# An Examination and Analysis of the Ownership, Funding and Quality Assessment Structures of the Public and Private Laboratory Sector in Ontario

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**Abstract**

**Purpose:** The thesis questions aim to address how the Ontario laboratory sector is organized, with a focus on aspects of funding, ownership structure, access to care, health human resources and quality assurance.

**Methodology:** A case study design used 15 semi-structured interviews and a document review.

**Results:** Lab funding models did not incentivize unnecessary testing in hospital, for-profit or Public Health Ontario labs. Quality assessment of lab testing was generally well measured for the analytical phase. The mechanisms that are available to ensure that private for-profit labs adhere to societal goals include regulation of professionals, maintaining a rigorous quality assurance program, and updating the Schedule of Benefits-Laboratory Sector regularly.

**Conclusion:** Legislation and funding models are changing for labs to reflect modernization due to technology and higher quality standards. All categories of labs need to work with government and regulatory bodies to ensure decisions prioritize the patient and the health care system.

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# CHAPTER 1 INTRODUCTION

## 1.1 Statement of the Problem

Laboratory services are essential to the health care system and are used to verify and monitor the well-being of Ontarians. Approximately 85% of medical decisions are made using laboratory tests [1]. The medical laboratory sector in Ontario has been operating as a well-established industry with publicly and privately delivered testing. In recent years, challenges that include concerns around value, access and quality have emerged. Accordingly, an understanding of the current landscape with respect to private and public laboratory companies and its implication on health systems organization will help provide evidence to support policymaking. The aim of this thesis is to review the categories of laboratories in Ontario and understand how the ownership structure, funding model, quality assurance and health human resources differ in the four types of Ontario laboratories. Understanding the implications of different models of funding and ownership may be useful to policy makers; therefore, any lessons learned could be used in other provinces looking at models of laboratory delivery and funding.

## 1.2 Research Questions

This thesis examines the implications of the public and private delivery of health care using the example of Ontario's medical laboratory sector. The thesis questions aim to address how the laboratory sector is organized, with a focus on aspects of funding, ownership structure, access to care, health human resources and quality assurance. One key issue is how labs are funded and if that creates incentives for labs to perform and behave in a certain way. This may or may not benefit the patient, health care system or taxpayer. Another issue that is explored is where and how patients can get their lab work done, and if this organizational structure impacts access to labs and access to expertise in more remote areas. A third element that is described is who performs lab testing and how does the professionals' accreditation and place of work impact their ability to perform certain tasks. A fourth element explores quality assurance in all phases of lab testing; this has been a problem in the past with issues such as the Walkerton Inquiry and the Tainted Blood Scandal [2]. These issues highlighted the need for better quality control of labs; this thesis accordingly looks at views from experts about whether accreditation and proficiency

testing provided by external organizations and internal lab quality programs provide adequate quality assurance.

In order to better understand the changing Ontario laboratory landscape and to make sense of the growing challenges, a preliminary literature review was conducted. It revealed a limited array of sources, with some documents that were originally commissioned by the Ministry of Health and Long-Term Care that were not made available to the general public[3]. As conversations with experts in the Ontario laboratory field ensued, it became evident that much of the knowledge that they possessed was not public information and there was in fact, a gap in the literature. An update on the current landscape of the public and private delivery of medical labs in Ontario would prove useful to understand the changes in funding models, access to tests for Ontarians, quality assurance programs and the health personnel primarily responsible for delivering lab services.

Investigations of Ontario's laboratory sector available from the literature have brought to light questions about the lack of modernisation of the Laboratory Schedule of Benefits, the limited number of newly introduced laboratory tests and the quality assurance management of current tests. These investigations led to recommendations on how the medical lab sector could be improved. One example was the Laboratory Services Expert Panel, which was mandated in 2015 to provide recommendations to the Ministry of Health and Long-Term Care on how to modernize the funding and services of for-profit community labs. As noted in section 5.7.1, The Ministry of Health and Long-Term Care has been developing and implementing Transfer Payment Agreements (TPAs) as part of the Community Laboratory Modernization Strategy, which will be tied to performance measures as part of the TPAs. A plan was proposed to introduce a New Tests and Technology Fund in 2018/19 to help community labs adopt tests that have evidence-based patient improved outcome and experience [4]. These issues reveal the need for understanding, monitoring and improving the medical laboratory sector in order to use the limited health care dollars and resources more effectively. The literature review revealed four key characteristics that are important elements of the laboratory sector: the organizational structures of labs, funding models of each type of lab, quality assurance measures and the human health resources that are required to operate a lab.

In understanding the implications of the key issues in the Ontario lab sector, one may find improvements in how labs are managed, operated and funded. These findings can, in conjunction

with further research, influence new policies to make the lab sector more financially sustainable, transparent and efficient [5]. As noted in section 3.4, the analysis recognizes that there are four categories of labs in the Ontario lab sector – hospital labs, for-profit community labs, Public Health Ontario labs and physician-owned labs. The thesis examines the following research questions, and how these do or do not differ by the category of lab:

1. a) Who pays for what in Ontario's lab sector?
   b) How do monetary incentives impact appropriateness of testing practices in each kind of lab?
2. What role does the private sector play in the delivery of lab services?
3. a) What are the quality assurance measures currently in place?
   b) What are the differences in voluntary quality assurance programs and mandated province-wide quality programs? How do they differ within the various categories of labs?
4. a) Who is allowed to perform tests? Can one kind of professional be used to perform a different role in the different categories of labs?
   b) Who is able to order tests?
   c) How are professionals involved with laboratory testing regulated?
5. Who delivers genetic tests in Ontario? What do the funding and ownership structures look like of labs that perform genetic testing?
6. How do experts, including our key informants, think we need to modernize the regulatory and funding framework of the lab sector?
7. What roles do regional partnerships between labs play in providing access to care?

## 1.3 Overview of Thesis Chapters

The remaining thesis chapters will aid in addressing the research questions and provide relevant findings and context to each question.

Chapter 2 provides the key terms and conceptual framework used to analyze the collected data.

Chapter 3 provides an overview of the Canadian health care system and the Ontario medical lab sector, including the background on key concepts, key stakeholders and relevant legislation that has helped shape the system to what it is today.

Chapter 4 outlines the methodological approach used for this study. A case study approach was used to provide a descriptive model of the current state of the medical laboratory sector in Ontario. Document review was used in combination with key informant interviews as a means of data collection. Limitations of the study are also discussed in this chapter.

Chapter 5 presents the results of the data collected from the document review and semi-structured interviews.

Chapter 6 provides a discussion of the research findings.

Chapter 7 offers the conclusions of the research and suggestions for potential future research.

# CHAPTER 2 CONCEPTUAL FRAMEWORK AND REVIEW OF THE LITERATURE

## 2.1 Defining the terms

The chapter will start by defining key health care system concepts such as: private and public; and financing, delivery and allocation. It will then review a theoretical framework that describes variables which impact the overall performance of medical labs. It will define production characteristics and discuss how these may affect the analysis of the performance of labs in Ontario. The aspects of the theoretical framework will lay the foundation for the rest of the thesis.

Defining the public and private health care sectors is critical to the understanding of their role in Ontario's health care system. The public sector refers to federal, provincial or municipal governments and government run agencies [6]. The private sector in health care is defined as provided or owned by an individual or independent company rather than by the government. This includes the corporate for-profit sector, small business, not-for-profit organizations, and individuals. A third term, the quasi-public sector is described as organizations that are legally private but highly regulated by the government. The rest of the analysis presented in this thesis will not be using this term, since labs can be classified into public and private.

The next set of terms that will help define the public and private sector is the distinction between financing (funding) and delivery of health care. *Financing* refers to how services are paid for, and in Canada can be done by provincial insurance plans, directly by the patient through private or work insurance or through out of pocket payments. *Delivery* of health care refers to how services (which could include individual providers, clinics, hospitals, etc.) are organized, managed, and provided [7]. Both financing and delivery of care can be described as combinations of public and private. A third element of health care systems is sometimes termed *allocation*, which refers to the models that define how providers can be reimbursed. Allocation is the link between financing and delivery of care, and recognizes that the different payment models that flow resources from payer to provider come with different incentives. Payment models can include a number of approaches, such as a fee-for-service model, capitation, global budgets, or activity-based funding [8].

A variety of financing and delivery options are available in Ontario and can be carried out in the public sector, private sector or both [9]. This is illustrated in Table 2.1, where the combinations of public and private sector financing and delivering of health care are shown. The Organisation for Economic Co-operation and Development (OECD) uses a similar model, with slightly different terms. This thesis touches heavily on these concepts, and will examine and analyze how these are used in the different types of laboratories in Ontario.

In Canada, the public financing-public delivery cell represents a small proportion of care; it includes such services as public health and health services for certain groups, such as the military. The private financing and public delivery cell is also not heavily used in health care in Ontario; it does capture non health care services such as public transit which are publicly delivered, but rely heavily on fare revenue. Publicly financed and privately delivered care describes most physician and hospital care in Canada. The last cell, private payment and private delivery refers to such services that do not need to be publicly paid for in Canada, such as pharmaceuticals outside of hospitals, most rehabilitation services and dental care [8].

**Table 2.1 Potential combinations of public/private and delivery/finance in health care [7]**

| | Public Funding | Private Funding |
|---|---|---|
| Public Delivery | National health service | User fees for public services |
| Private Delivery | Public insurance | Private insurance |

Although intimately related, ownership and financing models that are described by the terms *public* and *private* must be defined appropriately, as their definitions can vary between institutional settings. Boundaries between public and private are not always clear, and one must look at the ownership structure and broad framework of incentives to understand how certain organizations behave [7].

*Public* delivery of care organizations often have the following characteristics: their employees are considered civil servants, they may have a monopoly on a certain service type, and their operations are bound to transparency and disclosure provisions [8]. Public delivery of care is seen, although the evidence is mixed, to take minimal risks, which may hamper innovation in their field. This tendency is also attributed to public service being less flexible and nimble.

*Private not-for-profit* (NFP) delivery of care is provided by organizations that are operated by charitable organizations. They may receive their funding through a combination of charitable contributions, government contracts and/or revenues from other sources. Employees and volunteers are not considered civil servants, as they work at an arm's length from the government. NFP organizations cannot distribute surplus of revenue to individuals as profit but can spend it as perks for staff, education or research. They may receive tax exemptions from the government but can also go bankrupt if are financially mismanaged. It is important to note that many education and health services are delivered by NFP organizations and not public organizations. The majority of hospitals in Ontario are private not-for-profit, although in the past they have (misleadingly) often been called 'public hospitals' which reflects the fact that the majority of their budget comes from public sector sources of funding.

*Private, for-profit small businesses* delivery of care include entrepreneurs and businesses that are privately owned by health professionals but do not have shareholders. Most physician practices would be classified as private for-profit small businesses, or what Evans called "not only for profit", since ethical considerations limit the extent to which they would try to sell unneeded services [10]. Some private clinics and small hospitals are also private, for-profit small businesses. Their characteristic includes paying taxes, being flexible due to employees not being a part of the government, and having different accountability structures than NFP organizations[11].

*Private, for-profit corporations* pay taxes, cannot access charitable donations or volunteers, have access to capital through issuing equity and, as noted above, are expected to provide a return on investment to their shareholders. Their goals include maximizing the return on investment and increasing profit to shareholders. For-profit corporations play a role in Canadian health care, providing pharmaceuticals, retirement homes, and some services in hospitals such as food delivery. An example of private for-profit corporations operating in Canada are the corporations that provide assisted living and long-term care, such as Extendicare[12].

