potential solutions and well as ways to prevent medical errors". This is in line with the definition of accountability as "the process by which one justifies and takes responsibility for actions" (Emanuel & Emanuel, 1996).

The Excellent Care for All Act 2010

The Excellent Care for All Act became law June 2010. The MOHLTC took this step to improve the quality of Ontario's health care system and make sure every health care dollar is used to provide the best possible care. The government took this step to demonstrate its commitment to the highest quality of healthcare by stating that:

- The patient is at the center of the health care system.
- Decisions about patient care are based on the best evidence and standards.
- The health care system is focused on the quality of care and the best use of resources.
- The main goal of the health care system is to get better and better at what it does (Excellent Care for All Act, 2012)

Under this new law, all residents of Ontario will be guaranteed the following:

- Doctors, nurses and everyone working in health care will put their needs as a patient first.
- The best available evidence will be used to make decisions about the care they receive.
- The experience that they have as a patient will be an important part of health care quality.
- They will have more information and greater choice in the health care they receive (Excellent Care for All Act, 2012).

Table 3.5 Summary of reviews and mandates directly related to ML sector

Year	Reviews and Mandates	Impact on the healthcare / MLS
1992	Laboratory Services Review	This report made recommendations that impacted the cost and utilization of laboratory services.
1996-1999	Healthcare and Hospital Restructuring	The goal was to foster progress toward the development of a genuine, rational, health care system in which hospitals work efficiently both with one another and with all the other players that together provide the range of services needed by vulnerable people facing or experiencing risks to their health. The ML sector was re-structured under this initiative

The following section will provide a summary of the contribution of these two mandates to the Ontario medical laboratory sector.

Laboratory Services Review

The Ontario Ministry of Health and Long-Term Care (MOHLTC) launched an initiative to review laboratory services in 1992. This was done to address the increasing utilization and cost of laboratory services. A team of advisors representing major interest group, stakeholders, and providers of medical laboratory services from the public health, private not-for-profit (i.e., hospital-based laboratories) and private-for-profit (i.e., community-based laboratories) sectors participated in this committee. A final report was

released in 1994. The recommendations made called for the implementation of: 1) quality improvement programs, 2) centralized database and interactive information system, 3) an interactive delivery system, 4) human resource management, 5) regulatory system that is enabling rather than controlling, and 6) the establishment of the Laboratory Services Restructuring Secretariat (LSRS) which was later renamed the Ontario Regional Laboratory Services Planning in 2000 (Lab review, 2012).

One of the main accomplishments of the LRSR was to get the different sectors that are involved in the delivery of laboratory services talking and working on initiatives that would improve service and enhance patient care.

Healthcare and Hospital Restructuring Commission

The Health Services Restructuring Commission (HSRC) was established in April 1996. It was given a mandate to:

- "Make decisions on restructuring Ontario's public hospitals"
- "Make recommendations to the Minister of Health and Long-Term Care on reinvestments in and restructuring of other parts of the health system and other changes required to support restructuring generally, and the creation of a genuine health services system in the province."(HSRC, 2000)

The HSRC made several recommendations which resulted in the closure or amalgamation of several hospitals in Ontario. This resulted in closure of some hospital-based laboratories. The HSRC also recommended that not-for-profit hospital laboratories and for-profit community laboratories in the same vicinity work together in the delivery of medical laboratory services (HRSC, 2012). This resulted in several attempts within the laboratory sector to form public-private partnerships between hospital-based and community-based laboratories. Based on the typology used in this study; these partnerships were publicly financed and privately

delivered. The success of these partnerships was limited and resulted in the dissolution of the partnerships (Gamble, 2002).

3. Information directed towards potential users (patients, public, and private payers)

This approach to accountability was defined by Deber at el., as allowing market forces to work more effectively by encouraging rational choice of the 'best' care (Deber, 2010). There are many ways of providing information. In this thesis special attention will be paid to publicly available reports. The document review highlighted the work of the Quality Management Program- Laboratory Services (QMP-LS) which operates under the auspices of the Ontario Medical Association (OMA). The QMP-LS play a dual role of regulatory (discussed earlier in this chapter) and providing information. QMP-LS produce an annual report that is available to the public. The report contains comprehensive information on the performance of all participating laboratories on both the OLA accreditation and external quality assessment programs administered throughout the year.

A number of advocacy groups and professional organization such as : Clinical Laboratory Managers Association (CLMA), Canadian Society of Medical Laboratory Science (CSMLS), Ontario Society of Medical Technologists (OSMT), and the College of Medical Laboratory Technologists of Ontario(CMLTO), share information to the public and providers though different means such as journal publications, periodic reports, annual reports, and media publications. On a smaller scale, most laboratories produce regular reports that highlight their performance based on pre-established quality indicators such as turn-around times for laboratory services.

4. Reliance on professionalism and stewardship

The use of reliance on professionalism and stewardship as an approach to accountability is embedded in the belief that providers, as a group, wish to do the right thing ((Lemieux-Charles & Champagne, 2004). The document review highlighted the role of regulatory colleges and professional associations to which most of the physicians and medical laboratory technologists belong as playing a role in shaping stewardship.

1) The College of Physicians and Surgeons of Ontario (CPSO)

It is the responsibility of the CPSO to regulate the medical profession by ensuring that only individuals who have graduated from an "accredited" medical school or an "acceptable unaccredited" medical school are certified to practice medicine in this province. In addition to meeting the academic requirements and technical skills, all physicians must be mentally competent, practice with honesty and integrity, and be able to communicate effectively with others in the scope of their practice (CPSO, 2013).

The CPSO has in place a disciplinary committee that investigates complaints made by the public relating to professional misconduct or incompetence by one of its members. Upon conviction by the CPSO, a physician may face a range of penalties, including: revoking or suspension of certificate, restriction of scope of practice, or payment of a fine of up to $35,000. Another regulatory mechanism employed by the CPSO is peer assessment and continuing education requirements.

2) The College of Medical Laboratory Technologist of Ontario (CMLTO)

In order to become a member of the CMLTO, the applicant must be successful in passing the national certification examination administered by the Canadian Society of Laboratory Sciences (CSMLS). All members of CMLTO are expected to maintain their competence

throughout their career, continually enhance their knowledge and skills, and participate in the quality assurance program. All members must complete an annual registration. This process involves providing the College with information pertaining to scope of practice, professional portfolio, hours worked, and hours of continuing education completed. CMLTO members are also required to share their knowledge and information with other members of the health care team, thus enhancing inter-professional collaboration.

The CMLTO is mandated to deal appropriately with complaints and concerns about the conduct of member medical laboratory technologists. Once a complaint is received it is the duty of the College to investigate and take appropriate actions which may include a reprimand, fines of up to $35,000, suspensions, terms, limitations, and conditions on a certificate of registration, or revocation of registration (CMLTO, 2012). In addition, employers are required to report to the College any employee that was terminated, suspended or restricted to practice for reasons of professional misconduct, incompetence, or incapacity (CMLTO, 2012).

Canadian Society of Medical Laboratory Sciences (CSMLS)

The CSMLS is the national certifying body for medical laboratory technologists and medical laboratory assistants, and the national professional society for Canada's medical laboratory professionals. They are a not-for-profit organization that is funded entirely by membership dues and revenues from goods and services. They do not receive operational funding from governments or other organizations. The CSMLS has over 14,500 members in Canada and in countries around the world. Its purpose is:

- "To promote and maintain a nationally accepted standard of medical laboratory technology by which other health professionals and the public are assured of effective and economical laboratory services."

- "To promote, maintain and protect the professional identity and interests of the medical laboratory technologist and of the profession" (CSMLS, 2013).

Membership with CSMLS is voluntary but many medical laboratory technologists choose to belong to a professional group that will lobby on their behalf.

Medical laboratory technologists belong to many other professional organizations based on their scope of practice. Many medical laboratories participate in a variety of mandatory and voluntary regulatory and licensing organizations as a part of the total quality management program. Reliance on professionalism/stewardship as a variant of the exhortation governing instrument is an effective approach to accountability within the ML sector.

The document review suggested that in the medical laboratory sector a blended approach of policy instruments is often used. For example, the requirement that medical laboratory Technologists belong to the CMLTO can be viewed as regulatory. It is regulatory because there is a signed agreement with legal consequences. On the other hand belonging to the College can also be viewed as sharing information with potential users on the suitability of medical technologists to practice in the province of Ontario.

3.3 The Role of Independent Variable in the ML sector

The literature review identified policy goals, governance/ownership and the goods and services being delivered, and their production characteristic as independent variable that affect various approaches to accountability. The following section will look at how each of these is represented in the medical laboratory sector.

3.3.1 Policy Goals

The majority of medical laboratory services in Ontario are publicly funded and delivered as public not-for-profit, private-not-profit and private for-profit. The main

difference in policy goals is based on whether the services are delivered as not-for-profit or for-profit. The public health laboratories, Canadian Blood Services and laboratories found in hospitals are all examples of not-for-profit organizations. These organizations focus on maintaining a balanced budget and are not concerned with generating a profit. Their policy goals are centered on issues such as quality accountability, transparency, efficiency, and cost-effectiveness (Gamble, 2005). Governments at all levels are requiring greater accountability for cost and quality of service (Forest, Marchildon & McIntosh, 2004). Quality in the medical laboratory sector should take into consideration pre-analytical, analytical, and post-analytical phases of testing. An example of pre-analytical quality measures includes the correct identification of the patient from whom a sample is taken. An example of analytical measures is the production of accurate test results. Examples of post analytical measures include interpretation and reporting of results.

Private for-profit community laboratories are different from not-for-profit laboratories because they have as a policy goal to make a profit for the shareholders. The scope of the services that they deliver is primarily tests that are routine, high volume, and easily automated. They may discontinue offering services that are too costly because they are concerned with profit-making (Deber, 2002).

3.3.2 Governance/Ownership structure in place

There are two types of ownership structure in place in the medical laboratory sector: public and private. The public health laboratories are owned and operated by the government. They had been in operation since 1890 when the Ontario government established the first public health laboratory in North America (MOHLTC, 2012). Public Health Laboratory services are paid for and delivered directly by the government. The

employees are civil servants. The government is responsible for the day to day operation of the laboratories that provide a variety of specialized testing and epidemiological services.

The privately owned medical laboratories can be further subdivided into private for-profit and private-not-for-profit. Two examples of private not-for-profit organizations that are of interest for this thesis are the Canadian Blood Services (CBS) and hospital-based laboratories. The CBS operates as a charitable not-for-profit incorporated organization. It has a Board of Directors that is responsible for its day to day operations. The Minister of Health or its representatives are members of the board but do not have power to direct the operation of the CBS. The board of the CBS is responsible for maintaining a safe blood supply and for operating within its prescribed budget (CBS, 2013).

Hospital-based laboratories are privately owned by the hospital in which they are located. Most hospitals are privately owned and operate on a day-to-day basis without the interference of government. Most hospitals receive public funding from the government through transfer payment from the MOHLTC based on the hospital global budget. Hospital-based laboratories are funded from the hospital's global budget. In 2006 the Ontario government spent $824 million on hospital laboratories (Auditor's General Report, 2007). The range of services and structure of the laboratory depends on the type of hospital. For example, many small rural hospitals will have small laboratories that offer stat tests and many esoteric or routine tests may be referred out. The organizational structure in these rural laboratories may also be very simple. On the other end of the spectrum are the large laboratories located in teaching "Group A" hospitals (Public Hospital Act, 2012). These laboratories offer a wide range of routine, esoteric, specialized tests, infection control,

research, and teaching. The laboratory hierarchal structure tends be more complicated to take into account the academic, research, and clinical work that is being done.

Private for-profit laboratories are owned by either small corporations (e.g., physician's office or owner operated small to medium laboratories) or large corporations (LifeLabs, Gamma Dynacare, and CML Healthcare). The governance structure tends to depend on the size of the corporation. Typically, small corporations are owned by professional with no shareholders and large corporations are investor-owned with shareholders.

3.3.3 Production Characteristics

This section of the thesis will only examine the difference between hospital-based and community laboratories. The public health laboratories will not be included because of the specialized nature of the testing that they perform.

Generally speaking, both hospital-based and community-based laboratories deliver services that are publicly funded. However, some important distinctions (there are a few exceptions) can be made in the way services are produced. Fagg et al. noted that many of these distinctions serve to identify and separate the two (Fagg et al., 1999).

- Hospital-based laboratories are not-for-profit while community-based laboratories are for-profit.
- Hospital-based laboratories provide testing for critically ill patient usually on a stat basis. Community-based laboratories provide routine tests for community and long term care.
- Hospital-based testing is manual or semi-automated. Community-based are fully automated or semi-automated.
- Hospital-based laboratories offer more esoteric tests that support teaching and research but may not be profitable. Community-based laboratory tend to be involved in cream-skimming i.e. offer only tests that are deemed to be profitable.
- Hospital-based laboratories samples are usually for inpatients or outpatient clients. Community-based laboratories have many specimen collection centers from which sample are transported to the central laboratories for testing.

3.4 Unregulated or Under-regulated Medical Laboratory Services

The majority of medical laboratory services in Ontario take place in a highly regulated environment. The literature review revealed that there is a small unregulated sector. This sector is made up of: privately funded, publicly delivered uninsured for-profit laboratories such as those run by fertility clinics (Ministry of Children and Youth Services, 2013) and private insurance company. Unregulated medical laboratory services will not be the primary focus in this thesis.

3.4.1 Publicly Uninsured Services

Some of the services offered by this sector are not covered by Ontario Health Insurance Plan (OHIP). For example the Anti-Mullerian Hormone (AMH) test measures the level of a hormone in a woman's blood and is a good way to assess egg supply but this test is not covered by OHIP. The major concern is that there is no mandatory licensing or quality assurance mechanism put in place by the MOHLTC to govern this sector. The organization may choose voluntary accreditation by Accreditation Canada. However, without mandatory provincial accreditation there are no standards for the services offered (Ministry of Children and Youth Services, 2013).

3.4.2 Physicians' Offices

Physicians in Ontario are covered under the *Laboratory and Specimen Collection Center Licensing Act* to perform simple laboratory tests in their office. The major concern is that these tests are not subjected to Ontario Laboratory Accreditation quality assurance. In the Auditor's General's Report of 2007, the report stated that the "The Ministry indicated that it had initiated discussions with the College of Physicians and Surgeons of Ontario

regarding options for monitoring the quality of testing being performed in physicians' offices" (Auditor's General's Report, 2007).

3.4.3 Point-of-care-Testing

Point-of-care-testing is the term used to describe laboratory tests that are conducted outside of a laboratory. Testing may take place in the hospital, clinic, doctor's office, ambulatory care, pharmacy, or at home (Accreditation Canada, 2012). The aim is to deliver test results that are fast and accurate very close to the patient. The methods used range from simple (dry chemistry) to more sophisticated testing. One of the most common POCT available is the glucose monitors. The concern with POCT is making sure there is appropriate accreditation and regulation.

3.5 Summary

Canada has a healthcare system that is mainly publicly funded and privately delivered. Most of the planning and delivery of healthcare takes place at the provincial and territorial levels. The federal government plays a role in funding, information, research, and regulation of healthcare. The Ontario medical laboratory sector falls under the jurisdiction of the Ministry of Health and Long Term Care. The medical laboratory sector is mainly publicly funded and privately delivered as not-for-profit or for-profit entities. Many organizations are involved in the licensing, accreditation and regulation of the sector. Medical laboratories provide approximately 80% of the objective data for diagnosis, monitoring, and treatment of patients. As users of public funds, they are accountable to the public for efficient and effective use of resources to provide timely and accurate results.

CHAPTER 4

Methodological Approaches

4.1 Methodological Approaches

The goals of this thesis are to:

1. Identify and describe the accountability mechanisms used in the Ontario Medical Laboratory Sector (ML sector);
2. Determine if the accountability mechanisms vary by sub-sector within the Ontario ML sector; and
3. Examine stakeholder views on the advantages and disadvantages of the accountability mechanisms used.

To answer these questions, document reviews of peer review, grey literature, and semi-structured interviews were conducted. The term grey literature is used to describe information that has not been peer reviewed, published or indexed by major databases. Key stakeholders were identified from a cross-section of Ontario's ML sector.

Note that this project is part of a larger study examining and comparing the approaches to accountability across a number of different healthcare sectors. The purpose of this study is to examine the approaches taken by the Ontario ML sector. The author's specific role in this research project included a) collaborative participation with an interdisciplinary team, working in partnership with senior policy makers in the Ontario ML sector (Dr. Gregory Flynn, Managing Director QMP-LS) to assist in the development of research questions and research design specific to this study, b) completion of information for the research ethics board, c) data collection, d) data entry, e) data analysis, f) presentations at local conferences, g) preparing a

paper for publication; and a registered medical laboratory technologist with the College of Medical Laboratory Technologists of Ontario (CMLTO).

4.2 Research design

The research design is a case study approach. This approach allows the researcher to obtain an understanding of the complex issue of approaches to accountability in healthcare and specifically the medical laboratory sector as little information exists at the present time (Johnson & Reynolds, 2005). As noted in the literature review, the delivery and financing of medical laboratory services in Ontario includes both the public and private sector resulting in a number of different funding models and delivery structures as described in Chapter 4 (see pages 76 and 80). According to Yin, the case study method is relevant when addressing a descriptive question such as "what happened and/or an explanatory question such as "how or why did something happen" (Yin, 2003). The goals of this study are to describe the accountability mechanisms used in the Ontario ML sector and how these approaches vary by sub-sectors as described in Chapter 1 (see page 16). Noting the advantages and disadvantages of the mechanisms used provides further clarification as to why certain approaches to accountability are used and others are not.

The benefit of using a case study design is the ability to incorporate data from a variety of sources including documents, artefacts, interviews, and observation (Merriam, 1998). This study uses document review and semi-structured interviews for data collection. A case study approach is also useful in obtaining specific information about the human side of an issue, including options, behaviors, and beliefs (Mack at el, 2005). As indicated, semi-structured interviews were used to determine the views of stakeholders on the accountability mechanisms used in Ontario ML sector.

Another benefit of a case study approach is that it confirms information that was presented in previous research or found in the literature review (Yin, 2003). Data collection included document review of peer review and grey literature. Using a case study approach was helpful in this study because there was very little research available on examining the accountability mechanisms used in Ontario's ML sector.

4.3 Data collection

Data was collected through document review and semi-structured interviews. The following section will describe the process.

4.3.1 Document Review

A description of the document review process will be presented in the sub-sections below.

4.3.1.1 Literature Search Strategies

The focus of the literature review was to identify articles related to accountability in health care. The research strategy included using different sources. The first search was done using the computerised library resources at University of Ontario Institute of Technology (UOIT). The search engines used were: Pub Med, Ovid, EBM Reviews, and Medline. These sites tend to capture different literatures, and thus helped ensure that key references were not missed (Walters, 2007).

The collection of data from documents was done through electronic index searching, citation searching, and purposive collection from stakeholder websites. Most of the data was collected from documents dated 1995 to present. The researcher decided to use 1995 as a starting point as this was the year that the Ontario healthcare sector underwent major restructuring. It was

also at this time that many changes in the parameters of public policy affecting the delivery of laboratory services were made. Using this year as a baseline, the researcher hoped to be able to keep track of future policy changes and their effect on the ML sector. A few older documents were used mainly because they provided historical/longitudinal perspective on approaches to accountability. Most of the documents accessed were publicly available and readily obtainable in electronic (PDF) format.