### 2.1.1 Defining Medical Laboratories

Medical laboratories are facilities which exist to enable clinical tests to be carried out in order to obtain information about a patient's health.

The laboratory process is broken down into three phases: pre-analytical, analytical and post-analytical. The pre-analytical phase refers to test ordering, collection of specimens from the patient, and transportation of specimens to an appropriate facility for analysis. The analytical phase is where the test is conducted, and the post-analytical phase is the interpretation of results and reporting the results to the ordering practitioner [13]. How well each laboratory test performs can be described in terms of its 'sensitivity' and 'specificity'. Sensitivity refers to the measure of how good a test is in demonstrating whether the patient has a condition or not and is computed by dividing the number with that disease who test positive for that condition by the total number who had that disease (it can also be called the true positive rate). Specificity is a measure of the ability to correctly rule out disease, and is computed by dividing the number who do not have that condition and tested negative by the total number who do not have that condition (termed also as the true negative rate). Both are expressed in percentages [14]. These definitions are important when looking at the usefulness of tests performed in the lab sector.

In the pre-analytical phase, specimens are collected in specimen collection centres (SCCs) which are facilities where patient samples are drawn and then transported to laboratories where they are assessed, analyzed and interpreted. During the analytical phase, specimens are analyzed in labs which can be located in hospitals, in the community as a free-standing facility and in physician offices. The post-analytical phase is conducted in the laboratory where the tests are interpreted and results are described, and the results are sent to the requesting provider to guide in the treatment and diagnosis decisions of the patient. Labs are usually run by a Medical Director, and they employ medical laboratory technicians, medical laboratory technologists and pathologists, which are further described in section 5.5.2. In order for a test to be ordered, an authorized health care provider, such as a physician, dentist or nurse practitioner, must complete a requisition form which outlines the required testing for their patient. However, specimens can be collected not only in SCC facilities, but from Point of Care Testing (POCT) which is done at

the site of where the patient is located and can be interpreted without being transported to a laboratory. Certain lab tests require complex equipment and machinery that can be used for multiple tests; that represents fixed costs for the labs. The variable costs include reagents, supplies, technician time and pathologist time. This will become important when looking at lab efficiency and economies of scale later in the thesis.

As noted in the thesis, there are different categories of labs that are publicly and privately delivered, and a variety of tests that can be publicly and privately funded. The categories of labs are further described in section 3.4. The next section introduces a theoretical framework and describes how it is used in the context of the different types of labs in Ontario.

## 2.2 Theoretical Framework of Governance and Ownership of the Medical Laboratory Sector

As the population ages and more people will access the health care system, a need to provide Ontarians with the required care at the right time has been identified by the Ministry of Health and Long-Term Care [15]. This thesis employs an analytical framework to assess the objectives of the system, with a focus on goals that are related to quality, cost and ownership. The themes that are explored and discussed in this thesis are obtained from the analytical framework. This will be analyzed through the lens of the Ontario medical laboratory sector. These goals cannot be viewed in isolation, as measures taken to attain one goal may affect the others [8]. For example, quality measures may drive up the cost of lab operations, which would impact the bottom line of for-profit labs, and behaviours and incentives are altered [16].

In the context of health care, quality can be defined as delivered services which meet professional standards and are satisfactory to patients. Quality can be described using Gamble's framework which groups potential factors and variables into structure/inputs, process and outcome [17]. The input includes human resources, the accreditation and training of professionals, equipment and laboratory spaces. The process refers to the transportation of samples between specimen collection centres and laboratories and care pathways in the phases of lab work that is further defined in section 2.3.1. The outcome refers to the effects on the health status of patients. Because lab tests can play a critical role in patient diagnosis, treatment and monitoring, the results and accuracy of lab tests is of utmost importance. Regardless of the ownership type of medical labs, the policy goals of all labs are centered on producing high quality work in all aspects of the lab sector [17]. Figure 2.1 shows the theoretical framework created by Gamble,

which describes the above process by presenting the variables at play. The contextual factors that make up the governance and ownership structure directly impact the input, process and output dimensions.

**Figure 2.1 Theoretical framework by Gamble**

| Contextual factors | | | | | Inputs | Process | Outputs |
|---|---|---|---|---|---|---|---|
| Governance/ownership | Financing | Legislation/regulation | Accreditation | ę | 1. Health Human Resources<br>2. Research, information, education and training<br>3. Performance indicators<br>4. Structural/organizational factors<br>5. Population being served | Pre-analytical, analytical and post analytical phases | Technical proficiency, clinical proficiency (i.e., interpretation of results), and appropriateness of testing. |

Policy instruments are defined as interventions made by the government in order to achieve outcomes, which conform to the objectives of a public policy [18]. There are a number of ways to classify such instruments, but a common factor is the variation in the amount of coercion involved [19-20]. Some policy instruments or tools used in health care include legislation and regulations, financial incentives, information to the public and reliance on professionalism/stewardship by those providing services. The policy instruments used in this case example include legislation, regulation, financial incentives, and professionalism.

Regulation, which in Figure 2.1 is included as a contextual factor that directly affects inputs, process, and outputs, is a policy instrument that is widely used, including in health care. Regulation is a tool that requires people to behave in a certain way; it is used in the laboratory sector as one mechanism to ensure that the laboratory sector uses best practices in all relevant processes [21]. Regulation is used by a variety of actors, not all governmental, and can appear at different levels in health care including regulatory colleges of professionals, accreditation, medico-legal bodies and regional health bodies.

Many health care services are provided by health care professionals. There are several criteria which define professionals, including having a defined body of knowledge that must be

learned, providing services that could put their clients at risk if not done properly, and being in an "agency relationship" with the client, since that client would often not be in a position to judge whether the care is properly provided or whether the service is necessary [11, 22]. To ensure that people providing these services do so properly, most professions must be certified by a professional regulatory College; in general, these bodies are self-regulating, meaning that only those possessing that specialized knowledge themselves are in a position to judge competence. A common approach is to issue licenses (or certification) to those members who have met the designated criteria (usually including graduating from a recognized educational program). Although these regulatory bodies are self-governing, they require the government to give them the authority to enforce rules and handle patient complaints. The mission of professional regulatory bodies is established by statute, and their objective is to serve the public interest [23]. A related concept is 'controlled acts', which can only be performed by registered members of that profession. Using Gamble's model as shown in Figure 2.1, regulation of the level of inputs would include Colleges that health professionals belong to which hold them accountable to certain standards of practice. Output levels are monitored by regulatory bodies that assess the quality of results disseminated into the health care system. One key variable is the extent to which regulation is voluntary or mandatory, and who enforces its provisions (including the consequences of non-compliance).

Accreditation, defined as the process of recognizing someone has a particular status or qualification, is another way that institutions are regulated and are held accountable. At the process level, accreditation by government agencies that protect the public's interest is required for these agencies to operate [24]. Accountability has multiple definitions, but for the purpose of this thesis, accountability is defined as being answerable to someone for meeting specific goals and objectives [25].

## 2.3 Production Characteristics

According to the literature, it is important to assess the production characteristics of goods and services in order to measure performance in the health care sector. Those who have attempted to compare public and private delivery of health care services have used the concept of production characteristics which include contestability, measurability and complexity [8].

Contestability is a concept defined by Preker and Harding as follows: 'contestable goods are characterised 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' [26]. A contestable market is easy to enter and to exit.

Measurability describes 'the precision with which inputs, processes, outputs, and outcomes of a good or service can be measured' [26]. It is easier to monitor performance when measurability is high. Some parts of the medical lab sector have a high degree of measurability; for example, the accuracy of a test result analyzed during the analytical phase is highly measurable.

Complexity is defined as 'whether the goods and services stand alone or require coordination with other providers'[26]. Note this does not refer to how complicated the service is, but how it interfaces with other services. Laboratory services are a highly complex and an embedded service within the system of care, where providers order tests that are interpreted and treatment decisions can be made based on the results. What makes lab services complex is the urgent nature of some testing; if a test is needed immediately ("stat") for an emergency patient, the hospital labs have to be able to operate at any time of day in order to deliver the results. In contrast, goods that are considered low complexity are pharmaceuticals, because they can be ordered ahead of time and stored in the facility so that they can be made readily available to the practitioner and the patient when they are needed.

### 2.3.1 Applying Production Characteristics to Ontario's Medical Laboratories

The laboratory sector is considered relatively non-contestable because there are many barriers to entry such as licensing requirements, accreditation requirements, monopoly market power, high sunk costs (particularly to purchase specialized lab equipment and reagents), geographic location, trust and asset specificity [7]. Indeed, the major private for-profit community labs in Ontario have amalgamated and at the time of analysis 94% of the community lab test volumes were performed by two corporations [5]. In order to obtain a laboratory operating license in Ontario, candidates must obtain appropriate licensure and fulfill conditions outlined in the *Laboratory and Specimen Collection Centre Licensing Act* [27]. Accreditation requirements by the Ontario Laboratory Accreditation program run by the Institute for Quality Management in

Healthcare [28] present a long process to candidates of all lab categories trying to enter the lab sector. Accreditation requirements include those that display lab competence, safety and quality. The development of the requirements demonstrate compliance to the International Organization for Standardization (ISO) and cross referencing these standards to Canadian Statutes and regulations, provincial statutes and Health Canada Guidelines [28].

In terms of measurability, lab tests lend themselves to easily set performance criteria such as reference ranges, accuracy, precision and turn-around time [29]. In this way, the analytical phase is considered highly measurable. However, measurability of the pre and post-analytical phases are more difficult, as further described in section 5.4.1.

In terms of complexity, laboratory services are a highly complex and embedded service within the system of care, where providers order tests that are interpreted and treatment decisions can be made based on the results. Depending on the situation, these tests may need to be provided quickly, which makes it more difficult to close down and consolidate laboratories. Geographic location accordingly poses as a challenge due to the large area Ontario occupies and because transporting specimens from specimen collection centres to labs is a complex, expensive process; this may contribute to more errors in the pre-analytical phase of testing.

The next chapter describes the Ontario health care system, with a focus on the medical lab sector, and applies the concepts and terms introduced in Chapter 2.

# CHAPTER 3 OVERVIEW OF THE ONTARIO HEALTH CARE SYSTEM AND MEDICAL LAB SECTOR

## 3.1 Introduction

This chapter gives an overview of the Ontario health care system, applying key concepts and terms introduced in Chapter 2. The sections in this chapter will discuss the variables which have been identified as key concepts that will shape our understanding of the health care system and subsequently the medical laboratory sector. This includes the private and public sectors, what the legislation, regulation and licensing characteristics look like, followed by how health care is funded in Ontario. The same variables will then be briefly reviewed for the medical laboratory sector in order to provide context to the reader, before an in-depth analysis of each variable is provided as part of the thesis results in Chapter 5.

In Canada, health care is largely under provincial/territorial jurisdiction, although the federal government has limited responsibility for specific groups, such as refugees and the military. However, as noted in section 3.2, to receive federal funds (at the time of writing, provided through the Canada Health Transfer), provinces/territories must comply with federal standards established by the *Canada Health Act*. Accordingly, each province and territory has set up a single-payer system for universal insurance coverage of most hospital and physician services (as well as selected other services) through what has been called Medicare. The model being used for these insured services falls into the publicly funded and privately delivered classification described in section 2.1 [7]. As single-payers, provincial ministries contract with a range of independent health care organizations which may include various combinations of hospitals, diagnostic clinics, medical laboratories, long-term care organizations and primary health providers [30]. Approximately 70% of health care costs in Canada are publicly financed, which means they are paid for by the federal and provincial or territorial governments. The remaining amount is paid for privately, which includes out-of-pocket, private insurance plans (which may be paid for by employers), as well as charitable contributions (for example, which help pay for capital expenses incurred by hospitals).

## 3.2 Overview of the Legislation, Regulation and Licensing that Governs Ontario's Health Care System

There are several Acts and regulations which impact the way that health care is conducted in Ontario. This section is used to contextualize the health care system using public and private delivery of care, and the role of policy instruments such as legislation, regulation and accreditation, which were defined in Chapter 2.

In terms of what must be publicly financed, as noted in section 3.1, although health care is primarily the responsibility of the provincial/territorial governments, the systems are guided and shaped by the *Canada Health Act* (CHA). It sets out national principles that must be met in order to qualify for full funding under the Canada Health Transfer, a federal funding contribution for health care which goes into provincial general revenues. Five criteria are outlined as part of the CHA-public administration, comprehensiveness, universality, portability and accessibility. The CHA does not touch upon the subject of how health care should be delivered, only what criteria must be met to receive full federal funding. Health services that are funded publicly but are delivered by a mix of public and private providers, are not in violation of the CHA [31]. The legal basis for defining what services must be publicly insured in Ontario can be found in several pieces of provincial legislation. One of the most prominent acts is the *Health Insurance Act*, which dictates who is entitled to be an insured person under the *Act* and which health services are covered through the Ontario Health Insurance Plan (OHIP) [32]. To comply with the CHA requirements, the provincial government mandates that no provider can charge patients for any of the insured services provided in hospitals or by physicians which are deemed medically necessary [31]. Medically necessary services can be defined as services that help patients when they are ill and is delivered based on the patient's need and not their ability to pay [33].

Another set of regulations relates to managing who can deliver health care services. As noted in section 2.3, many services are delivered by regulated health care professionals. Licensing in health care refers to the authorization of a government or regulatory agency to allow a person or group of people to practice or engage in a given occupation legally. The applicants are deemed competent to engage in that profession once they have met educational and training requirements; one aim is to ensures the safety of the public's health [34]. Licensing is a way of regulating who is allowed to perform those activities; it may apply both to health professionals and to health care institutions. For example, Ontario physicians are licensed by the College of

Physicians and Surgeons of Ontario (CPSO), which is a body responsible for registering all practicing physicians and ensuring that they meet professional standards to allow them to practice [35].

The use of regulation of health care professionals as mandated by the provincial government ensures that all relevant key stakeholders adhere to the rules outlined by their governing bodies about who can deliver care. Regulated health professions must receive qualifications from regulatory bodies, stating that they are competent and knowledgeable enough to care for patients within their field. There are several organizations involved in regulating professionals who deliver health care. At the time of writing, Ontario had 26 regulatory colleges that regulated 29 distinct professions such as physicians, nurses, dentists and medical laboratory technologists. Their role and duty is to protect the interest of the public and to ensure that health care professionals behave in a safe and ethical way [30].

Other regulations apply to organizations delivering care, particularly hospitals. Ontario hospitals are regulated under the *Public Hospitals Act* [36]. Unlike many other provinces, Ontario has also retained individual Boards of Directors for each hospital; they are involved in oversight for managing such aspects as financial management and quality of care for their organization [38]. In addition, most hospitals seek accreditation from Accreditation Canada, which is a voluntary, nongovernmental organization which is affiliated with the global Health Standards Organization, with a goal to review and assess regional health systems and provide recommendations on how to improve [39]. Although this is a voluntary accreditation, many critics believe that accreditation should be mandatory in order to uphold quality of care in all health care organizations [40].

### 3.3 Structure of Ontario's Health Care Funding

The Ontario health ministry, the Ministry of Health and Long-Term Care (MOHLTC) is responsible for providing public funding to institutions, organizations and physicians. The MOHLTC does not directly provide health services, but rather creates the legislation and foundation for Ontario's health care system to operate in. It does this through various mechanisms, as described below. The MOHLTC is the payer for the Ontario Health Insurance Plan (OHIP), which provides all legal residents of Ontario with health insurance for all insured services (including hospital and physician care). At the time of analysis, Ontario had divided the

way it flowed funding to private providers. Funding for many services, including physician services and some other services (including most outpatient medical imaging and laboratory testing) were directly paid by OHIP. However, funding for hospital care and some community services was administered through a series of regional bodies called Local Health Integration Networks (LHINs). Although the CHA forbids user charges for insured services to insured persons, any of those additional services that would not be classified as hospital or physician care can charge user fees.

At the time of analysis, there were 14 Local Health Integration Networks (LHINs) in Ontario; LHINs are regional health authorities funded by the MOHLTC and given responsibility for the planning, coordination and distribution of funding to specified health services in their region, including hospitals, long term care homes, community health centres, mental health and addiction agencies, community support agencies and community care (primary care was not included, but paid for by OHIP at the provincial level.) LHIN boundaries were geographically based on population density, and their decisions were expected to be guided by a mix of provincial priorities and local health care issues and input from services providers and communities. In addition, since 2008, the provisions of the *Local Health System Integration Act* [37] required that all Local Health Integration Networks (LHINs) sign accountability agreements with all of the health services providers. As a result, all Ontario hospitals are required to sign a Hospital Service Accountability Agreement (the template for which has been modified over time) which enforces the way provincial tax dollars are spent. Subsequently, the Ontario government has announced its intention to replace the LHINs and a number of other provincial bodies with a new super agency, whose details have not yet been announced as of the time of writing.

### 3.3.1 Physician and Hospital Funding Models

Different sectors of the health care system are funded in various ways. One of the largest costs incurred by the Ministry of Health is physician payments. In 2017-2018, physician payments accounted for approximately 20% of the MOHLTC health care spending budget [41]. Physicians operate as independent health providers and are not considered government employees, and their funding does not flow through the LHINs but rather through the MOHLTC.

Historically, physician payment models were made up solely of a fee-for service model. However, more recently the MOHLTC has introduced a variety of new payment plans as part of a health care reform to promote interdisciplinary team based care to improve comprehensive care and control physician costs. The challenge is identifying the model that has the best outcomes for patients, taxpayers and benefits health care providers simultaneously. Physicians can receive payment under three main models which are a fee-for-service model, patient-enrolment-models and alternative payment plans (APPs) [42]. For those providers using fee-for-service, OHIP specifies what can be billed for each procedure, and the accompanying billing codes in a document called the Schedule of Benefits Physician Services. In 2015/16, the majority of physicians used the fee-for-service model at 55%, followed by the patient-enrolment model at 29% and16% used AAPs [42]. These models vary significantly by physician specialty.

Hospitals are funded by the province, and at the time of writing these funds were flowing through the LHINs, accounting for approximately 85% of hospital operating revenues. Other sources of hospital revenue include activities such as parking, cafeteria and charitable donations. Historically, hospitals were funded using a global funding model, which was based on previous years' funding [43]. In 2012, the provincial government introduced a new funding model that used a complex evidence-based model to provide efficient hospital care. It has since evolved to become known as Patient Based Funding. This is discussed in detail in section 5.2.1. At the time of writing, hospitals remain accountable to LHINs through service accountability agreements that stipulate service and financial outcomes. It is important to note that smaller hospitals are still mostly funded by the global funding model [43].

Funding for other programs within the Ontario health care system that comes from the MOHLTC include drugs, population and public health and special provincial programs such as Cancer Care Ontario. Mentioning these programs is important in order to highlight the vast breadth of services that are insured by the MOHLTC; however, going into detail into each program is outside the scope of this analysis. The purpose of the differing models for health care services is to create a funding model that has the best outcomes for patients, taxpayers and the providers.

## 3.4 The Four Categories of Ontario's Medical Laboratories

Laboratory services are an important part of the health care system and provide critical information to physicians about their patients. As of 2016, Ontario had approximately 540 specimen collection centres which collect patient samples and 200 labs that analyze the specimens [4]. There are four categories of medical labs in Ontario: private for-profit community labs, private for-profit physician-owned labs, private not-for-profit hospital labs and public not-for-profit Public Health Ontario labs.

Private for-profit community labs can also be referred to as corporate labs and community labs. These corporate labs that operate in the community are privately owned and return profits to shareholders. In Ontario, each of these corporate labs has a few laboratories but many more SCCs. There are eight corporate lab companies in, although two of them, Dynacare and LifeLabs, provide approximately 95% of the volume of community lab tests [5]. These community labs perform routine tests for such conditions as cardiovascular disease, infections, oncology, and infertility. They also perform some genetic testing and naturopath tests, which will be further described in section 5.6.

Physician owned labs are considered small business, for-profit labs and their surplus is profit that is made by the physician. These private labs are owned by small corporations such as the physician themselves, with no shareholders. Some of the most common tests that are done in these labs are fertility and methadone testing [5].

Private not-for-profit labs include hospital laboratories, which are operated by individual hospitals and are accountable to the physicians and hospital administration, who in turn were accountable to the LHINs (although, as noted in section 3.3, at the time of writing, this was being restructured by the Ontario government). Hospital labs are responsible for providing tests for inpatients, emergency patients that present themselves to the emergency room, and tests for patients whose physicians are affiliated with the hospital. The majority of large teaching hospitals in Ontario have fully operating laboratories that offer lab services in microbiology, chemistry, hematology, and transfusion-science [4].

Public Health Ontario Laboratories are public, not-for-profit laboratories operating in Ontario as crown corporations. Public Health Ontario Labs' mandate is to protect Ontarians by

delivering lab tests for such conditions as influenza outbreaks, HIV serology, water testing and food-borne illness testing. PHO operates as a separate entity from the Ministry of Health and Long-Term Care (MOHLTC) but within a broader accountability framework set in government directives [44]. There are 11 PHO labs in Ontario, which are operated by Public Health Ontario, and are overseen by the Ministry's Population and Public Health Division. They are accountable to the MOHLTC through the Chair of the Board of Directors; the Board is composed of up to 13 members who are recruited and appointed by the provincial government through the Public Appointments Secretariat, and are responsible for strategic plan and oversight of PHO [45].

The following section introduces the medical labs' funding, legislation, regulation and licensing frameworks, with Chapter 5 delving deeper into the nuances of the governance/organizational and funding structures of each kind of lab.