The inclusion criteria used were English Language articles only because of the lack of access to bilingual translators. The problem with this decision is that this thesis cannot be applied to French speaking Canadians. Articles from Canada, USA, England, New Zealand and Australia were mostly chosen because these countries have a publicly funded healthcare system or had the same economic status as Canada, thus making it easier to make comparisons (Deber, 2010; Marchildon, 2013). Only scholarly peer review articles were chosen because they ensured that the author's work, research, or idea have been scrutinized by others in the field that are qualified to perform an impartial review.

Citation chains from key articles were then analysed both backward and forwards; that is checking the relevant articles cited by that paper (backwards) and the materials citing that article (forward) to ensure accuracy (Kuper, Lingard, & Levinson, 2008).

The second literature search method employed was an internet search using the Google, and Google Scholar. Although these sources are not usually recognized as appropriate scholarly sources, they were chosen because of the nature of the research that was being conducted. The search strategy employed using such keywords as: indicators, accountability, accreditation, balanced scorecard, evidence-based laboratory medicine, funding for laboratory services, performance measurement, performance standards, and public health laboratories, alone and in

combination. The abstracts obtained were then screened for relevance. Articles and other citable material were then entered into a computerized searchable bibliographic data base, using the free software package Refworks.

A search for "grey literature" was conducted by visiting selected websites such as Public Health Agency of Canada (PHAC), Canadian Institute for Health Information (CIHI), College of Medical Laboratory Technologists of Ontario (CMLTO), The Canadian Society of Medical Laboratory Sciences (CSMLS), Ontario Society of Medical Laboratory Technologist (OSMLT) and the Clinical Laboratory Management Association (CLMA). Grey literature or unpublished articles are important because they provide a wealth of information that may not generally be found in published work. There not many scholarly papers on approaches to accountability written by Canadian medical laboratory professionals. Most of the information on accountability in the medical laboratory sector was obtained by looking at the original document archived in the different stakeholder organizations.

Data collected from documents was organized using two methods. The first was using an Excel spreadsheet to maintain a detailed record of all documents that were accessed. The second method was to save PDF copies of some documents deemed very important to a computer hard drive. A second excel spreadsheet was created using typology from the research questions to make it easier to track documents on file. A summary of data sources accessed is provided in Table 3.1 (see below). In addition to the summary of documents outlined below, certain websites were searched and read for organizational structure information and relevant website links to information related to accreditation or accountability. The decision on valuable websites to access was based on the literature review, suggestions from research partners and supervisors,

and the researcher's own knowledge of the ML sector. A complete list of websites accessed can be found in the references section of this thesis.

Document Review

The list of document sources reviewed are summarised in Table 4.1

Table 4.1 A summary of Documents reviewed

Type of Source	Sources Accessed	Data Used
Federal Government and Federal/Provincial/ Territorial (FPT) committees and organizations: (websites, indices, informants, documents, and administrative data)	1. Health Canada (HC) Main site www.hc-sc.gc.ca/index-eng.php Walkerton Commission www.attorneygeneral.jus.gov.on.ca/ Krever Commission www.hc-sc.gc.ca Cameron Inquiry www.cihrt.nl.ca/**Final**%20**Report**/index.pdf Romanow Commission www.hc-sc.gc.ca 2. Public Health Agency of Canada (PHAC) Main site www.phac-aspc.gc.ca/index-eng.php Laboratory Biosafety and Biosecurity www.phac-aspc.gc.ca/lab-bio/index-eng.php 3.Canadian Institute for Health Information (CIHI) Main site www.**cihi**.ca/ 4. Office of the Auditor General of Canada www.oag-bvg.gc.ca	HC Departmental Performance Reports (DPRs) 2000-2010 Final Reports from Krever,Walkerton and Romanow Commissions; Cameron Inquiry Discussion Papers Other selected reports and policy documents (strategic planning documents, specific program documents, working group/consensus conference reports including those published in *CCDR*)
Provincial Government (informant and administrative data)	Ontario Government, Ministry of Health and Long-Term Care Main site www.health.gov.on.ca/en/	Aggregate administrative records on legislations and

Type of Source	Sources Accessed	Data Used
		recommendation relating to medical laboratories
Legal Database	Canadian Legal Information Institute database (CanLII)4 Main site www.canlii.org/en/	Statutes and regulations (federal) Case law (federal and provincial) *Charter of Rights* Decisions
Stakeholders – providers and consumers	Canadian Medical Association(CMA) Main site www.cma.ca/ Quality Management Program-Laboratory Services(QMPLS) Main site www.**qmpls**.org/ College of Medical Laboratory Technologist of Ontario(CMLTO) Main site www.**cmlto**.com/ Canadian Society of Medical Laboratory Science (CSMLS) Main site www.**csmls**.org/ Ontario Society of Medical Technologist (OSMT) Main site www.**osmt**.org/	Position and policy statements Organizational information
Stakeholders – peer-reviewed literature	PubMed (MEDLINE) Main site www.ncbi.nlm.nih.gov/**pubmed** Google Scholar **scholar**.**google**.ca Scholars Portal www.**scholarsportal**.info/	Selected editorials, opinion pieces, policy statements by key stakeholders not accessed elsewhere
Mass media	CBC Main site www.**cbc**.ca/ The Globe and the Mail Main site www.**theglobeandmail**.com/ The National Post Main site	Selected media articles (event context)

Type of Source	Sources Accessed	Data Used
	www.**nationalpost**.com/ The Toronto Star www.the**star**.com/	

Each document was analyzed for its contribution in informing the research questions in this study. This information was placed into three board categories: historical perspective, governing instruments and independent variables. See Appendix H for a comprehensive list of documents reviewed and the contribution of each document.

4.3.2 Semi-structured interviews

Semi-structured interviews were conducted with key informants in the medical laboratory field. Qualitative research methods, such as key informant interviews, helped to obtain answers to questions on a broader level. These methods also helped to further expand and elaborate on areas that they felt were important to the issue being discussed (Bowling & Ebrahim, 2007). The use of semi-structured interviews allowed both the key informant and the researcher to ask for clarification in order to get a better understanding of the questions asked or the answers given.

Sample

The study took place in Ontario. Twenty individuals from, not-for-profit public health laboratories, private-not-for-profit hospital laboratories (large urban and small rural), and private for-profit community laboratories, educational and professional organizations were interviewed. Data design was guided by the categorization of the ML sector according to the delivery typology of Deber et al. (2010).

Sampling technique

In this study, snowball sampling, also known as chain referral sampling, was used to identify the individuals for the interview. This is a non-probability (non-random purposive)

sampling technique used to obtain information and knowledge, from extended associations, through previous acquaintances (Bowling & Ebrahim, 2007). Snowball sampling uses recommendations or referrals to find people with the specific range of skills that has been determined as being useful.

Inclusion criteria for this study were professionals working in the Ontario ML sector. The initial selection of informants was based on their position and/or role within the medical laboratory sector. As a result the following positions were identified: a) laboratory professionals with experience in supervisory or managerial positions, b) individuals representing laboratory professional organizations and c) individuals from academic programs responsible for training medical laboratory technologists. Key informants were chosen based on their position, knowledge, and experience with accountability approaches in the ML sector. According to Kumar (1989), they would provide the most valuable information in regards to our study. Participation in the study was voluntary. No incentives were given for participating.

Forty individuals were contacted and 23 consented to be interviewed. Those individuals who did not consent gave no reason for their refusal. There were three individuals who consented to an interview but did not respond to the follow-up email to schedule an interview date and time. As a result, only 20 persons were interviewed.

The interviews were conducted between May 2010 and October 2011. Individuals interviewed were from public not-for-profit (Public health laboratories), private not-for-profit (hospital laboratories), private for-profit (community laboratories), academic institutions, and professional organizations. The positions held by those interviewed included administrators, managers, physicians, educators, representative from professional organizations, and medical

laboratory technologists. Table 4.2 shows informants interviewed based on their profession and sub-sector.

Each informant was assigned a letter identifier and then assigned a chronological number based on their main position. For example laboratory manager was designated LM and assigned a number 01 (e.g., LM-01, LM-02).

Table 4.2 Number of Informants Interviewed by Position with Letter Identifiers

Sub-sector	Position	Letter identifier	Number interviewed
Not-for-profit	Administrator	AD	2
Not-for-profit	Laboratory Managers	LM	6
For-profit		LM	2
Not-for-profit	Laboratory Physicians	LP	2
Not-for-profit	Educators	ED	2
For-profit		ED	1
For-profit	Representatives from Professional Organization	PA	1
Not-for-profit	Medical Laboratory Technologist	MLT	4

As evident, the majority of persons interviewed were laboratory managers. This is not surprising since laboratory manager are usually responsible for regulation and accreditation, which is an important approach used to monitor accountability in the ML sector.

4.4 Interview Questions

The interview questions were designed to address the research goals in this study. The interview questions were developed in conjunction with the research team members from the Partnership for Health System Improvement (PHSI) on Approaches to Accountability. As previously stated, this is a research project funded by CIHR and features collaboration among an accomplished interdisciplinary team, working in partnership with senior policy makers across multiple healthcare sectors. The purpose of the overall study is to ascertain the factors affecting

the strengths and weaknesses of various approaches to accountability and whether these will have differing variation across sub-sectors depending on independent variable such a policy goals, governance structure, and production characteristics (Deber, 2010).

The interview questions were discussed over a series of meetings with the research team members. The questions were developed such that they could be generally applied across different samples and to allow for comparability across the different sub-studies, and across jurisdictions. To ascertain the factors affecting the strengths and weaknesses of various approaches, this study concentrated on four currently-used approaches to accountability: financial incentives, regulations, information directed towards patients/payers, and professionalism/stewardship (Deber, 2010). The interview questions guide was reviewed and approved by the researcher's supervisor.

The following questions were asked during the interview:

1. a. What are the accountability requirements for each of the defined function areas?
   b. To whom is your organization accountable?
2. What types of services does your organization contract out?
3. Are there services your organization would NEVER contract out? Why?
4. What approaches (internal and external) are/were used by your organization? For each approach state where it is used, how often it is used in that area, and who is holding 'you' accountable?
5. Were consultations carried out or was the approach imposed on your organization? If imposed, who was it imposed by?
6. If consultations were used, how were they carried out? How much input did your organization have?
7. Do you feel this process led to a better/worse approach to accountability?
8. What are (were) the strengths of the approaches?
9. What are (were) the weaknesses/challenges of these approaches?

10. Do the approaches used help your organization achieve its goals (are they aligned with the goals)?
11. How well do you think each approach ensures performance, equity, and financial stewardship?
    a. Has there been a change in your organization's ability to achieve these goals since the introduction of the accountability measures?
    b. Do the accountability measures help reveal, or address problems, and then fix them if identified?
12. Is it difficult for your organization to achieve accountability? Is there variation? If so, why?
13. Is there CEO – board accountability?
14. Who pays to meet the requirements or monitor compliance with the requirements (i.e., evaluation)?
15. Why do you think the performance measures used in the HSAA were chosen?
16. What activities do you think are important to be measured but are not currently being measured in HSAA or OLA?
    a. Why are these activities not being measured?
    b. Are these the same reasons why they excluded from the HSAA/OLA?
17. What activities are not measured in any way? Why?
18. Do you use these accountability measures to make decisions on performance?
    a. What do you use to make decisions about performance?
19. How easy is it for an organization like yours to enter your sector and provide services in targeted areas (or market)/specialized services?
    a. (*If easy*) Why is it easy to enter the system?
    b. (*If difficult*) What makes it difficult for an organization to enter?
20. Is it difficult for an organization like yours to leave target markets, make changes in service provision, or stop providing services?
21. Are there any consequences or rewards that result from not meeting performance criteria or accountability criteria?
    a. If so, what are the consequences or rewards?
22. Are the accountability/performance indicators tied to financial indicators/rewards?

23. Are there any unintended consequences that occur due to the accountability approach being used?

4.5 Conducting the Interviews

A total of 23 questions were developed (see above). Key informants, once identified were sent an email by the researcher and invited to participate in a semi-structured interview to provide their views on approaches to accountability in the ML sector in Ontario (See Appendix B). Informants were asked to forward their acceptance or declination to the email address of the researcher. A response declining to participate was followed up with a thank you letter. A response to participate was followed up with an email of the interview questions and a copy of the consent letter (See Appendix A for interview questions and Appendix C for consent letter). The researcher then followed up with subsequent emails and/or telephone calls with the intention of setting a date, time, and place for the interview. No response to the first email was followed up with a second email approximately two to four weeks afterwards. There were no incentives offered for participating in the interviews.

The time and place of the interviews varied based on the availability of the informants. Most of the interviews were conducted during the regular working hours of 9:00 a.m. to 5:00 p.m. The researcher travelled across Southern Ontario to conduct sixteen face-to-face interviews. The remaining four were conducted by telephone.

At the time of face-to-face interview, the researcher first went over the consent form with each informant and obtained a signed copy of the consent form from the informants. Informants who participated by telephone were also briefed on confidentiality at the start of the interview. Verbal consent was obtained and the participant was asked to return their signed consent forms to the researcher by fax or email.

Each interview began with a short introduction of the researcher and the purpose of the study. The researcher obtained consent to tape the interview and to take notes. Eighteen informants consented to be tape-recorded; the other two hand-written notes were taken by the researcher. The interview then proceeded with the researcher asking the questions, using the interview guide (see Appendix A). As the need arose, the researcher was able to ask for further clarifications or elaborations. The researcher would skip over a questions that the participant was not comfortable answering or that was already answered while answering another question. At the end of the interview, the participants were thanked for their willingness to participate. Participants were also asked if there was anyone else that they think the researcher should talk to. Any suggestions received were followed up by the researcher alone. Every effort was made to ensure confidentiality and avoid coercion. A thank you letter was sent to all participants (see Appendix D).

The interviews ranged in length from 45 minutes to 75 minutes, with the majority of interviews lasting 60 minutes. The interviews were either voice tape-recorded or hand written, depending on the preferences of the person being interviewed. A manual Sanyo 2-Speed dictation microphone and a digital Sony ICD-PX820 tape recorder were used to tape the interviews. All interviews were conducted by the researcher.

4.6 Ethics Approval

Ethics approval for the interviews was obtained from the University Of Ontario Institute Of Technology Office Of Research Ethics (REB # 10-036). See Appendix F and G.

Confidentiality and anonymity of the data was an important aspect of this research design. The data from the interview transcripts was removed of identifying information and the audiotapes were deleted immediately after transcription. This information was relayed to

informants in the consent forms and again prior to the interview by the researcher. All informants will be given a summary of the findings at the completion of the thesis.

4.7 Data Saturation

The sample size was determined by data saturation. Data saturation is achieved when further sampling does not generate any new data (Guest, Bunce & Johnson, 2006). In this study data saturation was achieved when further interviews were not revealing any new information but merely repeating what was heard before.

4.8 Data Triangulation

This research was designed to incorporate the principles of triangulation. Triangulation is a useful technique that aids in the authentication of data through cross verification from more than two sources with the aim to increase the credibility and validity of the results (Yin, 2003). Triangulation goes beyond repetition of data gathering to a deliberate effort to find the validity of data, observe its meaning and interpretation (Jick, 1979). In this study a combination of data triangulation and methodological triangulation were used.

4.8.1 Data-source triangulation

Data- source triangulation is the collection of data from different examples of similar cases (Yin, 2003). The purpose of data-source triangulation is to see if the phenomenon remains the same under different circumstance bases of the parties that are involved (Yin, 2003). Denzin described three types of data triangulation; time, space, and person (Denzin, 1989). In this study, data was collected at different points in time (May 2010 to October 2011) and in different spaces (across the Southern Ontario). The advantage of using data-source triangulation was that the researcher was able to compare and contrast the response of key informants based of geographical location (urban versus rural laboratories). The key informants were drawn from a

variety of professionals and sub-sectors within the ML sector, hence providing breadth and depth to the information received. Table 4.3 provides an example of person triangulation.

Table 4.3 Example of person triangulation.

Position	Geographical Location	Sector	Number interviewed
Laboratory managers	Urban	For-profit	2
Laboratory managers	Rural	For-profit	0
Laboratory managers	Urban	Not-for-profit	4
Laboratory managers	Rural	Not-for-profit	2

4.8.1 Method source triangulation

Methodological triangulation involves the collection of data using different methods. The purpose of using multiple data collection methods is to provide greater confidence in the interpretation of the findings from the data analysis. This study uses two data methods: document reviews (e.g., Legislation and Regulation) and key informant interviews to illustrate the "converging lines of inquiry" (Yin 2003). Table 4.4 is a summary of the methodological triangulation that was used in this study. The reason for using triangulation was to assure completeness of findings, provide a counterbalance for the margin of error, and to confirm findings.

Table 4.4 Methodological Triangulation

Document Review • Legislation • Regulations • Historical documents and reports from organizations, governments and associations • Newspaper articles • Presentation from conferences • Reports from inquiries **Key Informant Interviews** • Administrators • Educators • Laboratory managers • Laboratory physicians • Medical laboratory technologist • Representatives from professional organizations

4.8 Data Analysis

A description of data analysis will be presented in the sub-sections below.

4.8.1 Data analysis of documents

In order to guide the document analysis, the following questions were asked using the framework established by Deber et al. (Deber 2010).

1. What types of laboratory services presently exists?
2. How are the services delivered?
3. What type of governance structure is in place?

The approach taken in data analysis is what Miles and Huberman call a "mid-level" approach. The mid-level approach combines the creation of a detailed provisional structure (*a priori* approach) based on the conceptual framework, following which the coding approach is

revised, refined, and/or expanded (*inductive* approach) based on emergent themes (Miles & Huberman ,1994).

Documents of interest were manually coded and analysed. Documents were coded into the following broad categories: 1) policy events (timelines), 2) organizational shifts, 3) legal excerpts, 4) government performance reports, and 5) government laboratory expenditure. Interim themes and analysis were reviewed regularly with the thesis supervisor, following which coding was refined further to reflect emergent themes. Appendix H provides a comprehensive list of the documents reviewed and Appendix E provides a summary of categories into which documents was sorted and coded.

4.9.2 Data analysis of semi-structured interviews.

Eighteen semi-structured interviews were recorded using a tape recorder. The researcher took detailed notes with two of the interviewees. The first step in data analysis is transcription of the data. For the two interviews in which notes were taken this involved typing the notes into a word document and later re-checking the word document against the written notes.

For interviews that were recorded, the first step was to transcribe the audio files into a word document. For the first two interviews this was done by repeatedly listening to the tape while typing text into a word document. This was a very time consuming measure. With the help of the Information Technology department at UOIT a special software program, Dragon™, was located that would be used to convert voice directly into text. An amendment to the REB application was submitted and permission was obtained to use this software (see Appendix G for amendment to REB application).

The data was transcribed using the services of a paid transcriber. REB amendment was obtained to use a transcriber. (See Appendix I). After the data was transcribed using computer

software, the taped interview was then replayed several times to allow the researcher to make corrections for any translation error due to voice recognition. In accordance with the transcription process described by Denzin and Lincoln , the data analysis involved listening to the recorded sessions and writing down each word, pause, remark and statement to capture non-verbal behaviours during the interview, such as laughter and pauses made by both the researcher and the informant. Such details are considered an important part of the research process because they allow the reader to gain a sense of how the actual conversations took place and give a sense of the ease with which questions were answered (Denzin & Lincoln, 2000).

Upon completion of the transcription, the transcriptions were removed of any identifying information and replaced with identifying codes (e.g., the first manager interviewed was coded LM-01). The transcriptions were stored in a password-protected computer in the research supervisor's office. The list of identifiers was stored in a locked filing cabinet separate from the tapes, consent forms, and transcripts.