## 3.5 Overview of the Legislation, Licensing and Regulation that Governs Ontario's Medical Laboratory Sector

In order to better understand the nuances and intricacies of the lab sector presented in the Chapter 5 Results section of this thesis, this section provides an overview of the lab sector structure. Some of the fundamental guidelines on how labs are owned, operated and licensed are addressed through legislation, which in turn guides the creation of regulatory standards. Although there are many Acts that have impacted the evolution of labs in Ontario, the most recent and relevant for the laboratory sector that will be described here are *Ontario Laboratory and Specimen Collection Centre Licensing Act* (OLSCCLA) and the *Excellent Care for All Act*. All labs falling into three of the categories of labs- community labs, hospital labs and Public Health Ontario labs- but not the physician-owned labs, must comply with the OLSCCLA, which sets out guidelines on how labs are operated and licensed [46]. The Act dictates that all labs and specimen collection centres must be licensed and renewed each year. The renewal process provides the MOHLTC with information about the lab such as staff number, staff qualification and the kind of lab equipment used [13]. Licensing and inspection of medical labs is outlined in the OLSCCLA, and the type of license that may be issued determines the type of tests that the labs can perform [27]. It is important to note that although a license dictates which tests can be performed at the lab, it does not distinguish between tests that are insured or uninsured. This means that if a lab test is licensed but uninsured through the lab's particular funding model, the

lab can charge the patient for the test. The OLSCCLA also states that the Ontario Medical Association is responsible for carrying out quality management of all Ontario labs. However, these responsibilities have been moved to a department operating at arm's length from the OMA, called the Institute of Quality Management in health care (IQMH), which assesses the quality of all licensed labs. Each Ontario medical testing laboratory and specimen collection centre that is licensed by the Ministry of Health holds an IQMH accreditation certificate. As of July 2019, there were 200 licensed medical laboratories and 386 licensed specimen collection centres in Ontario [77].

Each lab receives mandatory accreditation from the IQMH and the labs may pursue non mandatory subspecialty accreditation from various other accreditation bodies. The subspecialty accreditations vary depending on the license they have for the types of tests they can perform. The MOHLTC covers the cost of most mandatory accreditation through IQMH for labs, but does not pay for subspecialty specialization that may be pursued.

All labs are regulated through licensure by the laboratory branch of the MOHLTC called the Laboratories and Genetics Branch. Although this Branch regulates licensure, other functions such as funding, operations and oversight fall under different branches across the MOHLTC. There are various components that are regulated by the laboratory branch for the different types of labs. For-profit community labs are regulated in what geographical location the specimen collection centres can be opened and shut down, how lab test quality is maintained and which staff can be employed. The Laboratories and Genetics Branch, however, cannot regulate what community labs charge patients for uninsured services. Regional partnerships between hospital and community labs are not regulated by the Laboratories and Genetics Branch. For-profit physician owned labs are the least regulated category of labs. Physical inspections are also conducted by the MOHLTC with on-site visits every two years [13].

*The Excellent Care for All Act* of 2010 mandates that the quality of the Ontario health care system is improved with each health care dollar used to provide the best care [47]. In the context of the medical laboratory sector, the MOHLTC is committed to ensuring all SCCs and labs are safe and effective.

The authority and powers of the regulatory bodies are set out in the *Regulated Health Professions Act, 1991* (RHPA) [46], and the Health Professions Procedural Code. The College of Medical Laboratory Technologist of Ontario (CMLTO) is governed by these laws, and the

medical laboratory technologists (MLTs) have their own statute, the *Medical Laboratory Technology Act* within the RHPA [48].This statute defines profession specific scope of practice, outlined requirements for entry to practice, misconduct and quality assurance regulations.

Health care professionals working within the laboratory sector, such as the physicians and medical laboratory technologists, are regulated by their respective Colleges, such as the Ontario Medical Association (OMA) and the College of Medical Laboratory Technologists of Ontario (CMLTO). The Colleges provide guidelines on training, continuing education, and a disciplinary arm in the case of patient complaints [49].

### 3.6 Medical Laboratory Funding Model

The funding models for each type of lab differ depending on the kind of laboratory it is; for-profit community labs, physician-owned labs, hospital labs and Public Health Ontario labs. For-profit community laboratories use Ontario's Schedule of Benefits-Laboratory Sector (SOB-LS) to submit billings that are publicly insured to OHIP on a per-test basis. The SOB-LS defines the payments that would be received by community medical laboratories that bill OHIP for insured laboratory tests. The fees are reported in LMS units, which stand for Labour, Materials and Supervision. Each unit has a value depending on the resources required such as type of staff required to perform the test, the reagents and supplies used and interpretation. There are also specimen collection fees that can be billed by the lab to help with transportation fees from the SCC to the laboratory. In addition, community labs are authorized to directly bill payers (or their private insurers) for those tests that do not qualify as publicly insured services. Patients may pay out of pocket or have their private insurance cover the cost of those tests.

Private, for-profit physician offices can bill OHIP through the Schedule of Benefits Physician Services. They can also charge patients for tests that are not covered under the Schedule of Benefits Physician Services. The majority of the tests that they provide are point-of-care testing (POCT), which are tests that are performed near the patient with results that are available quickly and that are covered by public funding. Examples of the most frequent point of care testing are pregnancy urine tests and methadone testing. Physician-owned lab testing is one of the fastest growing areas of lab testing in Ontario, with an annual reimbursement from OHIP doubling from the decade between 2005/6-2016/17 [5].

Public Health Ontario Labs are funded by the MOHLTC through transfer payment funding once specific reporting requirements are met [50].

Hospital labs are classified as private, not-for-profit labs; they are responsible for providing inpatient and some outpatient lab testing that is funded through the hospital's global budget and Patient Based Funding. As noted in Section 3.3.1, these hospital services are publicly funded. Hospitals are responsible for budget submission, documenting the number of lab tests performed and all relevant reporting to the LHINs.

A further in-depth look of the medical lab sector funding models is described in section 5.2.

# CHAPTER 4 RESEARCH DESIGN AND METHODS

## 4.1 Overview of Design and Methods

This study uses a case study approach [51], with the Ontario laboratory sector being the case. Case studies are used to describe and explore phenomena and aid in answering the question 'how'[52]. Ideally, a multi-method qualitative research technique is undertaken when performing a case study design. This method would also breed credibility and seek convergence through multiple data sources [53]. A case study research design is generally used to describe a phenomenon or situation in depth and in its natural context [52]. The research employed key informant interviews as the main data collection method, following an extensive literature review to provide context and justification of the need for the research [54]. Document review was used in combination with key informant interviews as a means of triangulation. Triangulation is a technique that aids in the authentication of data through cross referencing from two or more sources to increase validity of data [55]. Available documents were used to inform and validate data collected from the interviews. The key informants added valuable input that was not available elsewhere. The Ontario labs operate under universal guidelines within Ontario and these are described by each key informant. Therefore, this data is true of all, or most, Ontario labs.

A drawback of case study research is a potential lack of rigor by not following systematic procedure, which may undermine any study findings [55]. Another drawback is that case study research does not usually produce generalizable data. Like experiments, they are generalizable to specific propositions and situations, not to populations or all other similar cases [55].

### 4.1.1 Methods: Rigorous Content Analysis Process

When choosing analysis methods in qualitative research, one might consider phenomenology, hermeneutics, grounded theory, ethnography and content analysis [56]. The data was analyzed using a rigorous content analysis process, which is widely used in health-related disciples [56]. This method is suitable for identifying, analyzing and reporting patterns recognized within conducted interviews [57]. Generally, there is an idea about which themes might emerge and researchers are able to look for the themes within the data. This was the case for the research

questions used in this study, where the literature review helped illuminate possible concepts and themes, which were discussed during the interviews. Due to the nature of the study and aim to explore the landscape of the medical laboratory sector, it was unnecessary to perform some common qualitative analyses that generate themes such as word repetitions and comparing and contrasting themes. Word repetition is based on the notion that words that occur frequently are salient in the minds of participants [58]. The words become codes, which then establish a theme. However, the experts interviewed for this study did not all have similar expertise and knowledge about the studied area. Each individual contributed to the best of their ability and filled in the 'blanks' that may have been left by previous transcripts. Although there was much overlap, the goal of the study was not to identify how frequently an idea or meaning appeared in the transcript but instead focus more on depth and detail. The compare and contrast approach postulates that texts are either similar or different from each other and that difference is the theme itself. The researcher scrutinizes the transcripts and thinks about how the current sentence is different from the previous sentence and idea [58]. This approach was not used in the research as differences between answers for the research questions actually enhanced the understanding but did not assist in theme generation.

A strength of the content analysis approach is the strict, methodological step-by-step analysis process employed for data analysis. The categories are developed using the material employed in theory-guided procedure and the categories directly reflect the collected data. By applying the advantages of quantitative content analysis using categories to qualitative analysis, a systematic approach is preserved which distinguishes it from more interpretative processing of text material [59].

The four main stages of rigorous content analysis are decontextualisation, recontextualisation, categorization and compilation [57]. Decontextualisation is a process by which the researcher begins to understand the answers and breaks down the thoughts into what are termed 'meaning units'. These meaning units are the smallest unit of insight that the researcher can code, which would make contextual sense [57]. The coding was made easier by using the questions as the main themes. Sub categories for different responses were used for meaning units that pertained to each question. During the revision and refinement stages of the transcripts, the new codes were used. Some codes such as 'accessibility' and 'impact of legislation' were created throughout the analysis phase. This iterative and cyclical process improved the understanding

and meaning of the transcripts and created new questions for future interviews. The researcher used a coding list with explanations of the codes to increase reliability and avoid cognitive change, which could occur during transcript analysis [56].

Recontextualisation refers to the re-reading of transcripts with the full list of codes or meaning units over again, and consider the information that was not coded for any part of the research [56]. Although everything might seem important and relevant when a researcher is engrossed in the data, it is important to distance oneself and remember the primary research goals. This was done numerous times by the researcher in order to fully grasp all relevant themes and concepts introduced by key informants during the interviews.

Categorization condenses meaning units into themes by reducing the number of words but not the content [60]. During the analysis, the codes were the same as the meaning units which were stored in broader categories. In the literature, there is no specific strategy for how categorization should be performed, only that the categories should arise from the data it was collected in [57]. Memoing, which uses notes to record reflections made by the researcher about the learnings from the data, was used during the categorization step. Some interview questions were amended due to the memoing process, which helped in creating better questions that were more relevant to the thesis findings.

Compilation refers to the final step of analyzing and writing up the data. Qualitative content analysis differs from phenomenological based studies due to the objectivity that the researcher must maintain during the entire process [61]. Instead of analyzing how the key informants understand the phenomenon and immersing oneself into the data, the researcher must remain impartial and neutral to the collected data.

### 4.1.2 Analytical Rigor

Achieving analytical rigor and trustworthiness is perhaps one of the most important consideration when undertaking a research project that is qualitative in nature. To assess analytical rigor, one camp of scientists uses the concepts of credibility, dependability, transferability and confirmability as outlined by Lincoln and Guba [62].

Credibility assesses the study process and ensures no relevant data is excluded. Harmonized buy-in from colleagues, experts and informants is one of the main ways to achieve

credibility [57]. In the study, this was established by using triangulation of sources and member checking. Triangulation of sources examines the consistency of data sources within the same data method, and compares people's responses at different times and in different settings [62]. The interviews were ongoing for 8 months and most of the same questions were used for all of the key informants. The collected data was validated by the respondents that had different expertise. Member checking was done because some respondents asked for their transcripts once the interviews were transcribed. They then provided feedback and some clarity on some aspects of the data. Although this is considered a controversial technique for assessing credibility, the researcher found this useful as respondents had time to evaluate and reassess their answers. Two respondents were extremely thorough and required clarification from their colleagues before providing further additional information about certain topics. One of the drawbacks of this technique is that some people may regret their stories or provided data and may withdraw it or ask for it to be removed from the transcripts. In the case of the study at hand, this did not occur.