4.9.3 Data analysis and coding using computer software NVivo9™

NVivo9™ is a qualitative data analysis computer software package produced by QSR International. It has been designed for qualitative researchers working with very rich text-based and/or multimedia information, where deep levels of analysis on small or large volumes of data are required. One special feature of NVivo9™ is that it allows the analysis to put themes in 'nodes' which are like virtual filing boxes that allow the researcher to see all the information on a theme summarized together. The identification of themes is one of the most fundamental tasks in qualitative research (Ryan & Bernard, 2003).

NVivo9™ was used to analyze the transcripts from the key informant interviews. The transcripts were uploaded onto NVivo9™ on a password protected computer. Only the

researcher had access to the data base. The researcher had no previous experience using NVivo9™ and so in order to become familiar with the software, participated in two peer-training sessions and one on-line Webinar.

Using NVivo9™, the researcher created themes based on the analytical framework (Deber, 2010). The transcripts were then analyzed line-by-line, coded using key words or phrases and placed into the appropriate nodes (Ryan & Bernard, 2003). The nodes were compared with each other in order to put them into sub-categories. The researcher then compared the sub-categories back and forth in order to put them into the main categories or themes (Cutcliffe, Stevenson, Jackson & Smith, 2006). The themes were chosen according to the four governing instruments as well as core independent variables obtained from the analytical framework. The analytical framework includes four approaches to accountability; financial incentives, regulations, information directed at users (one form of exhortation instrument) and reliance on professionalism and stewardship (Deber, 2010). The core independent variables were policy goals (access, cost and quality), governance/ownership (including the public-private mix) and production characteristics (contestability, measurability, complexity) of the goods and services being provided in the ML sector (Deber, 2010).

4.9.4 Validation and Reliability of Data

Once the data analysis was completed, the researcher then went back and re-read the interview transcript and coding to ensure consistency and accuracy. In order to ensure reliability, one transcript in NVivo9™ was coded by another researcher not involved with the study. The result from the coding comparison query was found to within 85% agreement with that of the researcher. This step ensured validity of the coding process and reduces the chances of

researcher's bias (Richards, 2005). A summary of coding categories is available as Appendix E. The detailed analyses, including quotations, are provided in Chapter 4.

4.9.5 Storage of Research Data

At the completion of the thesis, hard copies of the consent forms and other interview data were sealed in an envelope and securely locked in a cabinet in the supervisor's (Dr. Brenda Gamble) office at UOIT. These will be destroyed after seven years. Data from the password protected computer and audio recordings from the digital voice recorder were deleted by the researcher.

4.10 Research Timelines

Data collection for the research study began in June, 2010 with the first pilot interview held with a laboratory supervisor. After the interview, the researcher received feedback on the relevance of the questions and the level of difficulty. This was used to help create prompts to be used for future informants. The majority of data was collected in the spring/summer months of 2011. Data analysis commenced in October, 2011 with completion in March, 2012.

4.11 Limitations of the case study and measures taken to address them in this research.

Bowling and Ebrahim define case study "as a research method which focuses on the circumstances, dynamics, and complexity of a single case, or a small number of cases" (Bowling & Ebrahim, 2007). It is used increasingly in research on health and health services. However a key dilemma that researchers face is proving that their findings are of the quality as that of traditional researchers who perform quantitative studies. This is because there are three main limitations in the use of case studies. These are: the potential for bias, the question of generalizability (especially for single case studies), and the length of time required to collect and interpret data (Yin, 2003; Johnson & Reynolds, 2005). However, there are ways to minimize the

effects of these and thus improve the validity and reliability of the research. The following is a description of how Yin's techniques for improving validity were implemented in this thesis to minimize the bias of the case study (Yin, 2003).

1. The potential for researcher bias.

To control for this the research was designed with a number of checks and balances to minimize researcher bias and maximize validity, accuracy and reliability of the interpretation. The following checks were used in this study:

- The sample was drawn from a wide cross-section of medical laboratory professionals representing a variety of different prospective from both for-profit and not-profit organizations as well as professional and accreditation bodies. These individuals were considered to be in a position to comment on accountability approaches in the laboratory services and were not coerced in any way to participate in the study.
- The majority of interviews were voice taped and where this was not possible detailed hand-written notes were taken.
- The data coding in NVivo9™ was validated by an independent coder and found to with 85 percent agreement of the researcher.
- The data collection source varied and included both document review and semi-structured interviews.
- Triangulation was employed to ensure accuracy of data collected and to validate the meaning and interpretation of data.

2. Generalizability of findings is not the goal of the study

Although this study provided useful information, no attempt will be made to generalize the insights gained to any province in Canada or globally. This is mainly because of the following limitations:

- the possibility of data collection bias
- sample size for the study was small (20)
- geographical location(mainly GTA)
- sub-sector bias(mainly not-profit)
- attention bias(mostly face-to-face lengthy interviews)
- researcher's bias with data collection

3. The length of time required to collect and interpret data.

The use of documents allowed the researcher to be able to review records dating back for 15 years. This time frame was chosen in order to track policy changes since the last major re-structuring of the Ontario healthcare system in 1995.This information was validated in the semi-structured interviews.

4.12 Conduct of Analysis

An analysis of the data from documents review and semi-structured interviews was done in four stages. This iterative analytical process included a number of distinct and interconnected stages. The conduct of analysis was guided by the conceptual framework established by Deber (Deber, 2002).

4.12.1 1 Stage I: Policy Instruments

The first stage of this research was to analyse policy instruments or governing instruments relating to accountability and how these affect the strengths and weaknesses of various

approaches to accountability in the ML sector. The research concentrated on four currently-used approaches to accountability: financial incentives, regulations, information directed towards patients/payers, and professionalism/stewardship—which represent variations on the 'expenditure,' 'regulation,' and exhortation' governing instruments. The documents reviewed as well as the interview questions were structured to answer to the following questions:

1. What types of laboratory services presently exists?
2. How are the services delivered?
3. What type of governance structure is in place?
4. Who is being held accountable?
5. To whom are they accountable?
6. What are they accountable for?

The conceptual framework established by Dr. Raisa Deber (2002) was used to draft the analytical framework for this thesis. The results are presented in Chapter Five.

4.12.2 Stage II: Independent Core Variables

Stage II of the investigation provides an overview of the three main independent core variables: a) policy goals being pursued, b) governance/ownership structure and, c) the goods and services being delivered. Under policy goals being pursued, issues relating to access and quality of laboratory service were examined. Key informants views on cost control, cost effectiveness and customer satisfaction are found in Chapter Five. The impact of governance/ ownership on for-profit or not- for-profit laboratories, legal responsibilities versus practical enforcement and the enforcement mechanisms (OLA accreditation) are found in Chapter Five.

The results on the impact of the three main areas of production characteristic: contestability, measurability and complexity are presented in Chapter Five.

4.12.3 Stage III: Healthcare Professionals' Views on Benefits and Potential Barriers to the Implementation of Accountability Measures in the Medical Laboratory Sector.

Stage III of the analysis examined healthcare professionals view on the potential barriers for the implementation of accountability measures in the ML sector. It examined the benefits, if any, of accountability approaches that are being used and how these may be adopted as best practices across the laboratory sector. It also analysed key informants views in order to determine if approaches vary by sub-sector (hospital versus community lab).

Some of this information was present in documents but was validated during the semi-structured interviews. The interviewees also provided new information that was not found in any of the documents that were reviewed. This information is presented in Chapter Five.

4.13 Summary

A mixed methodology including both document review and semi-structured interviews of key informant interviews was used in this research. The use of the case study approach allowed the researcher to place data examined from organizational documents such as administrative reports, missions and vision statements, and news clippings into the appropriate themes. The researcher formulated the themes using the analytical framework described earlier. The next step was a back and forth comparison of themes from both data collections methods (document and semi-structured interviews) in order to compare and contrast themes (Yin, 2003).

Documents provided historical as well as current information on approaches to accountability in the ML sector. These documents are useful in investigating past and current

legislation and regulation relating to the delivery of laboratory services. Further, the documents have the additional benefits of being unobtrusive, nonreactive, unbiased, and objective. In selecting the documents to be used for this thesis, special care was taken to avoid reporting bias by selecting peer reviewed documents or those from credible websites.

Twenty semi-structured interviews were conducted in accordance to the REB approval obtained from UOIT. The information generated from these interviews validated some of the information found in the documents reviewed as well as provided new fields of information directly relating to current approaches to accountability being used in the ML sector in Ontario.

Chapter Five

Results from Qualitative Data Analysis

5.1 Introduction

This chapter presents the results from the key informant semi-structured interviews. The semi-structured interviews were conducted to get a better understanding of the views of medical laboratory professionals on the approaches to accountability in the Ontario ML sector.

The data collected from the semi-structured interviews were designed to answer the following questions:

1) What types of laboratory services presently exists?

2) How are the services delivered?

3) What type of governance structure is in place?

4) Who is being held accountable?

5) To whom are they accountable?

6) What are they accountable for?

7) What are best practices approaches to accountability in the Ontario ML sector?

5.2 Semi-structured Interview Results

The data from the semi-structured interviews was organized into categories and common themes (see Table 5.1 below). The categories identified were guided by the analytical framework used in this study (see Chapter 2). To maintain confidentiality, all participants will be identified using pseudonyms.

Table 5.1 Categories and Common Themes

CATEGORIES	COMMON THEMES
Financial incentives	• Functional area of work • Accountability requirements to whom • Accountability requirements for what • Termination or reduction of contracts • Fines • Public reporting
Regulations	• Accreditation • Regional bodies (Local Health Integration Networks, or LHINs) • Regulatory and medico-legal bodies
Information directed to users	• Client satisfaction • Evidence-based practices • Internal and external indicators • Information directed to payers or care providers • Report cards
Professionalism/Stewardship	• Regulatory Colleges • Report cards
Core Independent Variables	**1. Policy Goals** • access • quality (including safety) • cost control/cost effectiveness • customer satisfaction **2. Governance/Ownership** • private versus public • not-for-profit (hospitals, Public health labs, CBS) • small business for-profit • investor-owned for-profit corporations ***3. Goods and services* being delivered** • contestability • measurability • complexity.

Views on Benefits and Potential Barriers	• Training • Funding • Human resources • Equipment/technology • Accreditation

5.2.1 Description of the Key Informants

Twenty individuals participated in the semi-structured interviews. Eight (40%) laboratory managers, five (25%) medical laboratory technologists, three (15%) educators, two (10%) medical doctors, one (5%) participant from a professional organization and one (5%) administrator. Seventeen (85%) of the respondents were female and three (15%) were male. This is not surprising as the medical laboratory sector is female dominated. According to the CIHI workplace survey done in 2011, 85.4% of MLTs are female and 14.6% are male (CIHI, 2013).

Three (15%) participants were from private-for-profit laboratories, 14 (70%) were from the private-not-for-profit laboratories. Two (10%) were from public health laboratories and one (5%) was from a private not-for-profit professional organization. (See Table 5.2).

Table 5.2 Number of Key Informants Interviewed by Sector, Position and Letter Identifiers

	Public health	Hospital-based	Community-based	Educational and professional organizations
Directors (D)		D1,		D2, D3
Managers (M)	M1, M2	M3, M4, M5,M6,M7	M8 , M9, M10	M11, M12
Medical laboratory technologist (MLT)		MLT1, MLT2, MLT3		MLT4, MLT5

The following sections will present the data collected from the semi-structured interviews.

5.3 The role and the importance of accountability

Accountability plays an important role in the medical laboratory sector. The relationships are complex and multifaceted. For example the CEO of a national not-for-profit professional association indicated:

> "We are required to follow the laws that govern not-for-profit associations. We are responsible for things like our certification seal and that's to industry Canada. So the actual seal that goes on certificates of registration we own the seal and the crest…… one of the things we are legally obligated to have clearly defined to industry Canada is how we handle this to prevent fraud. The other thing that we are responsible for under industry Canada is our bylaws; so because we're a national corporation we are responsible to industry Canada. We are also responsible to the laws of Ontario for workplace, the status of the disability act, occupational health and safety. We're also responsible for financial accountability to industry Canada. We do file reports with them as well as Canada Revenue Agency and we have some exemptions for some of our not-for-profit status ……. so for instance some things we collect GST or HST on another things we don't."

A manager of a regional hospital laboratory said:

> "We are accountable fiscally first to our executive vice president for maintaining a balanced budget….. accountability for performance to meet the anticipated customer demands and align ourselves with the strategic plan….we are accountable through performance indicators which are chosen and monitored to ensure that we are meeting the performance of expectations of our customers have includes things like turnaround time and accuracy…… So from a patient safety point of view we have direct accountability to the medical director and from the operational piece around fiscal management and performance to the EVP, we have a dual accountability."

A community laboratory manager states:

> "Accountability in its simplest form is to account for. This is supposed to be a neutral term not blame or shame. A constructive approach is to look at how we make decisions and who make this decision. Patient care is central to what we do."

Key informants often emphasized the complexities of the relationships with other organizations within which they operate and the different agencies to which they are accountable. One manager from the community laboratory sub-sector said:

> "There have a number of laboratory and diagnostic organizations to which we are accountable: Canada Nuclear Safety Commission, Ontario Medical Association and Ontario Laboratory Accreditation program, College of Medical Laboratory Technologist of Ontario, New York State department of Health, Blue Cross, Blue Shields, E- health Ontario, Health Canada, College of Physicians and Surgeons, College of Radiation Technologist of Ontario, FDA of America."

Another manager from regional program describes the role of their organization in terms of accountability this way:

> "Our mandate is to provide education and education resources and under that we develop education resources and also functional resources that hospitals can use to help improve utilization. We plan and facilitate educational events. And, one of our key roles is in communication."

In terms of accountability, one respondent from a hospital laboratory gave this perspective as an educator:

> "My role of educator, I am responsible for coordinating student lab technicians' rotations within our department. So, I am accountable, I am a partner with the academic institutions that we take the students from. So I am accountable to making sure the student cover the objectives set by the schools. I am also responsible for staff education. So, in that case I am accountable to my director of my department who is responsible or accountable to the VP and all the way up to the CEO."

A director of a teaching institution responsible for training medical technologists stated:

> "The primary goals of the organization are to be accountable to the employer for the appropriate education of marketable graduates."

This statement by a manager working in the hospital laboratory further illustrates the complexity of relationships:

> "Well, we are accountable to the physicians; we are accountable to the nursing unit. We are accountable to physicians, nursing units, to our partners, and our requirements are to provide timely testing results and high quality standards and we have to be fiscally responsible. So I am also accountable to the CEO and the budget. And, who are we accountable to? We are accountable to the LHIN and to the public."

5.4. What are the views on internal and external approaches to accountability used in the ML sector?

The literature review indicated that governments can use a number of governing instruments to ensure that private providers achieve accountability (Howlett & Ramesh, 2003). These include: exhortation, taxation, expenditure, regulation, and public ownership. The choice of policy instrument will depend on the sub-sector and the policy goals that are to be achieved. The approaches used may be internal or external.

5.4.1 Internal Approaches to Accountability

When asked what their experiences were on internal approaches used by their organization to achieve accountability, respondents cited numerous examples. There were variations in the responses depending on the sub-sector within the ML sector. Speaking from an administrative point of view, one manager from a not-for-profit professional organization said:

> "We have HR contracts with staff and volunteers for handling sensitive information, conflict of interest, IT policies."

Another key informant from the hospital laboratory shared this view:

> "Internally, we have policies and procedures as an organization; we have delegations of authority so we have financial accountability through delegation of authority. Organizational structures that are quite rigid that help with that accountability by being clear as to who you go to, we set annual goals and objectives as an organization, we have a business plan and an operating plan that guides how we behave, how we practice, what we produce, and in a sense those tools hold us accountable for our outputs. So, operating plans in particular, goals and objectives you know, those things will be tools, who we report, you know holds us accountable for output."

One director of laboratory services made this comment:

> "We are accountable for the financial aspects, to the board of directors, labour laws and real estate laws."

A manager with responsibility for the quality assurance programs of a large hospital laboratory

shared this strategy:

> "One of my own strategies around accountability at the bench level is to make sure that people have an awareness of what the goals are, how things are monitored, who is looking at the information, and ensuring that people are working towards the same goal and meeting an expectation. When something does not meet the expectation there can be individual accountability and there can be process accountability. So, my job is to make sure that the process is working effectively so now my job is also to make sure that individual people are actually performing the way they need to be."

Reflecting on the fact that the technologist who works at the bench level should be held to a high level of accountability, one manager from a hospital sub-sector had this to say.

> "I would have to say that people know when they are to report things and people do report things. People self-report things. I had someone ask me once, it wasn't that long ago, they asked me the question about when I disclosed the number of events we were reporting they said, really do think that is low because people are not reporting events the way they should be? And, my comment was absolutely not. I believe that the number of things that we are seeing I am certain that at least 80 percent of the things happening are being reported through that system. Because people understand their accountability to the system."

One of the most frequently cited internal approach used was surveys. There were several types indicated during the interview process such as staff, clients and patient surveys. In one hospital the laboratory manager had this to say about patient surveys:

> "Yeah! We have patient satisfaction surveys and those are through our outpatient department. There are client cards there asking for feedback."

One key informant from the hospital laboratory had this to say about getting internal feedback from clients such as physicians, nurses or other healthcare professionals:

> "Every two years we do a physician's survey. It is also tied into the employee opinion survey but they also survey our services so we get feedback on that. So, ours was just done in 2010 and we got 89% physician satisfaction. So, they were happy with our services and we were happy with that."

In reference to internal approaches to accountability, a key informant from a community laboratory stated that:

> "What we do, we have a comprehensive competency program that ensures that our employees are competent to perform the tasks that they have been assigned to. But, what we also do is provide some continuing education funding that motivates the employees to take courses but then we also provide some continuing education tools such as the ASCP lab program which provides 18 hours of continuing education and we also provide them with the opportunity to do the Colorado courses."

And when asked about how they got feedback from staff, one manager from the private for-profit sub-sector shared the following:

> "Every year we also do a staff survey, an engagement survey to see how staff are engaged, to see how comfortable they are working in this environment. And, then we disseminate the information. The patient survey results go always on our website and the staff survey results, each manager would use their own area, the results where they work on things if they do need to be improved."

Many of the key informants indicated that they had internal mechanism in place to tract and analyze data relating to specific patient focused quality indicators. For example one manager from a hospital laboratory talked about a practical way in which this is done:

> "Ok, so we track our error rate. It is a new indicator that we are tracking now and it is just not our error rate, it is external so all the pre-analytical errors rate so anything that...things like unlabelled specimens, unsuitable specimens so all that, so we are just learning to track and looking at trends and seeing not only trends in the types of errors but where are they coming from. So, then we can use that data and go to that area…."

Although education is not a primary focus of this thesis, there is a direct link between what is taught in schools and what is practiced in the clinical sites. Managers who are directly involved in teaching are also interested in internal approaches to accountability. Reflecting on their program, one director indicated:

> "Internally, we have endless student evaluation documents. Course documents take place in every course on a schedule. We also have a student satisfaction survey that is held…… before they write their CSLMS exam."

Many key informants also reported that they depend on an electronic device as an approach to provide or receive internal accountability. One manager from a hospital provided this feedback:

> "We have intranet. Specifically, the blood and tissue bank as it is called. One of our physicians has written a book, it's a guide actually, to help with transfusion call Bloody Easy. So, on the intranet we have something called Bloody News so if there is anything that we are trying to communicate in that way. We also do education, there are educational rounds to get the information to the clinicians and there is also, the final sort of it, the last resort is to broadcast key emails to all key persons etc."

Another key informant reflecting on the use of technology as an internal accountability measure said:

> "The outside vendors will have sometimes do teleconferences or webinars so you can access those later so you can put on a webinar for people that is particularly good but we do try to do something once a month."

The importance of professionalism was also highlighted as a key area to maintaining internal accountability. Many respondents stated that this was fulfilled by having all MLTs graduating from an accredited school, passing the national certification examination and become members of the College of Medical Laboratory Technologists of Ontario (CMLTO). One manager the public health sector stated:

> "The College of Medical Laboratory Technologists of Ontario (CMLTO) protects the public's right to safe, competent, ethical health care. They do this by regulating the professionals who conduct lab tests across the province. It is self-regulation."

Similar sentiments were expressed by another respondent from the hospital laboratory who said:

> "Every technologists, for the CMLTO, you've got the college that regulates our practice and we have to make sure that we maintain our quality assurance on an annual bases. 30 hours of quality assurance and then pay our licensing fees and ensures that we follow the

ethical guidelines and practice guidelines that the College sets out for us. And, obviously the College is the public's protective agency, exactly, and that's their outlet for complaints."

5.4.2 External Approaches to Accountability

The views of key informants on external approaches to accountability will be presented in the sub-sections below.

5.4.2.1 Financial incentives for performance

Financial incentives can be defined as a monetary reward provided for performance above targeted objectives or offered to encourage behaviour or actions that otherwise would not occur (Wodchis, 2004). This practice is becoming increasingly popular in some sectors of healthcare. All of the key informants said they were not recipients of any financial incentives for performance.

This response referring to financial incentives came from a medical director of laboratory service at a large academic hospital laboratory:

> "We make a budget every year and we submit to the government and then they say yes you may have this money or no you have to cut out this and every quarter you do variance reports you see how much you are off from the budget and then it gives you time to adjust to makeup in the next quarter. So certainly financial……..the manager does the financial pieces so I don't know what accountability may do. All, I know is that if the costs are too high, I am asked to review some tests to see if they need to be done or if we are doing too many. Things, like that. But, the actual details, I don't know."

Commenting on the financial approaches used in the organization, one key informant from the hospital laboratory had this to say:

> "We have an obligation to operate within the budget that we've been given. Are those always adequate? Sometimes yes, sometimes no, but I think you can always try, it challenges you to look at the activities that you are doing and the processes that you have in place and try to find better ways to come to the same means for less."

5.4.2.2 Information directed to payers, care recipients or providers

The literature review identified that the information is best disseminated in healthcare setting through instruments such as report cards, balanced score card, or best practices guidelines (Howells, 2005; Morris & Zelmer 2005). Many participants reported that they were familiar with these tools in their practice. Commenting on balanced score card, one manager from the public health sector had this to say:

> "I am big supporter of balanced scorecards, a big supporter of quality indicators, but I think, I don't want them to be so exclusive that we focus on only those and then we forget that we have other things we need to do as an organization in order to provide quality care. I am also a big supporter of best practices, of course being in a lab environment you and I both know that having to adhere to OLA requirements. There are CAP requirements; I mean those are all good things that provide structure to a lab and our primary responsibilities in labs is to maintain process control. So structure is a benefit to us because we can standardize practices, we can standardize how things work and so, I am very supportive of those types of structures that provide accountability."

Another key informant from the private not-for profit professional organization supported this view stating:

> "We have a business plan and an operating plan that guides how we behave, how we practice, what we produce, and in a sense those tools hold us accountable for our outputs. So, operating plans in particular, goals and objectives you know, those things will be tools like what we report, you know who holds us accountable for output."

Another manager from the hospital laboratory sub-sector reflecting on accountability indicator had this to say:

> "So, in the role of Operational Manager, and I have another partner who is also another Operational Manager here, so essentially we are accountable to, fiscally first, to our executive vice president for maintaining a balanced budget. So we have primary accountability to the EVP of the organization. So we are expected to operate within the budget allocation that we are given every year. We do participate in the budget planning process. We participate in strategic planning which is the next piece so along with fiscal accountability comes accountabilities for performance to meet the anticipated customer demand and align ourselves with the strategic plan."

The responses from community laboratory were similar. One manager stated that in their

organization, financial reports are shared with:

> "Everyone! The Government, CEO, Board of directors, shareholders and the public."

Another manager from a not-for-profit professional organization made this comment about information sharing:

> "We do a national report card which is essentially a report to the public and to our membership about how educational institutions are doing on the national certification exam. We also share that with deans and presidents of institutions."

A manager from the hospital laboratory commented on the use of balanced scorecards to maintain a patient focus:

> "Where I always looked at, regardless of what we did is we put ourselves into the position of the patient and tried to do what was best for the patient even if it meant it wasn't as efficient at least it was more effective for the patient. So, in a sense, having these balanced scorecards and external indicators may put pressure on us to focus on those things when in fact we should be really looking at patient centred care. That's the bottom line."

5.5 Regulations and Accreditation

All participants identified regulations and accreditation as the most frequently used form of external accountability approach used in the laboratory sector. There are 209 OLA accredited laboratories operating in Ontario (QMP-LS, 2013). Key informants were asked several questions in order to get their views on this subject.

5.5.1 Views on OLA consultations

When asked whether they thought appropriate consultations were done before OLA accreditations began in 2003 or if OLA standards were imposed on their organization,

respondents gave a number of different perspectives. Some managers were quite forthcoming with their views stating that OLA was imposed. Others felt that there were some consultation before OLA was implemented. One manager from the hospital laboratory sector stated:

> "Regulations by nature they are imposed. They are imposed on organizations."

Similar thoughts were shared by another manager from the public not-for-profit laboratory sector:

> "All of us may have a slightly different approach to how we are responsive to regulatory requirements and how do we get other people to be accountable to them but that is all about strategy. The reality is you don't have a choice."

Another key informant from the private for-profit laboratory commented:

> "So was it imposed? I would say yes."

One manager from public health laboratory sector shared similar views:

> "Initially some the accountability requirements such as OLA accreditation were externally imposed on our organization by the OMA".

There were also some disciplines, who found OLA standards easier to comply with than other disciplines. Speaking from a transfusion science point of view one manager from the hospital laboratory had this to say:

> "I think that it is better. There was a lot of work and there was a lot of resistance in the beginning. For example in the blood bank it really is no big deal because we've always followed standards, we have always been compliant with the AABB and CSTM and we have being do this for years even though it has been voluntary we have been going through the same assessment to make sure we are compliant. So, for us OLA was no big deal it was like polishing up some pieces to make sure."

One respondent from the regional program believed that there were some consultations before OLA implementation:

> "I can only talk about the area of transfusion medicine for OLA. There were consultations but the consultations were mainly for the AABB standards and CSTM standards. So, I see OLA just taking what was always there and just put in. I don't really remember OLA carrying out consultations themselves."

Another respondent from the public not-for-profit sector shared similar views that OLA regulations were not imposed:

> "But I don't think it was imposed. I think it was the way to go and I think the way they did it was very good. Early on they had information sessions, they tried to educate everybody as much as they possibly could about the process, the impact etc. So, I think it was a good step."

5.5 2 Views on the impact of OLA

Key informants were asked if they felt that the OLA accreditation led to a better or poorer approach to accountability. A hundred percent of the participants responded that OLA implementation was for the better. Respondents also indicated that OLA accreditation was not only required but vital to their continued existence. This is how a manager from the hospital laboratory sector puts it:

> "I think what it has done it has raised a different level of awareness for our profession and on some level has put on the map in terms of a more cutting edge approach to regulatory standards."

Similar thoughts shared by another manager from the hospital laboratory sector:

> "I believe that we are better off in Ontario. I believe we are producing a better outcome for our patients as a result of a program like OLA. I think that there are very tangible things that come along with that demonstrate for me and my organization that we are actually doing something better for our patients."

One key informant from a hospital laboratory shared this view:

"I think in the overall it is extremely better because it covers every aspect of the organization, how we do our job has to be accounted for."

Another manager from the hospital laboratory sector who also has experience as an assessor had this to say:

> "I think in general it is making everyone rise to a level of quality that is admirable and I really think Ontario is further ahead because I go around for Accreditation Canada, the other provinces, some of what I see in the other provinces they are not quite held to the same standards. They are coming up to it now because Accreditation Canada is going in there but because of OLA I think laboratories in Ontario are much further ahead."

One key informant from the community laboratories sector also confirmed what many managers in the hospital sector had been saying by stating that:

> "In the majority of cases it was better. Change is constant as we strive towards improvement. Part of our responsibility is to accept that we are accountable to society for mutual respect."

The views of a medical laboratory technologist who has not worked in any management positions were captured in this comment:

> "The OLA requirements are not unreachable and I think it sort of prompted the senior manager team to pay attention to the lab and to also make sure that they had an invested interest in making sure that we do well on our OLA. So, they make sure that we have the resources that we require to, in order to do well on the OLA. So, I think it was definitely a good thing."

Even organizations that are not directly involved in the OLA accreditation thought it is a very useful exercise. One educator had this to say:

> "Regulation is what really drives our business. You know we have the Ontario Laboratory Accreditation process and then there are also other regulations just for best practice, people are following and when you are a leading academic institution, you need to follow those, you need to be aligned with your peers."

Another corporate manager from a professional organization had this to say about OLA

accreditation:

> "My preference is that all jurisdictions in Canada have a model similar to Ontario with accreditation of program, certification of program, personnel, and continuing education requirements in both hospital and teaching facility. Accreditation is a best practice."

5.5.3 Views on the strength of OLA approaches

Several key informants also indicated what they felt were some strengths / benefits of the approaches used in OLA accreditation. One director of laboratory services spoke about the strengths of the QMP-LS program:

> "Everything that we do is measured against a set standards that are international recognized and are based on best available evidence that the international committee through international standardization (ISO) can achieve… So OLA and EQA themselves are both accountable to a higher authority, which tells us whether or not we are meeting the standards for organizations that do proficiency testing and accrediting bodies. So we too walk the walk of accountability at QMP-LS. There are not many examples to match the degree of accountability that you see in diagnostic laboratory services."

One community laboratory manger shared that was considered some of the major strengths:

> "Ease of measurement in term of faster turn-around-time; more cost effective; getting frontline workers to buy into the plan and feedback from physicians and patients."

For another manager from the hospital laboratory sector stated that it was ensuring that things were standardized:

> "The whole point of it is to make things, to make it difficult to make an error. Right? So you want to make things very standardized, so people know what they doing, not difficult, not complicated, simple processes and procedures."

Another key informant from the hospital sector commented:

> "One of the strengths was the level of flexibility that was built in the process especially when it came down to interpreting the standards…for interpretation and to be able to customize for your organization to meet OLA standards."

5.5.4 Views on the challenges of OLA approaches

Barr et al. (2005) stated that "collaboration is about working together in the face of both commonality and difference". When asked about what they felt were weakness or challenges of OLA accreditation approaches, many respondents cited lack of collaboration. They saw collaboration as working together not just alongside the team or worse, just being told what to do. As stated above, some managers thought that OLA accreditation was imposed and there was very little or no collaboration. There were also other issues that were identified by key informants. One manager of a large regional hospital laboratory with three sites spoke about the challenge of interpreting the standards:

> "When people have the appreciation of the why and sometimes when you are dealing with large number or regulatory requirements some of them don't always make sense to the people that have to implement….I struggle with that sometimes with the standards but overall, really at the end of this the intent is to have a safe system."

Commenting on the accreditation document, another respondent from the hospital sector had this to say:

> "I found them very, very difficult to interpret. To know exactly the depth and what exactly the documentation was looking for."

There was one manager from the hospital sub-sector who saw the way that OLA communicated its finding to the laboratory sector as a challenge to the organization:

> "I think about the program itself their accountability to the public on tangibles on what has 10 years of Ontario Lab Accreditation done for the public in Ontario. What is that? Specifically, show me some data……if we really wanted to measure something about the effectiveness of the program, the program should be coming up with some tangible data that demonstrates that they've actually achieved something by imposing that level of regulatory standard on clinical labs in Ontario and they have not done that to date." .

In reference to the challenges that were faced with the OLA standards, another respondent from

the public health laboratory shared a similar view:

> "I would say that there are probably some grey areas……their regulations maybe a little stringent."

Although agreeing that OLA accreditation was a good thing, one manager from the hospital sector reflected on the amount of human resources that it entails:

> "The downside I would say is that it just took so much time. The manager was responsible for updating all the SOPs. I probably had about 500 and that's basically a full time job."

Having been though the OLA accreditation twice, one manager from the hospital sub-sector felt that the over-riding weakness was of lack of communication:

> "I think where there is a problem is that there is not enough dialogue, not enough discussion about what exactly they are looking for. They either say yes it meets their criteria or no it doesn't and there is no, in some cases it doesn't seem like there is a lot of helpful material coming from the QMPLS or OLA assessors to help organizations fix the problems that they have."

In responding to this question one manager from the hospital sub-sector voiced what was their organization's concern with preparation for OLA accreditation:

> "There are more than 502 regulations for effective practice for all the testing that goes on, from pre-analytical to post-analytical. It covers the entire spectrum of what and how. Really they don't tell you how, but what you have to do in order to become an accredited facility and we are beholden with that because without accreditation we don't get our license to perform testing. So that's another stack in the chain for the Ministry of Health. Licensing through Ministry of Health and Long Term Care is tied to laboratory accreditation and every four years we are audited."

One hospital laboratory manager provided an example of a set of standards that were hard to achieve:

> "Another one is, is the space adequate? Well, no it is not but we don't really have control over that but you know that helps leverage us, gives us leverage in the future for trying to get extra space."

The ML sector is often characterized as a support service. Their biggest clients are the doctors who order laboratory tests. One medical laboratory director reflected on the challenges of making physicians more accountable for laboratory test:

> "OLA only controls the lab. But, the accountability of lab tests, part of it depends on the physicians. So, I don't think there was enough physician education to tell them when a test needs more work or what tests need more time, which tests cost more...they just order them and I feel that really there is no accountability for physicians ordering the tests. They just go down to requisitions and just order whatever they feel like and sometimes they are not what are needed."

Key informants also disclosed that although their primary focus is OLA, because it is mandatory, they are inspected, regulated, or accredited by other organizations. One manager from the hospital sub-sector was able to explain the possible duplication that occurs with Accreditation Canada:

> "Accreditation Canada, we are also obligated to meet those requirements and there is a lot of overlap. So, we have a very elaborate, a very robust accreditation process with OLA and so in my mind we should be coordinating that and looking at the requirements and if we meet OLA do they really need to come in and look at the labs again? Just sort of to check that off, I really don't think that they should be doing that because a hospital is a huge place and there are areas where there are no standards and this is the only kind of process for any accreditation to happen and I think they should be focusing more on those areas as opposed to duplicating what has already been done."

5.5.5 Views on whether accountability approaches help to ensure performance, equity and financial stewardship.

Several of the key informants interviewed stated that they believed that the accountability measure introduced by OLA and those that were in place before OLA has helped their organization achieve its goals. A manager from the hospital laboratory sector stated:

> "We were more diligent on staff training and quality control, it leads to a lot more paper work and really took a lot more time but in the end I think it was a far better approach to accountability."

Another response to this question came from a key informant in charge of the quality assurance program in a hospital laboratory sub-sector:

> "So, I think we are seeing quality improvements because we are actually having to produce the evidence, we are actually having to show what we do we say we do whereas in the beginning it was just really do you have the policies and procedures in place and now it is like show me, show me you are doing these things, where is the evidence."

Institutions that are involved in training medical laboratory students are subject to a different kind of accreditation by the CMA. When asked if this process actually helped their organization accomplish its goals, one director had this to say:

> "Yes, for a number of very simple reasons. We are a market driven, employer driven institution and that is one of our primary goals and our students could not work without this program being accredited. So it was kind of, we had to be accredited for our students to successfully graduate and enter the workforce."

5.5.6 Who pays to meet the accountability requirements?

Many of the key informants identified sufficient resource support as an important factor in meeting accreditation requirements. Resource allocation, though often expressed in terms of monetary value, should be broadened to include human expertise. All key informants felt that an important piece was overlooked in the preparations leading up to OLA accreditation. When asked who pays to meet the accountability requirements, one manager from the hospital laboratory sector said:

> "One of the regulatory requirements for the OLA program is: Has the lab management sufficiently allocated appropriate resources with which to carry the functions of the quality management system? There is actually a regulatory requirement that says you demonstrate to us, if you put the right amount resource into your organization to support and sustain a quality system. So we absolutely, the lab service every activity we do in terms of meeting a regulation, sustaining a quality system, and all of the components of that including the purchasing of external quality assessment. That absolutely comes out of our global budget for lab."

Other managers from the hospital sector shared similar opinions:

> "Accreditation is very expensive. Our accreditation fees on an annual base are ten thousand dollars, because it is a very expensive process and we have to support it. It used to come out of our Med Lab budget directly, which you know meant it had a significant impact on our operational costs. We pay for some of the ones from some of the external quality assurance that we do and we pay for that and it comes out of the lab budget. So, it comes out of the lab budget, yes."

One manager of a community laboratory stated that when it came to covering the cost for accreditation, their organization received no exemption. The simple answer to the question asked was:

> "The organization pays."

Another respondent from the hospital sub- sector replied by stating:

> "There was nothing in the whole structure of the accreditation process and the creation of OLA that gave any financial support."

5.6 Core Independent Variables

The following sub-sections will present the views of key informants on core independent variables.

5.6.1 Contestability

Deber et al. (2010) states that contestable goods are characterized by low barriers to entering and exiting markets. Non-contestable goods may be characterized by some or all of: monopoly market power, geographic advantages, high sunk costs, and/or "asset specificity" (a term meaning that it is relatively difficult to transfer assets intended for use in a given transaction to other uses). This particular question was answered differently depending on whether the key informant came from a community or hospital laboratory. One key informant from a community laboratory shared their organization's view on the contestability:

> "Extremely difficult. Since 1975 the MOHLTC has not issued any new Laboratory licenses. Anyone wishing to enter the market would have to do so by acquisition, consolidation or merger. Prior to 1992 there was no cap on laboratories services. The then government introduced an industry cap on community lab. This allowed for completion thus increasing market share for labs that were able to perform well. In 1999, the government policies change to one of individual cap which was retroactive to 1995. Under this new policy there has been guaranteed market share for community labs. This has resulted in lack incentives for completion for market share. This can only have negative consequences for patients as there is the possibility that the focus may shift from patient centered to care to making a profit for shareholders. Ultimately the MOHLC is accountable for the existing policies that govern laboratory services. For many persons who work in community lab, adopting a policy that allows for industry cap and removes cooperate individual cap would be a responsible policy decision."

Many respondents from the hospital laboratories also had their own views on contestability. One manager from a large hospital with three sites spoke the challenges that contestability (in terms of ease of entry and exit of the market) would present:

> "Ok, so I would just quickly say that there is a tremendous amount of resistance to taking away lab services from any one of our campuses. And, the resistance comes from physicians who expect increasing service levels not decreasing service levels. When you are part of a growing health network whose mission is to provide at home care, when I say that it means care in your community, access to the services that people need in their own communities it is always very challenging if you make decisions, operational decisions that testing can move from one location to another because it is going to be less expensive. To do that you always have to be; no ,yeah ;it is a moving services or relocating services or referring out services it is a very, very difficult thing to do in this climate because people have expectations and their expectation is that you do it faster and better."

For one key informant from the hospital sector, the driving factor behind any decision to enter or exit a particular market is all based on finances:

> "So, the issue is about how laboratories are funded. So, funding for labs has been a problem for many, many years. And, it is a problem in the sense that if you are not advocating appropriately for your own service in terms of you've got a long term plan and trying to fit in changes to technology and methodologies and what the organization

> may be doing in terms of provision of programs and services. That's the biggest challenges in terms of making the rights choice for what may be emerging in the next two or three years and being an advocate at the senior administrative level for the things that you need for the projected need that way."