Dependability and confirmability of data is assessed through the consistency and stability of the research findings. It's important to keep memos and rational behind coding decisions accessible as the iterative process of coding requires researchers to relabel and re-code as necessary [57]. Multiple researchers independently code the data and then discuss the codes and categories that are developed [63]. This is a form of triangulation, which confirms results between different researchers as a means of increasing reliability[56]. A second investigator, a PhD student from the Institute of Health Policy Management and Evaluation at the University of Toronto, analyzed the data collected for this thesis separately. This was done for the first four interviews that were transcribed and the new, updated coding schedule was then used for the rest of the transcripts during the coding process. As mentioned earlier, the nature of the iterative coding process ensured that the codes and categories evolved to reflect the collected data, then applied for the entire dataset.

Transferability is comparable to generalizability in quantitative research as the ability to apply the findings to other groups and settings. The representativeness of the sample would dictate how appropriate it is to transfer the findings to other groups, [57] presumably to other provinces. Case studies are often criticized because their findings are not generalizable to other cases due to the small sample size and typically niche scope of their findings [64]. Although a

range of experts were interviewed as part of the research, there was a greater number of community lab sector and hospital lab sector experts than any other type of key informant.

## 4.2 Data Sources: Document Review and Key Informant Interviews

Document review is considered cost effective and easily accessible, making it a widely used method in qualitative research [65]. As noted above, a document review was conducted in order to better inform the researcher of background information that would supplement and validate the data obtained from the key informant interviews. The lab sector is a complex structure and is made up of many systems; therefore, narrowing down the most important documents that were relevant to the research questions was an essential first step. The document review was used to provide context and improve the direction to the original research questions. The objective of the interviews was to supplement information collected during the document review and to provide the bulk of data and knowledge that was not accessible by any other means.

### 4.2.1 Data Collection

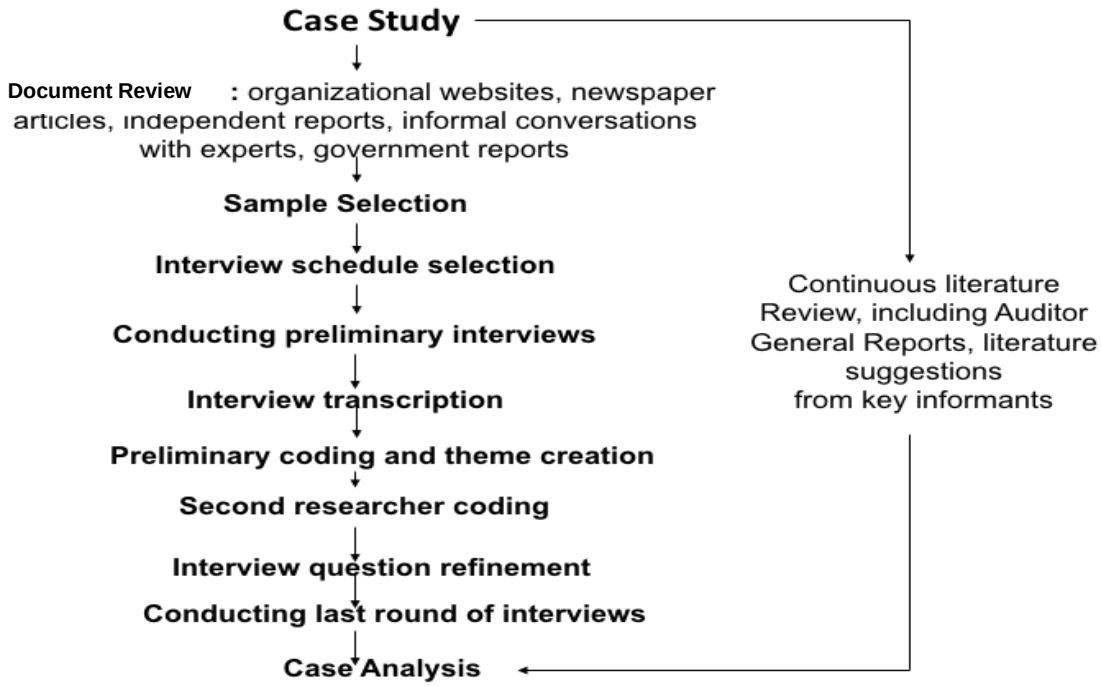
Document review primarily consisted of documents created by regulatory bodies, and reports that were commissioned by the Ontario government. In addition to the large amount of data collected through the initial document review, the data collection continued throughout the entire process as key informant interviews suggested new papers and documents that would be useful for the researcher. Websites of institutions associated with Ontario labs were visited and available data that pertained to funding models, organizational structure with regards to testing, quality assurance and health human resources was collected. There were some key documents that were not made available to the public, such as the Deloitte Review report completed in 2014 which was commissioned by the provincial government to make recommendations about the future of the public private ownership structure of Ontario's labs [3]. Accordingly, this document was not available, and was not used for the analysis. Appendix F provides a list of all documents reviewed and the contribution of each document for the major research questions.

The main source of data collection was a series of semi-structured interviews with key informants. The University of Toronto Research Ethics Board approved the interview guide,

which included both the interview questions and necessary follow up questions. In qualitative research, data collection can be based on 1-30 interviews; data should be collected until there is sufficient confidence in the answers because new information is not forthcoming (data saturation) [54]. In this study, there were 15 interviews conducted. At that point, data saturation had been reached as similar ideas and content were being brought up during the interviews.

Purposeful sampling was used to select the most well-informed experts in order to obtain the most accurate information. Snowball sampling was also used in order to allow subjects to recommend potential candidates for the study whom they believe could provide further insight [65]. Maximum variation sampling was used to study a broad range of subjects [66]. This brought a variety of perspectives for each research question. Figure 4.1 outlines the steps the researcher took during data collection, up until the data analysis stage.

**Figure 4.1 Data Collection Process**



4.3 Recruitment

After ethics approval was obtained through the UofT REB, recruitment began with introductory emails that provided consent and information about the study. Introductory emails by the supervisor were disseminated to more senior informants in order to connect the researcher. The goal was to ensure at least one representative from each key stakeholder organization was represented in the sample. Out of the 15 interviews, 4 were conducted by phone and 11 were conducted in person. The interview guide used is included as Appendix A; this was tailored with some specific questions to each participant that were devised to delve deeper into information the participant was more familiar with. For example, leaders in the community for-profit lab sector were asked about specimen collection center closures that had been mentioned in the news at the time of writing. The interviews were conducted between May 2017 and January 2018. Individuals came from various backgrounds, including private not-for-profit labs, private-for profit labs, academic institutions, government, and professional institutions. The informants were assigned letter identifiers based on their position plus a number. For example, the first lab manager that was interviewed by the researcher is LM1, the second lab manager is LM2, etc. As evident by the chart, the largest cohort interviewed were not for profit and for profit laboratory managers and directors, since not for profit hospital labs and for profit community labs make up approximately 94% of the total number of lab facilities in Ontario [5]. The lab managers and directors are some of the most knowledgeable individuals in the medical lab sector when it came to funding models, governance and organization of labs, quality and health human resources. They were also essential for the elaboration on key themes in Ontario labs such as the genetic lab testing programs and partnerships between hospitals in downtown Toronto and rural hospital labs in northern Ontario.

The researcher identified potential candidates who worked or were involved in any of the key organizations that were mentioned in the literature review. Subjects who have specific experiences were contacted, as critical case samples have the advantage of providing insight that may not be apparent to other informants [66]. Below is a list of key stakeholder organizations which were identified by the researcher and research committee as necessary to have a representative informant from. Individuals from each organization were contacted to interview. For a full description of each organization, please refer to Appendix G.

*Not-for-profit Professional Organizations*

In this category, two key informants were interviewed. One executive within the Institute of Quality Management in Healthcare was interviewed; this interview focused on quality management. The second key informant worked for the Ontario Association of Medical Laboratories. (PO1, PO2)

*Not-for-profit Laboratory Managers and Directors*

Five experts working in hospital labs were interviewed, one of whom had also worked in the private sector in other provinces. (LM1, LM2, LM3 LM4, LM5)

*For-profit Laboratory Managers and Directors*

Two lab managers from two different small labs and one director from a large lab were interviewed. (LMP1, LMP2, LMP3)

*Government Administrator*

One participant who was employed by the MOHLTC was interviewed. (GA1)

*Medical Laboratory Technologist*

A medical laboratory technologist (MLT) accredited by the College of Medical Laboratory Technologists of Ontario (CMLTO) was interviewed. She worked in a hospital setting. ( MLT1)

*Laboratory Physician*

Two physicians that worked as pathologists in hospitals in the Toronto area were interviewed. (LP1, LP2)

*Governance & Advisory*

One key informant who has sat on committees commissioned by the Ontario government for recommendations on the future of labs in Ontario was interviewed. (GAD1).

The researcher was unable to find experts from the private, physician owned lab sector or the Public Health Ontario Labs (PHOLs) who were willing to be interviewed for this study. However, physician owned labs make up only about 3% of all ordered test volumes [5]. The impact of this is described in Section 4.7.

## 4.4 Data analysis

Data analysis of the documents began by manually coding into broad categories that reflected the main thesis questions. Data analysis of the semi-structured interviews began when all recorded interviews were manually transcribed by the researcher. The de-identified data was retained and stored as described in the REB application, seen in Appendix E. It will be disposed of after seven years, as specified in the research protocol.

Initially, the researcher intended to use NVivo™ , which is a qualitative data analysis software, for the data analysis and coding process. However, after transcribing the interviews manually, the themes began to emerge naturally and no computer software was used for the creation of codes and themes. The main research questions created the themes of the study initially. Some respondents answered the questions directly, while others answered them in ways which produced new concepts that were grouped into categories and did not fall under themes that were a priori specified. The codebook can be found in Appendix D.

## 4.5 Limitations of the Study

A noted above, one major limitation of the study is that no experts who have worked directly or indirectly in Public Health Ontario Labs and physician owned labs were interviewed. The researcher sent numerous emails and left messages for various experts in these sectors but did not hear back from any of them. Although this appears to be a large portion of the service providers, in fact Public Health Ontario Labs and physician owned labs together only make up 5.6% of all volumes of tests performed in Ontario in 2015 [5]. Given the small amount, it is likely that the majority of data that was captured by all other experts is sufficient. The researcher gave special consideration during the document review in reviewing documents that provided further insight into these two lab service providers that did not have an interviewed representative.

Biased selectivity is a limitation that is relevant to this study as it suggests that available literature may provide information through the lens of corporate policies and agenda of the organization [53]. This may skew the perspective of the available data, which is why a second method is used to validate the information. For example, online newspapers articles described specimen collection centre closures in remote areas that impacted access for patients. However, the newspaper stories were incomplete and private lab executives elaborated on the stories, describing the issues from their perspective. This is discussed more in-depth in section 5.3.1.

The results of the study are not necessarily transferable to other provinces, as each jurisdiction has a different organizational structure of their labs. In this study, the collected data can be generalized to other jurisdictions that have a single payer system and multiple models for lab delivery. The data collected can inform other jurisdictions of public and private delivery of care, which can be seen relevant when amending or implementing system changes.

# CHAPTER 5 RESULTS FROM QUALITATIVE DATA ANALYSIS

## 5.1 Overview

As noted in Section 3.6, hospital laboratories are located within hospitals and operate as not-for-profit organizations that are predominantly publicly funded [13]. Hospitals labs receive their funding through a global budget, and a new allocation fund called Patient-Based Funding (formerly known as Health System Funding Reform, or HSFR up until 2017). This funding model is meant to provide incentive to shift funds to evidence based procedures and better integrated care for patients, and this is supported by evolving funding methodologies. Factors used in the calculation for funding include the number of patients cared for, the kinds of services provided and quality based metrics of services. As noted in section 3.6, The Patient Based Funding model is comprised of the Health Based Allocation Model (HBAM) and Quality-Based Procedures (QBPs). HBAM uses a fixed amount of funding for each health service provider based on the demographic profiles of patients that are served in the hospitals, as well as clinical and financial data provided by the hospitals [67]. QBP funding is allocated for specific procedures based on an evidence and quality based approach that is reflected in the price and is multiplied by volume of procedures [68].

The hospital labs receive their funding as part of the total hospital budget, as a total value which at the time of analysis was determined in advance by the LHINs. The budget targets are set by the senior management of each hospital and finalized by the hospital's Board of Directors. Targets are based on government funding increases or decreases, hospital activity, new programs and historical expenditure of the lab (LM2). If the funding is not used up by the lab, it goes back into the general hospital budget and is essentially taken away from the lab. Expenditures are posted quarterly, and if the lab overspends, it must justify the increase in spending and it may be removed from other departments (LM1). At the time of analysis, physicians that work in hospitals to support laboratory medicine departments, such as pathologists, were deemed to be independent contractors working within the hospitals. They can be funded through two means; the hospital budget or independent contracts negotiated between the MOHLTC and the Ontario Medical Association [69]. The key informants that were familiar with the hospital funding model were asked if they were aware if lab tests were part of the Patient-Based Funding or global portion of the budget but none of them were privy to this information within their respective

hospitals (LP1, LP2 & LM3).

## 5.2 What Are the Payment Models, and How Do These Differ by Type of Laboratory?

#### 5.2.1.1 Hospital Laboratories: Billing Patients

At the time of writing, hospitals could not independently bill the MOHLTC for the tests they perform. As noted above, under the funding model for hospital labs, the funding provided through the hospital's budget is intended to cover the costs of lab tests for inpatients as well as outpatients who come in to the emergency department or receive lab tests in hospital because of a physician affiliation with the hospital lab. Accordingly, when the hospital performs tests for outpatients who come in from the community and require tests that are not available in community labs, the hospital is prohibited from charging the patient or billing the MOHLTC beyond the funds already allocated via the hospital budget. However, this policy is under review, specifically for hospital laboratories located in northern or rural areas. The rationale behind this decision is that hospital labs in these communities do not have enough work to support laboratory staff and maintain a critical mass for quality control standards. Adding workload from the community will retain staff and maintain a critical mass for quality control standards. However, as noted above, at the time of analysis, hospital labs that perform outpatient testing must cover the cost from their hospital budget. Due to this, there have been instances of hospital labs in rural communities turning community patients away, and patients must then travel greater distances to reach community labs for testing (LM3).

One exception to this is The Hospital for Sick Children (SickKids) in Toronto. Although the same funding rules apply, because pediatric patients are notoriously harder to collect blood specimens from and the private labs in the vicinity of Sick Kids struggle to provide the service to such patients, Sick Kids has established an internal policy that it does not turn community patients away. Sick Kids must cover the cost of the specimen collection from their hospital budget (LP1). Some of the key informants suggested that if the government modified their current policy to allow hospitals to bill the Ministry for outpatient testing, patients would receive adequate care within the hospital they present to for testing, and in this way the hospital would be able to sustain the volumes (LM4). This is true for SickKids Hospital; however, it could also be relevant for other hospital labs such as the Children's Hospital of Eastern Ontario (CHEO).

#### 5.2.1.2 Hospital Laboratories: Billing other Hospitals and Community Labs

Hospitals can send lab tests for their inpatients to other hospitals if their equipment is broken or if they find their volumes for that test are too low to be cost effective to do the test themselves. The service agreement between hospitals allows the hospital that receives a requisition for tests from another hospital to bill the requesting hospital. There are similar agreements between hospitals and community labs; if hospital labs perform (and interpret) specialized tests for community labs, they can charge the community lab for them. Community labs are invoiced for each test that the hospital performs and interprets for them through these inter-institutional agreements.

The contracts between two or more hospitals or between hospitals and community labs vary within each hospital and are not overseen by any government body. As noted in the 2017 Auditor General Report, hospital billing for tests that were sent to other hospitals varied significantly. Some formulas included charging 70-100% of the Schedule of Benefits used by the community labs for tests completed by other hospitals. Other prices were derived from calculating the direct costs to the hospital related to performing the test plus a 30% overhead. In the 2017 Auditor General's report, three hospitals were compared in the prices that they charged other hospitals for the same tests and the difference varied from 31% more than the first hospital to 176% of the same test cost that was charged to a different hospital [4].

There are certain tests that are not insured outside of the hospital and for which community labs are able to bill patients. However, if the outpatient goes to a hospital that is affiliated with their referring physician, then the test is still covered under the hospital budget. An example of highly specialized tests that are not covered under the SOB-LS but would be covered under the hospital budget if ordered by an affiliated physician are: ANCA (antineutrophil cytoplasmic antibodies), Quantiferon Gold TB Testing (offered through some hospitals), Serum lysozyme, Antiphospholipid antibodies and Anticardiolipin antibodies.

#### 5.2.1.3 Hospital Laboratories: Other Funding Sources

Cancer Care Ontario (CCO) is another source of revenue for some hospital laboratories, since CCO covers the costs of tests that are specific to certain cancers. Some lab tests are

considered an insured service when following Cancer Care Ontario guidelines for establishing and following malignancies, but not as a general cancer screen tool. Patients that present to hospitals with specific requisitions from CCO have their tests done and billed straight to CCO by the hospital (LM3).

Pharmaceutical companies that are piloting studies and require lab tests use hospital labs; the companies cover the cost of the tests. Quite often, pharmaceutical companies pay for companion diagnostics to support their drugs; however, if the pilot is successful and the test is offered by the hospital to all patients and not just study patients, CCO will cover the cost of the test and include it in its budget (LM3). None of the participants were aware of the process that selected new tests to become a CCO insured test, but one participant said it was done using 'evidence-based research' (PO1).

### 5.2.2 Funding Model of For-Profit Community Labs

As noted in section 3.6, community labs are paid contractually by the MOHLTC – through a Schedule of Benefits-Laboratory Sector (SOB-LS) that captures all of the tests that physicians and other health providers in the community can order. Tests in the SOB-LS are called L-codes, which are reimbursed by the province on a fee for service basis. The SOB-LS lists the technical components of the lab tests as well as a professional interpretation fee which is included in the price of the test. The specific elements that are covered under each billing code are the collection and processing of specimen, interpretation and provision of results to the patient and provider [70]. The MOHLTC is paying the fee codes that are listed in the SOB-LS by using a formula that uses an average cost that is multiplied by the applicable individual fee for each service, as computed by the MOHLTC. The amount payable for an insured service rendered by a medical laboratory is 51.7 cents (the value for labour, materials, supplies) multiplied by the applicable individual unit value for such service as set out in the SOB-LS [47]. Proposed changes to the SOB-LS payment structure are outlined in Chapter 6.

There are also U-codes that denote tests that are available for patients but will not be reimbursed by the province, or are uninsured. The U-code tests are ordered by physicians and because the lab has a license to perform these tests, they are available for patients but have to be paid for out of pocket. It is important to note that if these tests were ordered in a hospital for an

inpatient, and the hospital was licensed to perform them, then they would be insured. The process in deciding why some tests are covered under OHIP while other tests are not was not explored in this thesis. However, it is important to recognize that community labs cannot perform tests that are they are not licensed to perform, except for those tests completed for the purpose of research by pharmaceutical companies, as noted earlier.

The fee for the service payment method for publicly funded laboratory test completed by a community laboratory is based on a service, funding and accountability agreement between the Ministry of Health and Long-Term Care and the Ontario Association of Medical Laboratories [5]. Since 1993, the Ministry had implemented a cap on the total funding from the government to the community laboratory sector, termed an 'industry cap' [4]. In 1996-97, a corporate cap was implemented to cap the funding that is given to each individual community lab. This is known as the market cap, or the market share that that lab has within the lab sector. A corporate cap is described as a pre-determined amount paid to a particular lab from the government that is tied to the market share of that laboratory. This is done in order to control overall lab test expenditures within the community lab sector. The corporate cap is established and reviewed every 2 years between the Ontario Association of Medical Laboratories and the MOHLTC [5]. This has not been changed or updated since 1997, since the time of implementation. To explain how market caps impacts test payment, one community lab executive said,

"I submit a claim for $10.00. I get paid $10.00. If I'm above my cap and I'm doing more testing, then that $10.00 for that test, now becomes $9.90. So, the actual price per test that we're getting paid gets reduced." This means that the market cap does not allow the community lab to recoup the full amount paid to the lab as outlined in the SOB-LS after the cap is reached, which benefits the government by controlling the cost.

At the time of writing, almost all community laboratories bill the MOHLTC beyond the corporate cap but are not paid for these billings. If they bill above the cap, they are not paid anything extra; however, this impacts the bottom line and theoretically decreases the amount they are paid for, for each claim. As noted in the example above, a $10 claim gets paid the full $10 but because the labs continue to do tests above their cap, that same $10 has to cover other tests that are not being paid. For example, in 2015/16 community labs billed the MOHLTC $868 million for tests they performed but were only paid $606 million due to the cap. [4]. This practice is described as a way for community labs to showcase the 'real' number of tests performed so

that the province is made aware of the impact of the cap on lab billings. Some experts question this practice as it may skew the year end utilization picture [5]. The consequence of this practice is argued by some as a tool to lobby the government for more dollars committed to community labs, and as proof that each year the cap is exceeded. Other experts see it as a means to maintain relationships with ordering providers by providing tests even though they are not paid for them.

Approximately 95% of the funding for community labs comes from the MOHLTC. The rest comes from a few different sources, a major one being patient out of pocket payments for uninsured services. For instance, some of the U-code billings that are included in the SOB-LS are used for genetic testing that are not an insured service but may be covered by private insurance or employer-sponsored plans. Community labs are able to choose how much they charge patients for uninsured services, without the involvement of the Ministry of Health. Based on competition law, labs cannot agree on pricing amongst themselves. One community lab executive stated, '… I had the Ontario Association of Medical Labs, come up with pricing, like a suggested retail price. But we don't anymore, because we were told not to by the Ministry' (LMP2).

The amount charged for the same tests that are listed as U-codes can vary between labs but the literature review and key informant interviews did not reveal any data about differences in pricing between the different community labs.

Similar to hospital labs, community labs perform research testing for pharmaceutical companies who are testing the effectiveness of medications. The cost of the testing is covered by the pharma companies themselves. One key informant noted that a possible advantage of entering into contracts with community labs over hospital labs is the extensive locations throughout Ontario, which would capture a more diverse sample and increase ease of access for patients (PO1). This would not be the case in rural communities where there are fewer community labs and outpatients must rely on hospital labs for their tests.

If a test is listed in the SOB-LS it is considered an insured service. However, some tests' coverage changes depending on what the tests are used for. For example, PSA (Prostate Specific Antigen) and CEA (Carcinoembryonic Antigen) tests are insured by the government only when used for monitoring an established malignancy. If performed for screening purposes they would be uninsured and the patient or private insurer would have to pay. As of 2018, Laboratory Requisition form have two tests, PSA and vitamin D testing, where the physician must indicate

when ordering whether or not the cost of the test will be covered based on the specified criteria (PO1).