Another hospital laboratory manager expressed similar views:

> "Everything had to be cost justified and approved. Unless you could build a business case for it, it didn't happen. Regardless of whether it improved your services or patient care if there wasn't the justification for the cost of doing it in the first place it would not happen."

Commenting on the ease to enter the market, one manager from the public health laboratory sector stated:

> "I would think that it would be very difficult for start- up costs for initially testing all the kits, that's what we call them, where we do all the testing you would have to have research and development section."

Another hospital manager had this to say:

> "I would like to think that there is a gap left and that the hospitals would be upset to see us go."

For some key informants, contestability was only an indirect way of speaking about the need for re-structuring and consolidation of laboratory services. One manager from a large academic (teaching and research) hospital sector said:

> "I think there is need to consolidate services. I don't think there will be a problem as long as we can still hit turnaround times and so each hospital may need to maintain some kind of lab but there are lot of testing that we should be able to consolidate. If it is not something that is needed STAT. Microbiology, histology, I think, especially downtown Toronto there is a lot of duplication of services that is expensive and it's not cost effective. So, I think we need to consolidate services and I think by doing that we can improve the service and take the best of each organization that comes together and build a stronger unified organization that is more accountable and more cost effective to run long term."

Another hospital laboratory manager was a bit more apprehensive about the impact on patient care:

> "I think you are going to impact client/patient care. The type of care delivery that you can give without having the processing and turnaround times and certain tests, can the turnaround be very, very quickly, so in terms of your emergency wait times, if you don't

> have any laboratory services on site you are waiting because there is transit time involved with the specimens, right? And, you are not going to send them one at a time; you are going to batch them. So you are already at least a couple of hours on to your turnaround time. So if it is an ambulatory care facility sure you can send it out but if it is an acute care facility, I don't think that is very feasible to entirely close down a lab."

For one manager from the public health laboratory sector, the process that would be involved in setting up a laboratory serves is a barrier to entry:

> "I would say no. It is not easy to enter the system. Not everyone can open up a licensed location. If you are licensed through the ministry of health there are certain requirements that you have to abide by."

One key informant from the hospital laboratory sub-sector thought that geographical location would definitely be a factor in determining the ease to exit the market:

> "It is a, it depends kind of answer, because it depends where you are located. If the market is super saturated in that area and the ministry feels that if you leave, the service of care for the patient will not be affected, then they would allow you to close. But then if you are the only show in town, no it would be very difficult to leave the market."

A medical director from a hospital laboratory shared this perspective on the ease of entry and exiting the market:

> "It is easy to leave the market. You can just decide that you are not doing this test anymore but it is hard to enter the system because labs are mostly funded by the MOH, right? And, you don't bill patients for it so you can't just start a lab and say I am testing vitamin D if you come and pay 200 dollars for that test. Nobody is going to do that. We rely on the government to pay you the money for the lab test. So, it is hard. Ontario does allow private labs. So, OHIP will pay private labs to do certain tests but it is only lucrative for them to do cheap ones, easy ones and also ones that are suitable for lab testing. They will do a whole bunch of tests like that because the cost is variable but they might not do antibodies investigations because it is very time consuming and if in a hospital OHIP pays to do a panel it is not worth their time to do it, so they don't do it. So they might do screens and if it is positive they might send it back to hospital for investigation and they would do the panels. So, yes. There are private labs and they have to rely on OHIP paying them, so yes, it is difficult to start up if you don't have, if you don't already have an infrastructure."

One key informant from the hospital sector thought that the type of service required would definitely be a factor in determining the ease to enter the market:

> "Ease of entry is pretty much dependent on the service you will be talking about. Ease of entry could be providing a new point of care service, right? Or it can be building a new laboratory on the east wing."

5.6.2 Performance Measurement

An important function of performance measurement is to ensure that all relevant information is being captured. Many of the key informants expressed the feeling that the very vigorous and stringent laboratory regulations and requirement have proven to be sufficient in capturing the activities that need to be measured. One manager from the hospital laboratory sub-sector spoke candidly about it this way:

> "I really can't think of anything that is not being measured because I think that with all of the requirements that OLA goes through it is pretty well measures everything. So, I've never really thought of anything that is not being measured. I think it is pretty thorough".

Another perspective was shared by a medical director who reflected on some of the pre-analytical accountability that needs to take place outside the laboratory settings:

> "So, I don't think there was enough physician education to tell them when a test needs more work or what tests need more time, which tests cost more...they just order them and I feel that really there is no accountability for physicians ordering the tests. They just go down to requisitions and just order whatever they feel like and sometimes they are not what are needed."

5.6.3 Complexity

Complexity was identified as one of the core independent variables that can influence how a laboratory achieves accountability (Deber, 2010). Complexity refers to the ability of the goods and services to stand alone or whether they require coordination with other providers. Laboratory services are viewed as having high measurability but gain much value by being embedded in the service that they offer (Deber, 2010). Key informants were asked about their views on contracting out services and were asked to provide examples of services that are contracted out. The majority of respondents acknowledged that contracting out was a fairly common practice within the ML sector. The rational for this practice ranged from financial

resources, lack of expertise, sample volume, to plain common sense. A laboratory manager from the hospital laboratory sector listed a number of things contracted out in their organization:

> "Not laboratory testing. We have a human resources professional on contract now to help us with things like compliance with the Ontario Disabilities Act and compliance with Occupational Health and Safety to help us make sure we are functioning appropriately……. We have contracted out an organizational redesign…….. Contracted out a governance review to experts in the governance world …. waste management, office cleaning……. legal is contracted out…….. contracted out research services…… professional development for our staff."

Another hospital laboratory manager spoke of factors that are usually taken into account before deciding to contract out laboratory tests this is laboratory testing:

> "Anything that does not, that we deem to be not feasible here would have to be referred out and paid for elsewhere and feasibility comes into it when we talk about the volume of, the complexity, do we have expertise in house to do it? Do we have medical support to do the testing? Do we see it as area of growth and of course that all plays into the strategic plan and how we relate our services to other programs."

Commenting on the impact of contracting out laboratory tests on patient care, one manager of a hospital laboratory had this to say:

> "The testing that we could potentially contract out would be testing that is more in the nature that you could transport specimens and not run the risk of degrading sample integrity. Typically, although our organization doesn't look at things like this, but typically when you talk about contracting out things like that, that would be more like microbiology services are often the first thing that people look at or the esoteric type of testing like Cytogenetic, which many laboratories in Ontario do not offer."

Another hospital manager stated that when it came to the matter the contracting out test the bottom line was:

> "So, again small volume, complex, or things that are large volume and that can be transported without running the risk of integrity issues with sampling those are the types of things that are traditionally looked at."

Similar views were shared by yet another key informant from the public health laboratory:

> "Tests that are not performed at the public laboratory that are beyond our scope or requires a test that does not have enough support at the lab we would put forward to other places like CDC in Atlanta or the Institute of Parasitology in Quebec which tests for all

> these weird and wondrous diseases that people get when they are travelling, to a class three laboratory in Winnipeg because we do not have a class three lab so when they are doing cultures for H1N1 they would forward those off there so that's the type of testing that we would forward on."

Interestingly, there were few organizations that reported that they were reference centers for work that that been contracted out. One manager from a large academic laboratory shared this view:

> "Typically because of the nature of the work we do and the specialized reference testing, organizations tend to send work to us rather than we sending work out. Realistically, there are times when we have to send certain work to other public health labs, like the NML, the national microbiology lab in Winnipeg or the CDC, but typically we don't contract out our work."

5.6.4. Never Contract out

In the present climate of fiscal accountability that appears to drive the need for greater efficiencies, laboratory managers were asked about services that they currently offer and would never contract out and why they felt that these services were so integral to their operations. The responses varied across sectors. One manger of a hospital laboratory gave this comprehensive list:

> "Oh for sure. The main chemistry tests, the main haematology tests, things like your bread and butter like glucose, your calcium's, functional panels, we wouldn't send those out, cardiac we would probably not send out, CBCs, certainly not coagulations...probably also not groupings and screens, blood bank, we would have to keep some sort of service here. I would say those for sure Chemistry, haematology, blood bank."

Reflecting on the list of "never contract out" a manager from an academic hospital stated:

> "One that comes to mind would be our phlebotomy services. We need the specialized skills in house for our patient population so I can't imagine ever contracting it out."

From the public health laboratory perspective, one manager stated:

> "Well, there are certain services that we provide that are legislated to provide, such as the HIV viral testing and tuberculosis testing. We would never contract those out."

5.7 Consequences for not meeting accountability requirement

Key informants were able to identify a number of consequences for not meeting accountability requirements. These include personal, financial, operational, and patient care. One manager of a not-for-profit professional organization identified their highest level of accountability:

> "From the financial aspect, Canada Revenue Agency obviously, even for individuals and for corporations carries force of law if standards are not met, audits or financial statements do meet criteria."

From an organizational point of view, a key informant from a not-for-profit professional organization spoke of the accountability to their members to deliver the services that they pay for:

> "Penalties for non-compliance could include voting in a new board of directors. They could result in, the easiest one being people could just not renewing membership; people could not contribute financially to your organization anymore if you don't deliver what you say you will."

All of the respondents indicated that they were personally responsible for meeting their job description and face personal consequences. One manager from the laboratory sector puts it this way:

> "My personal accountability is to the board of directors. I have a contract of service, just like any employee where it is clearly outlining my areas of responsibility. I have work that is assigned to me and failure to meet that could result in termination like any employee."

Another hospital laboratory manager expressed similar thoughts:

> "In a role like mine...consequences, yes there are you don't stay in a role like this unless you are performing at a certain level. And that's, really when you talk about accountability at this level of management in an organization like this that is part of the reality. You are a performer or you run the risk of not being in an organization anymore."

Commenting on their ultimate responsibility to patient care, one manager from the public health laboratory cited the most undesirable consequence:

> "Well, consequences could be death. Getting written up in the newspaper."

From an operational perspective, all laboratories need to be OLA accredited in order to operate legally in Ontario. One manager from the community laboratory spoke of what the consequences of not being OLA accredited would mean for their organization:

> "In terms of accountability for the lab though there are definitely accountability issues with accreditation, losing accreditation status and being unable to do any lab testing that you want to do because now you are unable to do it."

In the ML sector, many professionals identified themselves as members of a regulatory college. The regulatory colleges (CMLTO and CPSO) have professional standards that members must maintain in order to obtain their license to practice. One respondent from the hospital sub-sector captured this with this comment:

> "At a personal level in terms of practice there is the College. If we don't keep up our QA we don't get our license."

One director from a teaching organization reflected on what the impact of not obtaining accreditation would be for their organization:

> "Externally, it is pretty straight forward. Accreditation, you don't get it your program closes, you lose your students because they can't work and to be quite honest the liability that imposes ….. If they lost their accreditation and students were in the program would be really inconceivable to imagine because the students invest an awful lot of time in getting their education and if it closes down although you are allowed to continue to the end and write. It is still a big investment that to lose it isn't something I want to even consider!"

Another key informant from the hospital sector spoke of losing the ability to perform some testing because accreditation requirements were not met:

> "From a point of care bases, when I was unable to get the standards for a specific test in point of care we ended up losing that program."

5.7.1 Unintended consequences from not meeting accountability requirement

Many key informants stressed the importance of accountability in the ML sector. Many also agreed that for accountability to be effective there must be suitable consequences for non-compliance. When asked whether they thought there were any unintended consequences that occurred due to accountability approaches that are currently used in their organization, some respondents shared their views. One manager from the hospital laboratory sector shared a personal view:

> "This is my own personal experience and not necessarily in this organization but I have encountered elsewhere where the sole focus has been so much on the regulatory requirement that all the rest of the things are forgotten. So, it in some ways does not allow the innovation or the creativity that can happen when people don't have to focus so much on that within their own job roles."

Speaking of the conflicts with implementing their organization's strategic goals relating to innovation, one hospital sector laboratory manager made this statement:

> "Yes. Oh, I agree. That's a very big problem because I know our organization is very big on innovation but in the lab we are really constrained because everything that we do has to be within the regulations and it is very regimented and it is very difficult to think outside the box I guess because you've got so many constraints so it almost makes it difficult to see the big picture too and working with different professions because they have different accountability regulations and everything so it is a big issue."

Another key informant from the community laboratory sub-sector shared this comment:

> "There is the possibility that meeting accountability standards may slow the pace at which we proceed with some of our research and innovation, but we see this being more of a good thing than a negative consequence."

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One manager from the hospital laboratory sector provided this example of bureaucratic red tape that is involved in something as simple as purchasing equipment for the laboratory:

> "The one thing I can think of is the new government regulations when you are buying. Ok this is good, another area of accountability outside of OLA capital equipment. The process, they will request information… so it is like a 300 page document basically when what we use to do was negotiate right with the vendor. So, that is really bogging down the process in the past we use to be able to make capital purchases within maybe a year so it was still a long process and you still had to go through, and I think there is fair practice in that. Now, you have to do the new purchasing process which has to sit there for so long and then you look at those from the purchasing department, so it is about a two year process. It is about a two year cycle before you can get any purchases, any capital purchases then also within the institution trying to get that money for the capital purchases you have to go through a whole ranking process, everybody goes and pleads their cases and you get a list of equipment and then you rank it and the directors do this but I have been fortunate to go so it really is like a voting process, so then it is ranked. So, basically they draw a line over the money, so we have this much money and they rank everything in order than they draw a line. So, anything above that line gets down and anything below it doesn't then the deal making happens….."

A key informant from the not-for-profit laboratory sector gave an opposing view of how preoccupation with regulation can drive the need for innovation:

> "When you have a very good quality management system in place that is functioning well, so you are not putting fires all the time there is opportunity for you to be innovated and creative and improve on things."

Another manager from the public health laboratory shared the view that allocation of financial resources results in unintended consequences:

> "The unintended consequences are probably that you are spending a lot of money to meet the requirements and that money might be able to be better spent on other things that you do in the lab."

A medical director felt that one unintended consequence of accountability was its negative impact on teaching and research:

> "Education might be at risk because they tell me that I have to cut so many millions of dollars so I have to cut so many staff positions so the work that has to be done, patients have to be treated, the tests still have to be done so what suffers? Teaching. In terms of teaching we get a lot of med lab students so if I need to meet the financial goals and I have to do something to satisfy them I am not to devote so much to teaching. So, that's a

> risk. Certainly, research is another risk because we don't time for any more studies anymore. We don't have time to do studies."

Another manager from the hospital laboratory sector was able to look with optimism past the obvious challenges and point out an opportunity for advancement:

> "I think in some respects some of what we do perhaps should be transferred to other areas. One of the things, the quality system we've developed in the lab, we are probably leaps and bounds ahead of other areas in the hospital and they could look at that and learn from us. But, I don't think it quashes things because you know, if you have a regulation and you don't agree with it you can do research and validation and perhaps show that this is a better way and you can then convince people that that regulation can change."

5.8 Respondents Views on Additional Challenges to the ML sector

Key informants from the medical laboratory sector were also asked to comment on any other area that was not covered in the interview questions but they felt was very important to the approaches used to achieve accountability ML sector. These responses are presented below.

5.8.1 Placement for medical laboratory students to ensure a future of highly trained workers

A manager of a large academic hospital laboratory shared this concerns relating to training of medical laboratory technologists:

> "Placements all over, in all different areas, larger hospitals, smaller hospitals, public health, private labs everybody is just going to need to start taking students. In terms of saturation, I think the schools are going to need to really look at how many students do they really need to be putting out. I know that we say we have shortages coming up but depending on the geographical area we don't actually have shortages. So, downtown Toronto we really don't have a lot of staffing shortages right now, we have a lot of students coming out and getting jobs and there are a lot of students not getting jobs whereas the rural areas are struggling to recruit people. So, we need to make sure that we send students to those areas but the problem is if there is a hospital that has shortages they will be less likely to take students because of the workload issue. So, I hear that back-and-forth. I don't know what the answer is, if we could change the educational system a bit so we can pump out more students without having to train them in all five disciplines that's an idea. Training them up into specialities, core lab, microbiology, and histology genetics type of thing so that they are not having to do all the disciplines so

> they can specialize so we can increase placement without increasing individual work load that might work."

5.8.2 Full time jobs for medical laboratory technologists

One laboratory manager from the hospital sub-sector shared this view:

> "The issue is the lack of full time jobs for students that come out. I think that it is sad to find, to see students that are excelling in their field and they come out and they can't find a job. We have one person here who is our bottom person on the totem pole and she's young, she's intelligent but there is not enough hours for her. She works at two places just to get enough hours to make a living but it's sad that there are no jobs for these kids coming out and I know that there are going to be a lot of people retiring at the same time, here, within five years there is probably half the lab that is going to turnover but until then, it is not the lack of, the way the program is run, when they come out it is the fact that they can't find a job which is too bad."

5.8.3 Educating doctors about ordering laboratory tests

The views of a medical laboratory director are presented in the statement:

> "In the hospital, we can control them a little bit more, but in other labs they just do what tests are ordered and it could be part of our training. In medical school, nobody teaches you the costs of these things, who pay for these things. We just know that you order this test for this and if you are not sure you just order a few more but nobody ever said in our training what or I should say in my training, that is cost money to do these tests, or which tests are more costly than others. Now they are starting. They are starting to talk about tests and accountability in residence, during their training. But, in my days nobody talked about it in clinical terms so we just ordered whatever test we felt like."

5.8.4 The role of regulation in the ML sector

A medical director responded to the question about regulation by sharing this perspective:

> "I think there is a role for regulation but I think regulation is the weakest tool even though it may appear to the strongest tool. How do you continually work to improve and minimize error and that I think has to be a living instrument inside the organization. For example, our management review and how we look for opportunities for tracking our shortcomings where the system breaks down. So what I think is the strongest approach is at high level require through regulation that players within a defined area like labs, the regulation provides an architecture for certain things to be accountable, and then how that's done, I think, really has to reach a more fundamental human value which is people don't do the right thing because you're going to give them a few extra dollars. People

> want somehow, want to do the right thing because they somehow connect with a positive outcome: That is they care. So I see regulation not as a caring thing. It does not appeal to the human spirit that is doing things the right way for the right reason. So I think for example, the way we are trying to promote quality and accountability with our clients is through accreditation to be embedded in their expectation that they will have a quality system. That they will develop the tools to help them care but if you don't care about your outcome it's just a paper exercise. So for us, we are looking at creating an atmosphere that is non-punitive and based on identification of opportunities to improve and the science of improvement, empowering staff at all levels and fulfilling the intent of the regulation."

5.8.5 Doctors working together with diagnostic medical laboratory.

The introduction of electronic health records will allow for opportunities to improve patient care through on-line ordering of testing, the ability to add additional tests when required by doctors. The laboratories will have the ability to upload results directly to patient's records. As one manager from the hospital sub-sector puts it:

> "In transfusion medicine nothing is basically changing until there is a LIS (laboratory information system) that talk to each other."

Another manager from the hospital sector expressed the desire to see the laboratory services re-structured this way:

> "So, what I think should really happen is we should get a definition of what the service is, what the key programs are, and the different institutions where they are going to be located and then we can look at the services of the labs and do not I think we need to have an extensive lab offering every test under the sun in every hospital? No, I don't. I think we can have combined services, shared services."

5.9 Summary

In this study, key informants from both for-profit and not-for-profit laboratories identified patient care as their number one priority. Regulation was cited as the number one policy instrument that is used in the ML sector. Community laboratories have as one of their goals

making a profit for their shareholders while public health and hospital based laboratories were not concerned with making a profit but rather operating a balanced budget. Key informants provided an extensive list of internal and external organizations to which they are accountable. There is considerable variation in how laboratories services are governed/owned financed and delivered. This has implications not only for the policy goals but also the production characteristics that organizations may use to achieve these goals. The decision to use fully automated versus semi-automated desk top analyzers is closely linked to the delivery mode. Another factor identified by participants is the ability to contract out esoteric tests. Laboratory services can be classified as non-contestable, having high measurability and gain most of their value by been embedded in the system of care.

The experiences and perspectives of key informants on approaches to accountability were insightful and important for a more meaningful result. The fact that participants came from a cross-section of the ML sector (hospitals, community and public health laboratories, professional organizations and teaching institutions) as well as urban and rural settings gave breadth and depth to the wealth of information provided. The results of the interviews support the belief that Ontario laboratories are highly regulated and accreditation is an important part of this process. The present system of laboratory services in this province is not seamless. There is room for improvement especially in the area of funding, quality, and safety.

Chapter 6

Discussion

6.1 Introduction

This study was conducted to obtain a better understanding of the approaches to accountability that is used in the Ontario ML sector. The goals of this thesis were to:

1. Identify and describe the accountability mechanisms used in the Ontario Medical Laboratory Sector (ML sector).

2. Determine if the accountability mechanisms vary by sub-sector within the Ontario ML sector.

3. Examine stakeholder views on the advantages and disadvantages of the accountability mechanisms used.

The conceptual framework constructed by Deber identified four major approaches to accountability that are currently used in the health care sector in Canada and internationally (Deber, 2010). These were described in this thesis as: a) financial incentives b) regulations c) information directed towards potential users and d) reliance on professionalism and stewardship. This framework was used to guide the analysis and presentation of results in Chapter 5. This chapter will discuss the findings from Chapter 5. It will also present suggestions from key stakeholders on the advantages and disadvantages to accountability. The chapter will end with suggestions for future research.

6.2 Accountability Mechanisms

This section will discuss the views of key informants on the four approaches to accountability in the Ontario ML sector and seek to address the first goal of this thesis which is:

1. **Identify and describe the accountability mechanisms used in the Ontario's Medical Laboratory Sector (ML sector).**

6.2.1 Views on Regulations

Key informants identified regulation as the main approach used to achieve accountability in the ML sector. This is an important finding because physicians rely heavily on laboratory data in the diagnosis, treatment and monitoring of their patients. Key informants identified several organizations that play different roles to ensure that ML sector is highly regulated. The MOHLTC play an important role by creating legislations that defines what medical laboratories can do. The major piece of legislation used is The *Laboratory and Specimen Collection Center Licensing Act* which govern licensing and inspection of medical laboratories by the MOHLTC, and The Quality Management Program- Laboratory Service (QMP-LS) which is operated by the Ontario Medical Association (OMA). In reference to QMP-LS programs, one key informant stated, "I think what it has done it has raised a different level of awareness for our profession and on some level has put on the map in terms of a more cutting edge approach to regulatory standards."

Key informants identified other organizations that are involved in the regulation of the ML sector: a) Industry Canada for bylaws, workplace disability act, and occupational health and safety, b) Revenue Canada for not-for-profit or for-profit status, c) Canada Nuclear Safety Commission for the safe use of nuclear material, and d) Regulated Health Professional Colleges

(CMLTO and CPSO) for licensing, continuing education assessment, and to protect the public interest.

The majority of the ML sector is publicly funded and so the ML sector is accountable to the citizens of this province for the quality of the service that they provide. Laboratories ensure that they are providing high quality, safe, cost efficient, and effect service by maintaining technical and clinical proficiency. Laboratories demonstrate their technical competency by participating in, and achieving OLA accreditation. Many laboratories also participate in other voluntary accreditation programs such as CAP. These extra activities help to build confidence in the system. Key informants indicated that they used various indicators including quality control, quality assurance, turn-around times, and surveys to monitor their performance.

Key informants conceded that although laboratories traditionally have excelled at measuring quality using quality indicators, quality indicators are only an indirect measurement of quality. As note earlier in this thesis, there have been numerous cases where patients suffered adverse effects due to faulty laboratory results. Many clinical laboratories now have total quality management programs that are designed to reduce or eliminate laboratory errors. These include: quality assurance programs, accreditation, education, and the use of state of the art technologies to reduce human errors. The results have been a reduction in analytical laboratory errors in some places (Bonini, et. al, 2002). However recognising that the quality of the laboratory results are only as good as the quality of the specimens analysed, there is a new focus on pre and post analytical laboratory measures. To address and fix these challenges will require huge efforts and inter-professional collaborations across the healthcare sector.

The responsibility of specimen collection is often outside of the jurisdiction of many laboratories. To address the problem of patient identification and proper specimen collection will

require collaboration with the phlebotomists, doctors and nurses etc. Another area identified for quality improvement is the ordering of appropriate laboratory tests by the patient's physicians.

On the post- laboratory analytical side, one of the challenges that key informants identified is using technology to communicate laboratory results to doctors in a timely manner. The safe transfusion of blood products was also cited as another area of concern.

The Walkerton Inquiry determined that errors in the pre-analytical and post-analytical stages of laboratory testing contributed to the tragedy. Some of the key informants suggest that the mandate of OLA be expanded include more pre and post phases of laboratory analysis.

6.2.2 Views on Unregulated Laboratory Sector

The majority of publicly funded laboratory have to be licensed by the Ministry of Health and accredited by OLA in order to operate in this province. The exception is publicly funded laboratories in doctor's offices that are not covered under these guidelines. This is an important finding since key informants identified the OLA program as an important part of the approach to accountability in the ML sector. The Auditor's General Report for 2005 recommended that:

> "To help ensure that laboratory tests conducted in physicians' offices are properly performed and produce accurate results, the Ministry should assess whether the quality-assurance processes required for other medical laboratories should apply to laboratories operated by physicians"(Auditor's General Report for 2005) .

All key informants in this study acknowledged that there were many benefits to be gained from being OLA accredited including the recognition that the laboratory is able to carry out tests in a credible, reliable, and accurate manner. Key informants felt that it constitutes best practice to have all laboratories in Ontario OLA accredited.

6.2.3 Views on Point-of-care Testing

Key informants identified point-of-care testing (POCT) as one area of laboratory testing that needed to be more closely regulated. Point-of-care testing is laboratory tests that are performed outside the medical laboratory at locations such as the patient's bedside, physician's office, home, or in a drug store. Currently, accreditation for POCT is done by either Accreditation Canada or OLA. Key informants believe that putting more POCT testing under the jurisdiction of OLA would ensure better standardization and greater accountability across the province.

6.2.4 Views on the challenges of Regulations

The current OLA accreditation document contains some 509 regulatory standards that laboratories must attain in order to become accredited. Some key informants identified a number of difficulties with the accreditation process. One was interpreting some of the OLA regulations for their particular laboratory. It was felt that while OLA provided the standards, individual institutions were left to come up with how they would implement these standards in order to be compliant. It was suggested by one key informant that OLA should provide more help to laboratories by making more human resources available to provide advice on implementing the standards before an actual accreditation inspection.

The cost for meeting various accountability requirements including proficiency testing and accreditation were mentioned as an area of concern. Several key informants that were interviewed expressed disappointment that there were no financial allocations made for laboratories to implement the OLA program, especially in the early years when it took huge amount of human resources to get ready for an OLA inspection. Currently the cost for meeting accreditation is built into the laboratory budget.

The QMP-LS program is based on total quality management principles, which encompass the pre-analytical, analytical, and post- analytical phases of testing. During an inspection, OLA assessors determine if the laboratory is compliant by observing persons at work, asking questions and reviewing standard operating procedures and records. Key informants expressed their frustrations that OLA does not have the authority to address some of the pre-analytical phase of testing such as the ordering of the correct tests or patient identification. Also some post-analytical phase of testing such as the administration of blood products or the correct interpretation of laboratory results falls outside of the jurisdiction of OLA. This is an important finding because many instances of laboratory error occur at the pre-analytical and post-analytical phases of testing (Carraro & Plebani, 2007).

Some key informants from the interviews spoke what they consider to be "duplication" in the type of the accreditation that they participate in. This was particularly in reference to OLA and Accreditation Canada. For example all laboratories have to participate in the mandatory OLA program. However, if a laboratory is located in a hospital that is taking part in the Accreditation Canada program, the laboratory will automatically undergo a second round of accreditation. Key informants felt that a laboratory that is OLA accredited should be exempt from this, leaving the assessors with more time to look at other areas of the hospital that have no other accreditation standard.

6.3 Views of Financial Incentives

Financial incentives are defined in the literature as the adjustment of payments to induce providers to behave in the desired manner (Evans, 1984). For example, Ontario's hospital accountability agreements contain financial incentives for balanced budget. As stated earlier, the province publicly funds the majority of laboratory services. All of the key informants

interviewed in this study said they did not receive any financial incentives from the MOHLTC based on their performance as managers. There was some discussion as to whether community laboratories benefit from financial incentive in the form of the current corporate capping and guaranteed market share that exists with this sub-sector.

6.4 Views of Information directed towards potential users (patients, public, and private payers)

The literature identified information directed towards potential users such as patients, public and private payers as a valid tool for achieving accountability. The sharing of information is a key component of the ongoing activities in performance measurement and improvement (Barnsley 2005). Some examples include report cards (*e.g.*, for hospitals), audit reports, publicly available inspection reports, and quality indicators, including adverse events (Baker 2004). This study showed that information sharing is widely used in the laboratory sector to achieve accountability. Many of the key informants identified the ways in which this was done:

- Quarterly or yearly reports that are available to both internal and external stakeholders.
- Audited financial reports for annual general meetings.
- Publication of a list of all laboratories that are licensed, and which services or tests they are licensed to perform.
- Development of quality indicators around key area such as performance measurement and improvement.

6.5 Views on Professionalism/Stewardship

According to the literature, this approach to accountability relies on high trust and the expectation that providers as a group wish to do the right thing, but may need support in clarifying best practices (Deber 2010). Many of the key informants interviewed indicated that this is a valid approach used in the laboratory services. The training received in educational institutions prepares individuals for entry to practice as professionals. The regulatory colleges

also play a role in maintaining continuing education and professional standards of practice as an integral part of the yearly licence renewal for all their members.

6.6 Views on Independent Variables.

This second section will discuss the key informants' views on independent variable in order to address the second research goal, which is:

2. Determine if the accountability mechanisms vary by sub-sector within the Ontario ML sector

In this thesis, it is postulated that the approaches to accountability will have differing success when applied to various categories of services, and within various sub-sectors, with the likely outcomes depending upon: a) the policy goals being pursued, b) the governance/ownership structures and relationships in place, which in turn affect who will be accountable, and to whom, and c) the goods and services being delivered, and their production characteristics.

6.6.1 Policy Goals

The findings from the research data indicated that there were no variations in policy goals. All key informants identified patient safety as their number one priority. This is an important finding because the ML sector provides approximately 80% of objective data that is used in the diagnosis, treatment, and monitoring of patients (CMLTO, 2013). Key informants also indicated that laboratory testing plays an important role in epidemiology, especially in disease control and surveillance. As a result, high quality, accurate, and timely laboratory results are required to ensure timely, valid, and accurate tests beneficial to the healthcare system because they can result in reducing the length of stay, mal-practice cost, and inquiries. They are also beneficial for the patients because they can result in better health outcomes.

6.6.2 Governance/ownership structures in place

This section discusses the governance/ownership structures and relationships in place, which in turn affect who will be accountable, and to whom and for what. An important finding of this thesis is that ownership is one variable in which a difference in the approach to accountability by sub-sector was seen.

1) Accountable to whom?

Key informants stated that they felt that they were accountable to the MOHLTC. The method of accountability varies based on the sub-sector. The public health laboratories have a direct accountable to the MOHLTC. Hospitals and community laboratories have what can be termed a "third party" agreement which is one in which funds from the MOHLTC are transferred to another party such as OHIP or the LHINs.

In terms of administrative accountability, key informants from the hospital and public health laboratories said they are accountable to their boards. Key informants in the community laboratory sector said they were accountable to their board of directors and shareholders. The findings from the interview data demonstrated that key informants from all sub-sectors had the following "accountability to whom" in common: 1) to their patients. One key informant even went further to say that this principle was so entrenched in their organizational culture that "everyone treats each sample as if it belonged to someone they love", 2) The licencing and accrediting bodies, 3)The Regulatory Health Professional Colleges, 4) Frontline healthcare providers, especially doctors and nurses, and other professionals such as suppliers, manufacturers, and 5) To the students and new staff to provide them with a well-rounded training that is suitable for entry into the profession.

Some key informants indicated that they had dual accountability which made their jobs more complex. This is an important finding because the literature suggest that one of the nuances of approach to accountability is that one size does not fit all and there is a need to define accountability for what and to whom (Deber, 2012). For example, one participant stated that "so from a patient safety point of view we have direct accountability to the medical director and from the operational piece around fiscal management and performance to the VP, we have a dual accountability".

2) Accountable for what?

Several key informants indicated that they were accountable for the financial resources that they managed. Respondents in the private not-for-profit laboratories spoke about the importance of maintaining a balanced budget. Respondents from the private-for-profit also identified maintaining a balanced budget as well as making a profit for shareholders.

All key informants also indicated that they were accountable to providers and patients for timely, reliable, and accurate results. Some informants indicated that they were accountable for the persons (human resource) that they directly or indirectly managed. Key informants explained that they had performance indicators that were used to gauge how they were doing in terms of reaching policy goals. Two examples of performance indicators shared were turn-around time for glucose test and the number of samples rejected in transfusion science because the patient was incorrectly identified.

6.6.3 Production characteristics

The ML sector is not homogeneous. There is considerable variation by sub-sector in how laboratories are organized. Key informants stated that the production characteristic chosen by a laboratory is influenced by whether it operates as a for-profit or not-for-profit entity.

The data analysis revealed some important findings about community laboratories (there are exceptions) that operate as for-profit entities: 1) the population served is different than the hospital, 2) people in the community are generally healthier than those in hospital, 3) long term care homes represent another group -who generally have co-morbidities, and 4) the majority of testing done is routine, high volume, and low cost per unit tests.

Key informants provided some important findings on hospital laboratories(there are exceptions) that operate as not-for-profit entities: 1) they provide service for patients who are admitted to hospital or those who use their out-patient clinics, 2) tests are required in an urgent manner, 3). they tend to perform a greater amount of esoteric testing to support the research, teaching, and innovation that is going on in that particular hospital, and 4). they perform many low volume tests that are not financially profitable but are medically important.

The decision to use fully automated versus semi-automated desk top analyzers is closely linked to the type of testing required. Community laboratories that perform high volume routine tests are more likely to be fully automated. Hospital laboratories that perform urgent low volume tests are more likely to use semi-automated analyzers or do manual testing.

Key informants were asked to comment on the practice of "contracting out" testing to other laboratories. The participants in rural laboratories said that they were more likely to contract out some of their esoteric tests because it was more financially viable and sometimes the expertise to perform the tests was not available in their laboratories. Another factor that drives the decision to contract some laboratory services is the need for additional accreditation for speciality tests from organizations such as OLA, CAP, and the Canada Nuclear Safety Commission (CNSC). Many of the key informants reported that they actively participated in this practice either as the laboratory that contracts out some of their tests or as the reference center

that accepts work from other laboratories. One key informant said "The only concern was ensuring that the facility to which you are contracting out services is accredited to perform those tests and that the turn-around times for results are compatible with your organization's expectations".

One of the most recent challenges to regulation is the availability of point-of-care tests at the bedside, pharmacy, at home, or in a doctor's office. The major challenge that these present is ensuring the level of accreditation is as rigorous as those that take place in the traditional laboratory settings. Another area of concern is the increasing use of new and emerging technologies such as molecular and genetic testing. The challenge is ensuring that individuals performing these tests have both the theoretical and technical competency to do so. The impact of these on accountability in the ML sector would be interesting area for future research.

An important finding of this study was the confirmation (based on documents reviewed) that medical laboratories in Ontario have a high degree of contestability, measurability and complexity or embeddedness. Although laboratory tests have high measurability, they gain much of their value by being embedded within a system of care in which appropriate tests are ordered, accurate and timely analysis is done, and results are interpreted and acted upon in the correct manner (Deber, 2002).

6.7 Key Stakeholders Views on Other Issues That Influences Accountability

The following section presents the views of some of the key stakeholder in the ML sectors on topics that they view as directly or indirectly influencing the approaches to accountability. It seeks to address the final research goal which is:

3. Examine stakeholder views on the advantages and disadvantages of the accountability mechanisms used.

6.7.1 OLA Accreditation (regulation)

The OLA program was introduced in 2003. During the interviews, all key informants felt that OLA should continue to be mandatory for the medical laboratory sector in Ontario. As one respondent stated, "I think what it has done it has raised a different level of awareness for our profession and on some level has put on the map in terms of a more cutting edge approach to regulatory standards." It was suggested that the role of OLA be expanded to include monitoring the quality assurance programs for unregulated laboratories such as those operating in physicians' offices to ensure that they meet the same standards as other accredited laboratories. In addition, it is suggested that the mandate of OLA be expanded to include certain aspects of pre-analytical and post-analytical processes (e.g. phlebotomy and blood transfusion).

6.7.2 Funding of Laboratories (financial incentives)

During the interviews, some participants indicated that the government funding of hospital laboratories has not increased proportionately to match the increased cost of laboratory testing. As new and emerging technologies such as molecular and genetic tests are introduced, the cost of providing these tests has substantially increased laboratory costs. Key informants suggested that it was now time for the MOHLTC to conduct a detailed analysis of what the "true" cost of utilization of laboratory services is and that the funding of hospital laboratories be adjusted to meet the existing realities.

During the interviews, key informants suggested that the MOHLTC should review its position on individual cap. It is documented that since the implementation of this policy the

numbers of small community laboratories has decreased. There is need for a study to show how this has impacted patients, especially those that reside in rural communities.

Public health laboratories and other organizations such as the Canadian Blood Services (CBS) are directly funded by the MOHLTC. The suggestion from key informants was that the MOHLTC continue to provide adequate funding needed to ensure optimal operation for these organizations.

The allocation of financial resources in the ML sector is an important part of any approach to accountably because laboratories in Ontario are publicly funded. The MOHLTC is accountable to taxpayers to ensure that their money is being spent in the most cost efficient and effective way.

6.7.3 Integrated Laboratory Information System (LIS). (Information to potential users)

Key informants identified the inability to share laboratory information among all the healthcare team members across the province as a barrier to better patient care. Participants felt that a fully integrated province-wide laboratory LIS is a key component in any effort to re-structure laboratory services in Ontario. The benefits of an integrated LIS system to patients and healthcare service providers have been well documented. Patients benefit by having a smooth flow of information as they navigate through the system from family physician, to hospital, to homecare and long term care settings. Quick access to laboratory test results by practitioners translates into quicker decision making, faster turn-around times, and a reduction in duplication of laboratory test. It will also eliminate the need for manual re-entry of laboratory test results that were done elsewhere, an exercise that is not only time-consuming but it is also error prone. This increases the cost to the healthcare system. The benefits to the practitioners are better

opportunities for interprofessional collaboration among members of the healthcare team. The end result is better patient care and better outcomes.