Generally, tests that screen for cancer and tests completed on patients that are asymptomatic are not a publicly insured service and must be paid for out-of-pocket or through private insurance. There are separate agreements with organizations such as CCO that cover the cost of diagnosing prostate cancer and screening for colorectal cancer [4]. The Colon Cancer Check Program (CCSP) was developed by the community labs and provides colon cancer screening. They receive reimbursement from the Ontario government through CCO for each test result that is reported to CCO; these payments come from program specific funding (PO1). The CCSP pays for the fecal occult blood test (FOBT) screening test for colon cancer only for individuals who meet the program eligibility requirements (this includes people that meet certain criteria such as older age, range of symptoms, family history, etc.). The FOBT test can only be claimed by labs that have entered into a Participation Agreement with the Ministry under the Laboratory Services Funding Framework Agreement for the Colorectal Cancer Screening Program [71]. Otherwise, patients must pay out of pocket or through private insurance for the test.

As noted above, labs may also generate revenue from doing testing for private sector companies. In addition to testing for pharmaceutical company research, they may do testing related to workplace safety. An example of this is the recent random drug testing that the Toronto Transit Commission (TTC) has started doing on its employees (PO1). Other companies that test drivers of transportation vehicles also enter into contracts, usually with community labs such as Dynacare or LifeLabs. This, along with out-of-pocket payments and research contracts, makes up the rest of the approximate 5% total 'other' revenue of community labs.

### 5.2.3 Funding Model of Physician-Owned Labs

Physician in-office testing provides on the spot, point of care testing for patients, which is billed by the physicians to OHIP using the Schedule of Benefits Physician Services. In 2013/14, they performed 3.9% of the total volumes of tests done in Ontario, costing the government approximately $90 million. The point of care testing that physicians provide in their offices use a different billing code and different fee than if these tests were completed in community labs [5]. This provides the provincial government with the ability to track the use of point of care testing in physician owned labs, which has been growing significantly over the past 10 years [5].

### 5.2.4 Funding Model of Public Health Ontario Labs

Similarly to how hospital labs are funded by their hospitals, Public Health Ontario Labs receive an operational budget from the Public Health Agency of Canada. Accordingly, they are paid indirectly, rather than directly, by the Ministry of Health for the testing they perform. Some of the funding allocation for lab services is used for communicable disease surveillance, outbreak response and research [4]. Unlike private and hospital labs, the funding PHO labs receives only needs to cover the cost of completion of specimen analysis and sending results back to the referring physician. Generally, community or hospital labs collect the specimens, and as one respondent put it,

"So, we (for-profit community labs) become, in fact, the courier system for the Public Health labs at no charge' (PO1). In 2015/16 PHO spent $101 million to perform 5.5 million laboratory tests, which accounts for 2.1% of total publicly paid lab test volumes completed in that fiscal year [4].

### 5.2.5 Monetary Incentives Impacting Appropriateness of Testing Practices in the Four Categories of Labs

After reviewing the funding models of the different labs in section 5.2, one of the research questions pertained to how monetary incentives impact appropriateness of testing practices in the different kinds of labs. Appropriateness of testing means doing what is best for the patient, which would mean that one would neither over utilize nor underutilize resources. Just as one should not withhold necessary testing, it is also not appropriate to provide care that is not needed [11]. Therefore, tests that are not required for patients should not be performed. This hones in on the principles of what drives volumes in private, for-profit and not-for-profit organizations. The factors which influence the incentives for testing could be monetary in nature, which links to the funding model of the various lab types. A block funding model, such as that used in hospitals, would incent labs to perform fewer tests. A fee-for-service model may incent labs to perform more tests and receive more compensation. One assumption is that professionalism (and regulatory approaches) would help ensure that labs were not overly influenced by these fiscal incentives. Another factor is the appropriateness of the tests, which links to the quality piece and what processes are in place to ensure patients receive the tests that they need and do not receive

the tests that they do not need. The responses from the key informants who participated in this study mainly focused on hospital labs and community labs. The responses among hospital and community lab experts were similar, with almost all of them agreeing that monetary incentives did not determine utilization or volumes. One key informant said that from his experience, ethics and quality decision-making about doing what is best for the patient is no different in both environments (GAD1).

Two of the key informants said that physicians that place the order determine utilization, whether it be proper or improper utilization, and the physicians are not influenced by the labs. This is true of physician owned labs, where the physician orders the test and performs the test as well. There is, however, a difference in the way hospital and community labs can respond to the requisitions (LMP2 & LM1)

"…the private labs, because of the way the legislation sits, they have to do what is asked, whether they think it's stupid or not. In a hospital, not so much" (LM1).

Two key informants concluded that for-profit labs are not able to manage physician utilization or ordering, which the MOHLTC has attempted to make them responsible for. Being the gatekeepers for utilization is not part of the medical lab's mandate nor, as felt by for-profit labs, is it their responsibility. Key informants within the for-profit lab sector stated they did not have the authority or means to change ordering behaviour of community physicians. If physicians are ordering unnecessary testing, one way to change that is to educate the physician. At the time of writing, there were minimal means to educate physicians through paper and e-communication, and the government holds community labs responsible for the education of physicians about appropriate test ordering. One key informant described a time when the MOHLTC discussed the possibility of hospital clinicians training community physicians about proper ordering practices and standardizing the ordering practices, but nothing came of it (LM3). The document analysis has suggested that there are other ways of changing physician test ordering behaviour. For example, Naugler described a method that created provincial laboratory formularies which describe usefulness and a limit in number of tests done within a time period using best practices [72].

The Ministry attempted to incentivise for-profit labs to reduce unnecessary ordering by imposing a Utilization Discount Modifier (UDM) on labs, which adjusts their billings annually based on physician ordering practices [5]. The Expert Panel identified this practice as being

ineffective, since all for-profit labs billed above their cap, and did not get paid for the tests billed over the cap, and the modifier did not impact total payment. At the time of writing, the community for-profit labs have not taken up the responsibility of educating physicians on proper test utilization in order to reduce unnecessary testing.

Community labs cannot challenge a physician's order, and what the physician orders through a laboratory requisition is followed. This is partly because the OMA regulations say that a laboratory does not have the authority to change the lab requisition. In this example, there are no monetary incentives that impact the appropriateness of testing, but the factor influencing testing is regulation by the OMA that may in fact be detrimental to the health system by not providing a means to ensure physicians are ordering appropriate tests.

Hospital labs have been more successful in changing utilization practices within their labs. Managers working in hospital labs described a process in which knowledgeable clinical chemists and microbiologists that work within the hospital labs identify errors and patterns of misuse of testing. They manage this by using decision trees that are approved by the Medical Advisory Committees, and the decision trees help in creating algorithms that ideally would avoid unnecessary tests. This is hospital specific and the education of physicians working in hospitals is left up to the discretion of the hospital. These algorithms of testing have been successful in changing testing practices due to the close proximity and influence of requesting physicians to the labs. The incentive to reduce unnecessary testing is also linked to the funding model- a global budget does not incentivise the hospital to perform a high volume of tests. All hospital lab budgets come from the hospital's budget, therefore pressure to reduce cost causes hospital labs to respond by using tests more efficiently. One key informant stated;

"We probably have more authority [than for-profit labs] because we can say to our clinicians here are the certain tests that have next-to-no value, and if you are ordering a urea and creatine, you only need one. We've actually done this in the last 12 to 18 months."

Due to the fee-for-service payment model of for-profit labs, they would be theoretically incentivised to increase test volumes in order to maximize their revenue from the MOHTLC. Therefore, decreasing utilization of lab tests by educating physicians on more efficient testing practices may not be beneficial to the for-profit labs. One key informant argued that in the interest of monetary incentives, both community labs and hospital labs do not want to perform a high volume of testing and that this incentive does not drive utilization. Community labs reach

and exceed their corporate cap each year; therefore, doing extra tests for free essentially is not in their financial best interest. Depending on how much of the test ordering is considered inappropriate, a decrease in ordering may benefit for-profit labs to the extent that they are otherwise performing tests they are not being paid for. Both funding models are similar for hospital and community labs in the sense that there is a 'ceiling' for both of them; a funding cap for for-profit labs and a finite hospital budget for hospital labs.

For-profit labs are not able to refuse patients once they have reached their cap, but they are able to implement some cost saving practices such as shortening their working hours. As noted in the 2017 Auditor General Report, in 2015/16 community labs exceeded their corporate cap by $30 million, an amount they were not paid by the provincial government due to the cap agreement. Hospital labs perform specialized, expensive tests with funds flowing from the finite global budget and represent a cost for the hospital; therefore although they can't turn tests away, they try to avoid testing that does not provide additional value to the patient and the physician.

### 5.3 The Role of Privately Delivered for-profit Health Care in Ontario's Laboratory Sector

This section speaks to the decades old debate about the role of private for-profit companies delivering health care, in this case for-profit community labs providing laboratory testing. Section 5.2.2 describes the for-profit community lab funding model in Ontario, which tests are insured, the type of tests that are not insured and how that works within the rest of the laboratory sector. With this knowledge in place, one can begin to understand the advantages and disadvantages of for-profit delivery of care. The literature provides extensive arguments for for-profit versus not-for-profit delivery of health care, but when honing in on specifically Ontario's medical lab sector, the majority of the key informants interviewed for this thesis argue that not enough efficiency, transparency and accountability is provided to Ontarians when lab tests are provided by private, for-profit corporations. In the following sections, the characteristics of accountability, transparency, competition and incentives which influence the behaviour of labs are discussed through the lens of for-profit community labs.

### 5.3.1 Accountability and Transparency Between the For-Profit Labs and the Government of Ontario

Each year in Ontario, approximately 19 million requisitions are provided to almost 8 million community patients that are accessing the community lab system (LMP1). There was a general consensus among the key informants that there is a lack of accountability and transparency among the for-profit community labs. As previously noted, community labs are private companies in structure, and as some of the other private entities that operate within the health care sector, do not have to make their earnings public. Their financial reports, which include revenue, expenditure and profits, are not available to the Ontario Auditor General, in contrast with other institutions in Ontario which are publicly funded. Community labs are not obliged to provide information that pertains to how much it costs to perform a test to the Ministry of Health, which has real consequences on the future of medical labs. The new price list of the Schedule of Benefits was introduced in 2017/18 used test costs from different settings, such as hospitals, because real costs from community labs were unavailable [73]. This fundamental flaw in the accountability and transparency structure between the for-profit community labs and the Ontario Government that is embedded in the Ontario system makes it more likely that future test prices updated in the SOB-LS will be inaccurate, among other negative repercussions.

There is frustration among key informants that work in or are familiar with the private, for-profit sector, arguing the government does not provide sufficient regulation around oversight of performance metrics and do not take corrective action when targets of the performance metrics are not met. This lack of regulation undermines the laboratory's accountability to the patients it serves. As one key informant put it,

'Private for-profit companies in a support role, arguably, have a role in public health care if they have been disciplined by a structure of policy. That does not exist today in Ontario so this is a renegade part of health policy that has caused harm, but because the data has been delinked, we can't determine, any of us, what the consequences are for patient care' (LMP3).