The introduction of new technologies such as an integrated laboratory information system and electronic medical records presents additional challenges in relation to accountability. Issues of high concerns include: high acquisition and ongoing maintenance cost, proper training and technical support, confidentiality and privacy concerns as it relates to who has access to patient information. Despite these concerns, it is generally believed that overall, the benefits outweigh the risk that may be involved. The suggestion from key informants is that the MOHLTC expedite the process to have an integrated laboratory information system to fully implementation across the entire province of Ontario. An area for future research would be exploring what accountability measures are in place once the Ontario LIS is fully operational.

6.7.4 Shortage of Human Resources (professionalism/stewardship)

Many of the key informants interviewed expressed concern about the shortage of human resources in the medical laboratory sector. According to a recent survey, approximately 65% of MLTs working in Ontario are 45 years and older (CIHI, 2010). Many of them will be eligible to retire at 55 years old. This presents a huge challenge as two-thirds of the current workforce could be retiring in the next 10 years. This potential human resource problem is further compounded by the fact that insufficient numbers of new MLT graduates from accredited schools have been entering the workforce (CMLTO 2010). The number of physicians with specialty in laboratory medicine is also declining. According to research conducted by Dr. Terence Colgan, a pathology professor at the University of Toronto, the number of laboratory physicians and pathologists decreased by 1.8% and 1.4% respectively, from 1998 to 2008 (The Canadian Journal of

Pathology, 2011). This could adversely affect accountability in the ML sector as laboratory physicians play a vital role in the quality and safety of laboratory tests results.

There are several barriers to human resource sustainability in the current laboratory medicine system in Ontario. According to the CLMA, the current education, certification, and regulatory systems in Ontario are inadequate in sustaining human resource needs due to an inability to attract and sustain motivated individuals in a career in Laboratory Medicine (CLMA, 2011).

Some key informants identified the lack of sufficient clinical placement sites as a challenge that they have to deal with on an on-going basis. This restricts the number of graduates that can be admitted into the program. Some of the key informants commenting on this issue said they simply would not be able to take more students unless they were given the financial and human resource support to do this.

The difficulty for internationally trained medical laboratory technologists to enter the workforce was highlighted as a barrier. In 2010, The CSMLS received 230 applications for prior learning assessment (PLA). The majority of the applicants (90%) did not meet Canadian standards immediately (CSMLS, 2011). The gaps identified in their education/experience must be remediated before they are eligible to sit the CSMLS national certification examination. Currently, there is only one structured bridging program in Canada. It is offered at Mohawk College and only has eleven spaces because of the challenges to find enough clinical placements (CSMLS, 2013). The majority of internationally educated MLTs are left to address their deficiencies on their own. Many of them give up in frustration and end up working at whatever jobs they can find (CLMA 2010).

Key informants and the document review proposed a number of possible solutions to the human resource problems that were identified. The idea of a seamless continuum of education with clearly outlined career paths was presented by the CLMA (see Appendix H). This should follow a natural progression pathway, with no need for back-tracking. The advantages of this system would be that laboratory professionals would be able to have easy access to career pathways without unnecessary bureaucracies. There would be clear career options such as moving into education, research, or management within reasonable timelines.

Addressing the human resource issues that were discussed above will not only foster greater accountability within the medical laboratory sector, but will ensure a sustainable healthcare system for future generations. In many developed countries such as Canada, patient safety is ranked high on the agenda of healthcare workers. However it is important to recognise that the quality of the laboratory results are only as good as the quality of the specimens analysed, and the technical competency of the individual performing the analysis. Adequate investment in human resource in the ML sector will have huge impact on approaches to accountability.

6.7.5 The need for Leadership and Policy Directions (Policy goals)

The field of laboratory medicine is constantly changing as new technologies emerge. There is need for leadership and policy direction from the MOHLTC to help laboratories keep up with the challenges they face. The ML sector look to the MOHLTC for policy directions on issues such as: What tests should be performed? Will the test be covered by OHIP? Who will be licensed to perform the tests? Key informants suggest that the MOHLTC needs to have open and constant dialogue with experts in the field (pathologists, scientists, MLT etc.) to help them frame and implement the right policies.

6.8 Study Limitations

The research provided valuable insights into the approaches to accountability that is being used in the Ontario medical laboratory sector. A mixed methods approach using a case study design with both quantitative (document review) and qualitative (semi-structured interviews) was used. The following limitations were experienced.

For this study, access to key informants was initially obtained by identifying key stakeholders, some of whom were already research partners with the study. In addition, key informants were asked to refer other potential interviewees. Although the researcher made every effort to maintain confidentiality there is the possibility of data collection bias. Although the researcher contacted each participant individually, potential respondents may have learnt about the study before they were officially contacted.

The qualitative sample size for the study was small (20). This affected the diversity of the sample and limited the responses. The majority of the key informants were from the Greater Toronto Area (GTA) and worked in private not-for-profit hospital based laboratories. The majority of the respondents were also in management positions. Therefore this study may not have captured the views of the entire province of Ontario. It also may not have captured the views of all the professions represented in the medical laboratory sector.

Attention bias was one of the limitations faced during the key informant interviews. Attention bias refers to when people are aware of their involvement in a study and as a result of the attention received may give more favourable responses than those who are unaware of the study's intent (Kumar, 1989). The majority of the data was collected as face-to face or telephone recorded interviews. This may have influenced respondents to not disclose their "true" views on some of the questions asked. The willingness of participants to disclose personal information or

views to persons they do not know or trust (including researchers) may be limited or absent. It takes time to build trust with participants that will lead to full and honest disclosures. Because the researcher only met with the participants at the time of the interview, there was limited opportunity to build trust. Because the researcher was also the data collector, it is possible to have researcher's bias with data collection.

Based on the literature review, this research is a starting point for looking at approaches to accountability within the Ontario medical laboratory sector. One study is not sufficient to answer all the questions that need to be answered. Although this study provided useful information, it barely touched the tip of the iceberg. The results of the data analysis and subsequent discussion strongly suggest that there is need for more quantitative and qualitative research.

6.9 Recommendations for Future Use

The purpose of this research was to study the approaches to accountability within the Ontario medical laboratory sector. This study helped to broaden the understanding of which approaches are been used and what are the perceived advantages and disadvantages of each approach. It also identified gaps within the present system that should be addressed in future research.

6.9.1 Extending the study to cover all of Ontario and other provinces in Canada.

The majority of the participants in this study were from the greater Toronto area. Other parts of the province were not well represented. Since some of those laboratories operating in rural Ontario may face a different set of challenges, it would be beneficial to get their views. A second step would be to extend the study to cover other provinces in Canada. Conducting such wide scale qualitative research may be time consuming and potentially expensive. Therefore the researcher will need to secure adequate funding.

6.9.2 Quantitative data collection.

In this study only qualitative data was collected from key informants. This significantly impacted the number of persons that were interviewed. The inclusion of a quantitative survey will probably increase the potential of obtaining more information from a wider cross-section of medical laboratory professions. The information gathered would provide even more information on accountability approaches to laboratory medicine in Canada.

6.9.3 Inter-professional collaboration

The question of accountability is not confined to the medical laboratory sector but has a much wider implication right across the healthcare sector. This study is a part of a larger study that is looking at "Approaches to Accountability" in eleven other healthcare sub-sectors. Future research will provide information that can be used to create best practice accountability guidelines that can be used inter-professionally across the healthcare sectors both nationally and globally.

Chapter 7

Conclusion

The ML sector in Ontario provides approximately 80% of the objective data for diagnosis; monitoring and treatment of patients. Almost all laboratory services are publicly funded. Services are delivered by the public (e.g., public health laboratories), not for-profit (e.g., hospital based laboratories, Canadian Blood Services) and for-profit (e.g., community based laboratories, physician offices) organizations. Accordingly, the governance and ownership structures as well as the actors involved (e.g., Boards accountable to shareholders) vary. Nearly all laboratories in Ontario are regulated by the Ontario Laboratory Accreditation (OLA) body. In addition, several other stakeholders are involved in the ML sector: medical laboratory technologists, technicians, scientists, physicians, managers, owners, government (Ontario Ministry of Health and Long-Term Care), regulators (College of Medical Laboratory Technologist of Ontario), professional associations (CSMLS, OSMT), licensing bodies (MOHLTC), and accreditation bodies (Canadian Medical Association's Committee on Conjoint Accreditation, and QMP-LS).

A number of stakeholders inside and outside the MLS are involved in the delivery of quality laboratory services and are therefore accountable. Regulation is required to ensure the delivery of high quality laboratory services, which is important for patient care. Regulation is the main approach to accountability in the ML sector. Ontario Laboratory Accreditation (OLA) and licensing by the Ontario government is mandatory in all laboratories except those found in physicians' offices.

Quality and safety are top priorities and concern for costs and resources exists within the sector as a whole. Laboratory services can be classified as non-contestable, highly measurable and high complexity. The validity and reliability of the analytical stage of testing is highly

measurable. Laboratory results gain much of their value by being embedded within a system of care, in which providers order tests appropriately and are aided in interpreting and acting upon their results. The pre/post analytical stages are just as important as the analytical stage in measuring performance and ensuring accountability.

While the ML sector is highly regulated, the implementation of more mechanisms to enhance accountability in the pre/post analytical phases is needed. The importance of this is further highlighted by the advancement of point-of-care testing at the bedside, the pharmacy and at home, which is not currently fully captured by the accountability mechanisms currently in place.

The ML sector in Ontario is not homogeneous. There is considerable variation in how they are financed and organized. It is the responsibility of the MOHLTC to implement policies that will ensure accountability, transparency and sustainability for future generations.

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Appendix A

Interview Guide

THESE ARE ORGANIZATIONAL QUESTIONS BUT DIFFERENT PEOPLE MAY BE CHOSEN TO ANSWER DIFFERENT PARTS AS DEEMED NECESSARY. PILOTING WILL HELP DETERMINE WHO THE BEST CANDIDATE TO ANSWER DIFFERENT PARTS IS.

*** At least 2 weeks prior to the 'interview' an email will be sent to the interviewee with a list of the questions s/he will be asked.*

*** Any text in italics is for the interviewer, not to be read out to interviewee unless needed.*

*** Prompts are in bold and indicated with the word "***PROMPT***".*

Opening:

"Thank you for agreeing to meet with me today."

"Is it okay for me to tape this interview?"

CONFIDENTIALITY:

- Your participation in this interview is completely voluntary and you may choose to stop it at any time.
- Your name or any identifying information will not appear in any report or publication of this research unless you give consent or it is otherwise publicly available.
- Your interview transcripts and recording will be safely stored on a password protected computer and only research staff will have access to this information.
- Confidentiality will be provided to the fullest extent possible by law

"I would be quite happy to send you a transcript of the interview, for you to correct or amend as needed."

"Remember, there are no right answers to any of these questions, I just want to talk with you and learn from your experience."

Introductory Questions:

1. What types of services (key function areas) does your organization provide?

2. What are the main goals of your organization? **[PROMPT – mission, vision, values OR cost, quality, access]**

3. What is your role in this organization?

Accountability Questions:

Accountability is defined as:

"The obligation to answer to an authority that conferred a responsibility, by an agent who accepted it, with the resources and delegated authority necessary to achieve it, and with the understanding that inadequate performance will result in an intervention" (Shortt and MacDonald 2002, 27)

General:

1. For each of the functional areas of your organization in the following table please answer:
    a. What are the accountability requirements for each of the defined function areas?
    b. To who is your organization accountable? (*there may be more than one possibility for each service*)

Functional Area or Individual	Accountability Requirements:	Whom accountable to?

Resource Dependence:

2. What types of services does your organization contract out? **[PROMPT – core activities such as patient care or support services]**

3. Are there services your organization would NEVER contract out? Why?

Approaches:

4. There are a number of approaches (*governing instruments*) that can be used to achieve accountability. Some are external and others are internal. Some examples are:

   External:

   a. Financial incentives – payment in the form of pay for performance,
   b. Regulations – including signed agreements
   c. Information directed to payers or care recipients – report card, or balanced score card
   d. Information directed to providers – best practices, and/or

   Internal:

   e. Accountability approaches used internally by your organization.

   What approaches are (were) used by your organization? For each approach state where it is used, how often it is used in that area, and who is holding 'you' accountable:

Never Used	Seldom Used	Sometimes Used	Frequently Used
1	2	3	4

Approach:	Where Used (for what):	Frequency of Use:	Who Accountable To:
		1 2 3 4	
		1 2 3 4	
		1 2 3 4	
		1 2 3 4	

For each approach find out where (for what) it is being used and who they are accountable to for that approach. **[PROMPT – for what, to whom]**

In cases where there are multiple accountability requirements:

5. Were consultations carried out or was the approach imposed on your organization? If imposed, who was it imposed by?

6. If consultations were used, how were they carried out? How much input did your organization have?

7. Do you feel this process led to a better/worse approach to accountability?

8. What are (were) the strengths of the approaches? **[PROMPT – e.g., ease of measurement]**

9. What are (were) the weaknesses/challenges of these approaches? **[PROMPT – e.g., difficulty of measurement]**

10. Do the approaches used help your organization achieve its goals (are they aligned with the goals)? **[PROMPT – Need to know the goals – mission, vision, values]**

11. How well do you think each approach ensures performance, equity, and financial stewardship?
    a. Has there been a change in your organization's ability to achieve these goals since the introduction of the accountability measures?
    b. Do the accountability measures help reveal, or address problems, and then fix them if identified?

12. Is it difficult for your organization to achieve accountability? Is there variation? If so, why? **[PROMPT – variation can be in terms of who is holding the organization/individual accountable, the level of accountability (organization or individual), the department or functional group being held accountable, etc.]**

13. CEO – board accountability?

14. Who pays to meet the requirements or monitor compliance with the requirements (i.e., evaluation)?

<u>Measures</u>:

15. Why do you think the performance measures used in the HSAA were chosen?

16. What activities do you think are important to be measured but are not currently being measured in HSAA?
    a. Why are these activities not being measured?
    b. Are these the same reasons why they excluded from the HSAA?

17. What activities are not measured in any way? Why?

18. Do you use these accountability measures to make decisions on performance?
    a. What do you use to make decisions about performance?

Contestability: [ease of entry and exit from the 'market']

19. How easy is it for an organization like yours to enter your sector and provide services in targeted areas (or market)/specialized services?
    a. (*If easy*) Why is it easy to enter the system?
    b. (*If difficult*) What makes it difficult for an organization to enter?

       [PROMPT – sunk costs, high start-up costs, complexity of services provided, licensure, accreditation, etc.]

20. Is it difficult for an organization like yours to leave target markets, make changes in service provision, or stop providing services?
    - (*When easy, the organization can sell building, equipment, or other infrastructure to a new entrant or another market easily. Switching costs are low.*)

Consequences:

21. Are there any consequences or rewards that result from not meeting performance criteria or accountability criteria?

a. If so, what are the consequences or rewards?

22. Are the accountability/performance indicators tied to financial indicators/rewards?

23. Are there any unintended consequences that occur due to the accountability approach being used? **[PROMPT – teaching to the test, risk aversion, quashing of innovation, etc.]**

Closing:

"Would it be okay with you if I contacted you later with a couple questions should any come to mind upon reflection? We can address them over the phone."

"Are there any other areas we haven't touched on that you want to comment on?"

"Is there anyone else you think I should talk to?"

APPENDIX: B Invitation Letter

University of Ontario Institute of Technology

2000 Simcoe Street North

Oshawa, Ontario

L1H 7K4

Name:

Title:

Address:

Invitation to Participate

Dear Ms. /Mr.

This is an invitation requesting your participation in a confidential research study based on your experiences with accountability measures within the medical laboratory community. This survey is being conducted at Faculty of Health Sciences, University of Ontario Institute of Technology, and aims to determine what methods of accountability are been used and the strengths and weaknesses of each method.

This study will be conducted in the form of a semi-structured interview where a series of questions will be asked about your opinion on accountability in health care as it relates to your sector. Some general demographic questions will also be asked. The interview should take approximately 30-60 minutes and participation is completely voluntary.

The interview questions will be sent before the scheduled interview so that there will be time to prepare the answers. Should you wish to withdraw, you may do so at any time and all of your responses will be completely destroyed. However, we do hope that you will participate and provide as much information as possible to help create a representative sampling of opinion from a diverse group of professionals working in the medical laboratory field. All of your responses will be held in strict confidence.

If you have any questions, please do not hesitate to contact me for more information about this study. Acceptance or declination to this invitation to participate can be communicated by email to lavern.bourne@uoit.ca

Thank you in advance for providing this important information.

Sincerely,

Lavern Bourne BHA, MLT

MHSc Graduate student

University of Ontario Institute of Technology

2000 Simcoe Street North
Oshawa, ON L1H 7K4
Tel: 905-721-8668 ext. 3612

Email:.Lavern.bourne@uoit.ca

APPENDIX C: Consent Letter

Title: Accountability in Health Care

Investigator: Ms. Lavern Bourne

Research Supervisor: Dr. Brenda Gamble

Background and Purpose of Research

Accountability in health care is stressed by all levels of government and the tax-paying public with respect to the health outputs produced (i.e. patient outcomes, decreased wait times, cost containment, and quality of care) from the inputs used (public funds derived from tax revenue, medical services utilized). Accountability requires that all parties know their roles, responsibilities, and performance expectations. In the past there has been considerable variation in how accountability is defined and measured in the Canadian health care landscape. **In this interview, we are trying to understand your views on accountability in your sector of health care and the strengths and weaknesses of the protocols that you follow.**

This study is being conducted by researchers from the University of Ontario Institute of Technology. It has been approved by the Health Sciences Research Ethics Board at the University of Ontario Institute of Technology File **#: 10-036**. The text below describes this study. Please read this information carefully before you decide if you are willing to participate in this study.

Who is participating?

Stakeholders from the Ministry of Health and Long-Term Care, Local Health Integration Networks, and acute care hospitals across the province of Ontario will be participating in this study. This means that many of your colleagues may also be interviewed.

What does the study involve?

You will be asked to answer a number of questions in the form of a semi-structured interview. These questions will ask you about your opinion on a number of areas related to accountability in health care as related to your sector, as well as some general demographic questions. This interview should take 30-60 minutes to complete.

Contacts

This research is being conducted by Lavern Bourne as part of the requirements for the Master's degree in Health Sciences at the University of Ontario Institute of Technology. This research is being supervised by Brenda Gamble, PhD (University of Ontario Institute of Technology). If you have any questions about the study, you may contact Lavern Bourne at 905: 721- 8668 ext. 3612 or email at Lavern.bourne@uoit.ca or Brenda Gamble at 905: 721- 8668 ext. 2934 or email at brenda.gamble@uoit.ca.

You waive no legal rights by participating in this study. If you have any questions about your rights as a participant, you may contact the Ethics Review Office of the University of Ontario Institute of Technology at Tel: (905)-721 8668 x 2357 or email compliance@uoit.ca

Benefits / Risk of the Study

There are no personal benefits or risks to the study, but we anticipate that the results should be helpful to decision makers in improving how accountability is being implemented. The questions included in the interview are of low sensitivity. If you feel uncomfortable at any time you are free to discontinue participation, either temporarily or permanently.

What about confidentiality?

The information collected will not be used to identify a particular organization or individual unless express consent is received or the information is already in the public domain. You will have the opportunity to review your response to ensure that we have correctly captured your views. Your responses will only be used for the purposes of this research study and will not be accessed by anyone outside of the research team. All electronic and paper records will be kept in a secure location and will be maintained for 7 years after study completion and then destroyed.

Voluntary Participation / Withdrawal

Participation in this study is completely voluntary. If you choose to participate, you may exit the interview at any time without any consequence

Compensation

You will not receive any compensation for participating in the study.

Publication of Results

The results from this study will be published in academic journals and presented at conferences. It will also be shared with the participants in the study, including through workshops.

Funding of Research

This study is being funded through CIHR.

Consent

I have read the above information and by signing below I provide my consent to participate in this research study.

_____

Printed Name

_____

Signature

_____

Date

APPENDIX D: Thank You

Name:

Title:

Address:

Dear Sir/ Madam,

Thank you for participating in our research project. Your analysis of healthcare accountability models used in your organization was truly helpful and insightful. You have provided valuable information that will assist in the successful completion of this research project.

If you know of someone who might be interested in participating in this study, please do not hesitate to share their contact information with me. We will be following up in the future with an invitation to attend a participant's workshop where the result from the data analysis will be presented.

Thank you again for your assistance.

Sincerely,

Lavern Bourne BHA, MLT

MHSc Graduate student

University of Ontario Institute of Technology

2000 Simcoe Street North
Oshawa, ON L1H 7K4
Tel: 905-721-8668 ext. 3612

Email: lavern.bourne@uoit.ca

APPENDIX E: CODE BOOK

This coding structure is intended to pull out important themes from accountability documents including contracts, legislation, and accreditation.

Categories	**Sub-categories**	**Sub, sub-categories (as needed)**	**Description**
Identifiers	Who is involved	Which organizations are involved in the accountability relationship	
		Creator	Code for accountor (exp. CCAC or Accreditation Canada)
		Recipient(s)	Code for accountee (exp. Service provider or physician)
	Document/tool	The type of documents being coded	
		Contract/agreement	Service contracts or agreements used to purchase/procure services from service agencies, organizations or individuals
		Accreditation	Any documents related to getting or maintaining accreditation from an accrediting body
		Legislation	
	Duration of document	Start date	When the agreement/contract/legislation was put into effect
		End date (If any)	When the agreement/contract/legislation is no longer in effect
		Option to renew	There is an option to renew for the agreement/contract/legislation In instances where there is an end date. Code yes/no. Can add sub-coding tree regarding rules regarding renewals (i.e. required amendments).
	Jurisdiction	Ontario	
		LHIN	
		Municipal	
		Community/CCAC	
		Other province	

		International	
	Sector	Hospital	
		Primary Care	
		Public health	
		Home and Community	
		Long-term care (nursing homes and homes for the aged)	
		Labs	
		Public health labs	
		Cancer care	
		Province-region (LHIN)	
		Professional organizations (either for-profit or not-for-profit)	
		Community health centres	
Communication and oversight	General communication	Stipulated requirement for communication procedures that are to be followed between organizations/individuals in the accountability relationship. (exp. The Service Provider shall immediately notify the CCAC regarding any client who contacts the service provider with any complaints).	
	Monitoring	Stipulated requirement for monitoring activities, general (not necessarily attached to reporting requirements) (exp. The CCAC may, during the Agreement Term, monitor the quality of the Service Provider's performance of the Services.)	
	Oversight	Stipulated requirement for direct oversight of activities by an external body. (exp. The service provider shall permit the CCAC to access the service provider's premises in order to audit account and agreement records).	
	Reporting	Stipulated requirement for reporting.	
		Consistent structure	Reporting follows a consistent procedure (exo. The Service provider shall follow the procedures for reporting a Risk Event).
		Training	Training is required for the accountor in order to comply with reporting requirements

			(exp. The service provider is required to attend a training session regarding how to fill out report forms prior to the start of the agreement).
		Routine	Reporting occurs at regular, stipulated intervals (exp. Quarterly, Annualy)
Consequences (sanctions)	Consequences of non-compliance with accountability requirements (i.e. not meeting indicators, not providing reports as requested). Relates to the type of sanctions discussed in the documents.		
	Termination/reduction of contracts	Loss or reduction of contracts which is due directly to either: poor performance, misconduct, non-compliance with reporting requirements, or any breach of agreement. (exp. The CCAC may terminate a contract if the CCAC determines that a service provider has committed serious misconduct)	
	Fines	Accountees charged fines due to poor performance, misconduct, non-compliance with reporting requirements, or any breach of agreements/contracts/legislation.	
	Public reporting	Accountees are required to publicly report any poor performance, misconduct, non-compliance with reporting requirements, or any breach of agreement.	
	Reduced funding	Accountees will have reduced funding from accountor for poor performance, misconduct, non-compliance with reporting requirements, or any breach of agreement. (exp. The service provider may suspend all or part of payments to the service provider if the service provider fails to perform any of its obligations under the agreement).	
	Increased funding	Accountees will have more funding from accountor for poor performance, misconduct, non-compliance with reporting requirements, or any breach of agreement.	
	Suspension of license/scope of practice (individual level)	Individual service providers will have license suspended and/or a reduced scope of practice for poor performance or misconduct.	
Purpose (the purpose of the accountability tool)	Financial	To ensure/support financial accountability	
		Pay-for-performance	Pay-for-performance used as a means to ensure accountability of individuals or organizations
		Financial reporting	Accountor required to report financial information (exp. Annual or quarterly financial

			reporting to accountor required as part of agreement).
	Performance	To ensure/support performance accountability	
		Access	Performance related to access to healthcare (exp. The service provide must deliver services in geographic area identified in agreement. Exp. The service provider is responsible for providing services to a client as of the time that it accepts a referral).
		Quality	Performance related to quality of care (exp. The service provider must be an established provider of health care services).
	Political, democratic	To ensure/support political accountability (i.e. equity and fairness)	
	Procedural	To ensure/support procedural accountability; ensure the process of service delivery is appropriate.	
Performance (how is performance identified)	Unit of analysis	At what level is performance measured	
		Client	Performance measured at the level of the client (exp. Require client satisfaction surveys)
		Provider	Performance is measured at the level of the provider (exp. Individuals delivering services must possess appropriate trainings and qualifications)
		Organization	Performance is measured at the level of the organization. (exp. The service provider shall obtain appropriate accreditation)
	Client satisfaction	Performance is monitored using client satisfaction surveys	
	Evidence-based practices	Quality performance identified through the use of evidence-based practices	
	Professionalism	Performance demonstrated by association with professional body (i.e. college of physicians, nurses association)	
	Experience	Performance demonstrated through past experience	
	Skill testing	Performance tested by organization imposing accountability – use of skill testing.	

	Management standards	Performance dictated by appropriate financial and administrative standards.	
	Indicators, set internally	Performance monitored using indicators set internally by the organization being held to account.	
	Indicators, set externally	Performance monitored using indicators set externally by organization imposing accountability requirement.	
		Professional association	Indicators set by a professional organization or college (i.e. College of Physicians and Surgeons).
		Government	Indicators set by government body
		Accreditation	Indicators set by accrediting body
		Consultant	Indicators set by external consultant
Financial (how is financial performance identified)	Accounting practices	Use of appropriate accounting practices. (exp. Service provider must keep accurate and systematic accounts using standard accounting practices).	
	Auditing	Regular auditing of financial statements required (exp. The Accountor may audit)	
	Quarterly reporting	Provision of quarterly financial statements (exp. Financial reports must be remitted quarterly)	
	Annual reporting	Provision of annual financial statements (exp. Financial reports must be remitted annually)	
	Budget	Did the organization stay within budget (exp. Service providers must stay within budget)	
Political, democratic	Conflicts of interest	All potential conflicts of interest must be identified and reported by one or all organizations within relationship. (exp. Service provider personnel do not use their position for personal gain).	
	Promote values	Accountability tool serves to promote common values and goals.	
	Equity	Accountability tool promotes equity, i.e. equitable access to services. (exp. Service providers must provide services to all referred clients).	
Procedural	Will vary depending on sector and how services are delivered. For example in the home and community care sector accountability requirements include procedural rules around the procurement of services and the RFP process itself as a means to hold purchasers accountable for the awarding of contracts.		
Responsibility	Will vary depending on sector, type of service and who is involved in the accountability relationship. This code will assign the types of responsibilities identified for each party within the accountability relationship.		
Transaction Costs	Training	Additional training of personnel required to meet accountability requirements, i.e. additional personnel	

		professional training.
	Time	Additional time required to meet accountability requirements
	Human resources	Additional personnel required to meet accountability requirements
	Equipment/technology	Require purchase of equipment or technology to meet requirements, exp. New computer systems to meet reporting requirements
	Accreditation	Require accreditation to meet accountability requirements, which requires additional costs.

Appendix F: REB Application

RESEARCH ETHICS BOARD
OFFICE OF RESEARCH SERVICES

Date: November 4th, 2010

To: Lavern Bourne (PI), Brenda Gamble (Supervisor)

From: Raymond Cox, REB Chair

File #: 10-036

Title: Approaches to Accountability in Ontario Medical Laboratory Sector

The University of Ontario Institute of Technology Research Ethics Board has reviewed the above research proposal. The application in support of the above research project has been reviewed by the Research Ethics Board to ensure compliance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS) and the UOIT Research Ethics Policy and Procedures.

DECISION: Approved

COMMENTS AND CONDITIONS:

This project has been approved for the period of **November 4th, 2010 until November 4th, 2011** and is subject to full REB ratification at the Research Ethics Board's next scheduled meeting. The approval may be extended upon request.

Please note that the Research Ethics Board (REB) requires that you adhere to the protocol as last reviewed and approved by the REB. The Board must approve any modifications before they can be implemented. If you wish to modify your research project, please contact REB Administration, to obtain the Change Request Form.

Adverse or unexpected events must be reported to the REB as soon as possible with an indication of how these events affect, in the view of the Principal Investigator, the safety of the participants and the continuation of the protocol.

If research participants are in the care of a health facility, a school, community organization or other institution it is the responsibility of the Principal Investigator to ensure that the ethical guidelines and approvals of those facilities or institutions are obtained and filed with the REB prior to the initiation of any research protocols.

Section F, Article 1.13, Review Procedures for Ongoing Research of the TCPS http://www.pre.ethics.gc.ca/english/policystatement/policystatement.cfm requires that ongoing research be monitored. A Final Report is required for all projects, with the exception of undergraduate projects, upon completion of the project. Researchers with projects lasting more than one year are required to submit a Renewal Request annually. Contact REB Administration to obtain a copy of the Renewal Request/Final Report form.

Please quote your REB file number on all future correspondence. Thank you.

REB Chair Dr. Raymond Cox, FBIT raymond.cox@uoit.ca	Ethics and Compliance Officer Sascha Tuuha, (905) 721-8668 ext. 3693 compliance@uoit.ca

Appendix G: Amendment to REB Application

RESEARCH ETHICS BOARD
OFFICE OF RESEARCH SERVICES

Change Request and/or Study Renewal Form

For Office Use Only:

Date Received: REB # _____

1.0 Purpose

This form must be filled out for all Research Projects that are:

1. Requesting Changes to a previously approved Protocol, or
2. Renewing your Protocol AND Requesting Changes, or
3. Wishing to Renew your Protocol without any Changes.

Please note that if there are significant deviations from the original approved protocol, the REB may request a new REB Application or additional information.

2.0 Instructions

For all users of this form, fill out Sections 1, and then follow directions from each Option. Submit **ONE Signed Softcopy** of this form along with all attachments to compliance@uoit.ca. Hand written forms will NOT be accepted.

Section 1a: Principal Investigator Information	
REB File #:	10-036
Project Title:	Approaches to Accountability in Ontario Medical Laboratory Sector
First Name:	
Last Name:	Bourne
Email:	lavern.bourne@uoit.ca

Section 1b: Status of Protocol	
☒ **Option 1 (Changes ONLY) Proceed to Section 2 and complete all relevant sections**	There have been Changes to the Protocol since receiving original REB Approval. I am requesting the changes found in this form approved.
☐ **Option 2 (Changes AND Renewal) Proceed to Section 2 and complete all relevant sections**	There have been Changes to the Protocol since receiving original REB Approval. I am requesting to have the changes found in this form approved. This study is continuing and requires renewal until Research Project Completion Date.
☐ **Option 3 (Renewal ONLY) Proceed to Section 6**	There have been NO Changes to the Protocol since receiving original REB Approval and I am requesting a Study Renewal.

If you have selected **Options 1 or 2**, continue and complete all sections of this form.	
Section 2 ~ Leave BLANK if there are NO Changes Requested	
2a: Co-Investigator (list ONE, if applicable)	
First Name:	
Last Name:	
Position/Affiliation:	
Email:	
2b: Faculty Supervisor (for Student Projects only)	
First Name:	Brenda
Last Name:	Gamble
Position/Affiliation:	Assistant Professor UOIT
Email:	brenda.gamble@uoit.ca

Section 3 ~ Leave BLANK if there are NO Changes Requested	
3a: General Project Information	
Title of Project:	
Faculty Investigators:	
Student Investigators:	
Co-Investigators:	
Research Start & End Dates:	
Locations:	
Other REB Approvals:	
Risk/Level of Project:	
Funding of Project:	
Conflict of Interest:	
3b: General Project Information	
Purpose/Rationale for Research:	
Methodology/Procedures:	
Previous Experience/Expertise:	
Participants Involved in Study:	
Recruitment Process/Materials:	
Compensation for Participants:	
3c: Benefits and Risk	
Possible Benefits:	
Possible Risks:	
3d: Invitation/Consent Process	
Informed Consent/Absence of Consent:	
Use of Deception:	
Process of Parental/Guardian Consent:	
3e: Confidentiality	
Procedures to ensure confidentiality:	
Who will have access to the data? List ALL individuals:	The Faculty of Health Sciences , Computer Instrctional technologist, Nigel Stein has access to a special licensed data analysis software that allows for transcription of recorded voice messages to a word text document. Nigel will be assisting me with using this technology to transcribe the interview data.
3f: Secondary Use of Data	
Plans for Using Data for Other Purposes:	

APPENDIX H: Comprehensive list of Document reviewed and their contribution to the thesis

Articles	Historical perspective	Governing instruments				Independent variables				
		financing	regulation	information	professionalism	Policy Goals	Governance ownership	Production characteristics		
								contestability	measurability	complexity.
Romanow Report	**X**									
Krever Inquiry Report	**X**									
Walkerton inquiry Report	**X**									
Cameron Inquiry Report	**X**									
Human pathogen and Toxins Act 2009	**X**									
Laboratory Biosafety Guidelines			**X**							
Auditor General Report 2007	**X**	**X**	**X**							
Laboratory service review	**X**					**X**				
Laboratory Service Restructurin	**X**					**X**				

g Secretariat (LSRS)										
Health Services Restructuring Commission(HSRC)	**X**					**X**				
Quality Management Program-Laboratory Services(QMP-LS)						**X**		**X**	**X**	**X**
Government Legislation and Regulations						**X**				
Ontario Laboratory Licensing Policy						**X**				
CSMLS reports and Publications					**X**					
CMLTO Reports and Publications					**X**					
CLMA Reports and Publications					**X**					
OSMLT Reports and Publications					**X**					
Mass Media	**X**									

Appendix I: Amendment to REB Application

UOIT
CHALLENGE INNOVATE CONNECT

RESEARCH ETHICS BOARD
OFFICE OF RESEARCH SERVICES

Change Request and/or Study Renewal Form

For Office Use Only:

Date Received: REB # _____

1.0 Purpose

This form must be filled out for all Research Projects that are:

1. Requesting Changes to a previously approved Protocol, or
2. Renewing your Protocol AND Requesting Changes, or
3. Wishing to Renew your Protocol without any Changes.

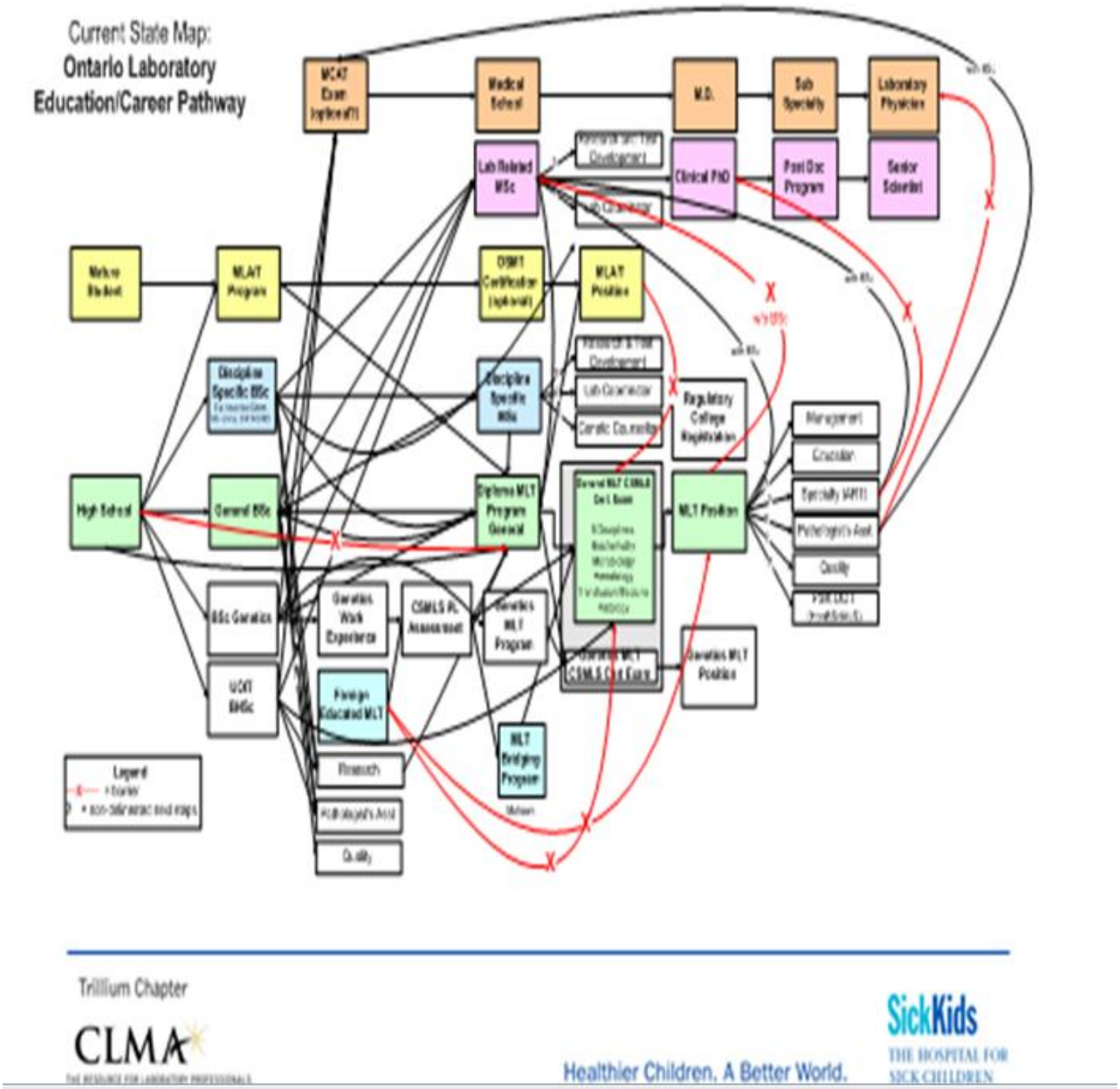
Please note that if there are significant deviations from the original approved protocol, the REB may request a new REB Application or additional information.

2.0 Instructions

For all users of this form, fill out Sections 1, and then follow directions from each Option. Submit **ONE** Signed Softcopy of this form along with all attachments to compliance@uoit.ca. Hand written forms will NOT be accepted.

Section 1a: Principal Investigator Information	
REB File #:	10-036
Project Title:	Approaches to Accountability in Ontario Medical Laboratory Sector
First	

Appendix J: Current map of Ontario Laboratory Education pathway



Trillium Chapter

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Appendix K: Future map of Ontario Laboratory Education pathway