One example of the lack of accountability to patients is the for-profit community and hospital SCC wait time data, which is collected by the labs but there is no system in place to take corrective action when necessary. The Ministry does not monitor wait times at SCCs, and labs measure their own wait times against targets set by themselves. One survey conducted in 2013 found that 30% of patients identified wait times in hospital and community SSCs as a priority. At

that time, patients were waiting between 30-40 minutes for testing, instead of the acceptable time of 5-20 minutes. The document review did not contain any data on Public Health Ontario or physician-owned lab wait times [4]. The key informants talked about the government not incentivising community labs to keep the public interest or benefit as a priority, which includes access to specimen collection centre, turnaround time for test results and ensuring patients do not get unnecessary tests done. As one key informant noted,

"You must use market conditions to discipline private companies but at the same time you have got to put a fence around that so every time they make a competitive decision it's also beneficial to patients and for the health care system. That has not been done for labs" (LM2).

Although two key informants that work in the private for-profit sector voiced their concern about the lack of regulation around operational decisions that impact patient care, one community lab expert felt that the tight control the government has on community labs is stifling. "…they're (the government) running private labs but they have so many restrictions it's painful. They can't close a location unless the Ministry gives permission," (LMP1). It appears that although many operational decisions have to be run by the government, the foundational policies that govern community lab behaviour may not always ensure that patients' care is the bottom line. This is most evident when looking at convenience of locations of SCCs, wait times that can be unnecessarily long and out of pocket cost of testing. The lack of regulation imposed on the community labs perpetuates the issue of accountability. One lab expert that worked in the hospital lab sector for decades felt that the private nature of community labs, that lacked the requirement to report performance metrics that impacted patient experience and quality of care, did not allow them to prioritize patient care. He stated;

'But she works for a large American corporation and all they care about, if you read their annual report, is their bottom line' (LMP1).

Lack of funding transparency between the community labs and the government was a theme that came up in three interviews when discussing the regulatory framework of the community lab sector. There are instances from both the government and the community labs side that show behaviour of mistrust and hidden agendas, which damage relations, deepening the problem. For example, in mid-2017 the Ontario government issued a Health Insurance Act regulation amendment concerning fees for lab tests and lab testing standards for the Ontario public to read and provide feedback, for 15 days, that was then implemented without the chance

for impacted community labs to comment or react to. The details of the Ministry Labs Strategy were not shared with the labs or any other key stakeholders, particularly not key information pieces about the changes that impact the funding system. There was significant pushback from community labs that insisted the regulation got put out in a very non-transparent way, with little information that would allow for meaningful feedback. The Ministry of Health responded that it followed the usual rules of disseminating health care announcements and that there is no requirement to post more than a summary of the proposed changes to the regulatory registry [73].

Better policy design and funding transparency would ensure governments have access to how money is spent by the community labs, which in turn would lead to better value for money. Economies of scale may be reached if labs perform tests using equipment that is used for multiple tests and represent a fixed cost, with the variable costs consisting of reagents and technicians. This will ensure that what labs are paid is fair relative to what it costs them to run tests. There are some labs that are being paid as much as $380 million by the MOHLTC, but it is not itemized in the public accounts due to the private nature of the agreements with the government (LMP1).

### 5.3.2 Competition in the Medical Laboratory Sector

Economic theory argues that competition moves resources to where they are needed most at a cheaper price, since those charging more will be unable to attract consumers. Competition in health care is different from market competition in that price cannot be the only driver for competing businesses due to the potential adverse consequences that may result from poor quality care [11]. The quality of the health care cannot be overlooked in order to achieve a cheaper price. Competition is also different in health care than in other sectors of the economy to the extent that one is talking about need rather than demand; needing a medical test or medical procedure is a very different experience than wanting a variety of options of consumable goods.

Creating a model where competition is desired could be detrimental to health care as the laws of capitalism and competitive advantages are not as relevant in an industry where patients' needs, and not demands, are catered to (and where it is deemed inappropriate to provide care that is not needed). In addition, increasing demand for services among patients due to increased

competition might not be beneficial for patients, as many times patients may not have the expertise to make these decisions themselves.

There is a considerable literature that argues against competition in the health care field, particularly in medical laboratories. In New Zealand, competition between publicly funded, privately owned labs resulted in increased test volumes without any price reductions [5]. Competition could lead to the elimination of smaller laboratories that can't compete with the economy of scales that would be achieved by their larger lab counterparts. Collusion on lab test prices that are uninsured in a market place with few competitors, could lead to a lack of competition, since the labs work together to agree on a price [5].

A health care model with competition might also assume that the quality and efficiency of work performed in some for-profit organizations is inferior to others (possibly as reflected by lower prices)[74], but strict quality regulations such of those in Ontario, implemented by the Institute of Quality Management in Healthcare, are intended to preclude this variability in services. The argument of efficiency in competitive marketplaces is contested by the difference in definition of efficiency in health care. In the private sector, efficiency might be defined by increased profits, expanded market share and in some ways improved quality of products. In the public sector, efficiency could be described as improved volume of patients and quality of care and a generation of a financial surplus if the first two priorities are met [75].The latter definition fits with the desired outcome of efficiency in the medical laboratory sector. At the time of writing, a competitive bidding process was being implemented in Ontario for community labs and aims to increase competition between for-profit labs. It is considered to be a method to reduce costs and procure services (refer to section 6.3.1 for further description on the proposed competitive bidding process).

In 2013, LifeLabs bought the second largest company at the time, CML, and it became the largest medical laboratory in Ontario. As of 2018, LifeLabs receives 63% of all community lab funding from the Ministry, together with Dynacare making up 95% of the total funding to community lab service providers [4]. During the merger, the company CEO commented on the 'increased operational efficiencies, more government negotiating leverage and the ability to expand nationally' that the combined entities would bring [73]. Other advantages included better positioning the company to successfully navigate the increasingly challenging health care funding landscape [73]. There was no mention of the impact on patient care, which was a major

concern for stakeholders who opposed the merger (LMP1). One key informant maintained that there is no benefit for the public from the sale of these entities. At the time of the merger, one key informant claimed that CML was making a profit of 45%, with the return on equity the third highest in the country for all for-profit labs (GAD1). In this case, competition has been reduced by decreasing the number of different labs offering similar services. This does not incentivize the mega-lab to provide superior service with patients not having a different option to go to other labs.

### 5.3.4 Appropriateness of Testing as an Incentive to Perform or not Perform Lab Tests

One of the posed research questions was what incentivises appropriateness of testing practices in each kind of lab. The key informants believed that most labs, including for-profit community labs, were incentivized by the appropriateness of a test and not monetary compensation. The hospitals discontinued certain testing because they were considered of little value in terms of having low sensitivity and low specificity. The driver there was not monetary incentives but simply non-value testing (LM3). One key informant noted that we are not in the position to understand wastefulness or non-value tests because diagnostic codes are not needed for requisition forms, which would answer the question, why are you ordering this test? (LMP1).

Reflex testing pertains to follow up lab tests being ordered after the initial tests show a positive or abnormal test result (GA1). When abnormal results occur and the next step is to order another test, this happens automatically in a hospital setting, because it is part of the algorithms. This is considered efficient, because the lab does not have to wait for the physician to review the positive result and order the next appropriate test, assuming that the algorithm is correct. However, under the current regulatory system, community labs cannot order reflex tests and have to get the physician to order them. The lab expert interviewed considered this a waste of time and resources because it delays the final result of the test as the lab waits for the physician's response to the positive test result for follow up testing (LM1). In addition, because the current funding model sets a fixed price schedule (which may or may not include reflex testing), community labs do not get paid additional funding for reflex testing and have to absorb the cost. An example of frequent reflex tests are those for HIV/AIDS, which use a drop-down menu or decision tree whose next tests are based on the first three tests' results. There are nine different

tests, and the type of test ordered next depend on the results of the previous test. When physicians order nine of the required HIV tests, and the first three come back negative, it would be unnecessary to conduct the remainder of the six tests because the first three show a negative outcome. The remaining six tests whose outcomes depend on the first three are defined as the reflex testing that are either necessary to conduct if the first three tests are positive or unnecessary to fulfill if the first three tests are negative. Community physicians must order all 9 tests right away; however, hospital labs can identify that if the first 3 tests are negative, they will not proceed to conduct the next 6 tests, which saves both time and money (LM1). Community labs are not able to do that because they must follow the requisition of the physician and do not have the authority to change the requesting pattern, even if it would be more efficient.

A document provided by the MOHLTC online titled 'Schedule of Laboratory Fees-Preamble' describes an exception to the rule above, whereby a medical director of a community laboratory could add further appropriate tests if a test yields results which would be insufficient or meaningless to the ordering practitioner. The complexity of various results of a lab text could prove to be inconclusive, and follow up tests are required to provide a conclusive test result to the physician [76]. The extra tests could then be claimed by the laboratory to receive reimbursement from the MOHLTC. Both examples above indicate the complexity of the appropriateness of testing debate.

### 5.4. Quality Assurance Management in Ontario's Medical Lab Sector

Maintaining quality within the medical laboratory sector is crucial to preserve safe, timely and appropriate care to Ontario's patients. In order to hold labs accountable to the highest standards of care, institutions that assess quality have been created. This section discusses the results that answer the thesis questions: What are the differences in voluntary quality assurance programs and mandated province-wide quality programs? How do they differ within the various categories of labs?

As noted in section 3.5, the *Ontario Laboratory and Specimen and Collection Centre Licensing Act* states that the Ontario Medical Association (OMA) is responsible for carrying out quality management of all Ontario labs. A department operating at arm's length from the OMA, the Institute of Quality Management in Healthcare (IQMH) was developed in order to assess quality and competence of all licensed Ontario labs. Initially, the laboratory quality management

program began operating under the OMA in 1974 and was later transferred to IQMH in 2015. IQMH undergoes international peer evaluation to maintain its International Standards Organization (ISO) signatory status [77]. The accreditation is important to confirm the laboratory is producing high quality results and the public can be confident that the system will identify any errors and correct them. At the time of writing, all labs except for physician owned labs were mandated to be accredited by IQMH. Under this directive in 2016, all specimen collection centres were required to be licensed under the IQMH. Previously, only laboratories required licensure to operate, but that changed with the amendments to Regulation 683 of the *Excellent Care for All Act.* The Ministry has been relying on IQMH to assess whether the labs are meeting all quality standards and ensure timely corrective action is taken if they are not [4].

The program within the IQMH that is responsible for Ontario Laboratory Accreditation (OLA) and external quality assessments is called the Quality Management Program – Laboratory Services. The OLA is responsible for accrediting and examining laboratories and specimen collection centres, which includes looking at processes within all three analytical phases. The standards are based on the ISO standards for quality, which means that labs that are accredited by OLA are compliant with international quality standards. All labs receive full reassessment visits every 4 years during which 500 requirements are assessed, and surveillance visits are alternated during a four-year cycle, so that every two years the lab is assessed in some regard [77].

The MOHLTC pays IQMH approximately $4.6 million for all required quality assessments for the accreditation program [5]. The MOHLTC covers the cost of the mandatory accreditation and some of the proficiency test costs undergone at IQMH for the for-profit community labs [5]. The hospitals have to pay for IQMH accreditation using their own hospital funds, and Public Health Ontario labs fund their accreditation process through funds allocated from Public Health Ontario. All voluntary accreditation programs such as Accreditation Canada, are paid for by each lab.

Another mandatory program available at IQMH is the Proficiency Testing program that provides objective and independent assessments of specimen testing and interpretation of test results by using comparisons to peers. This information can then be used by labs for quality improvement initiatives, or to assess how different instruments can be used for the same test and therefore assess reliability [77]. Errors are defined as an instance where a laboratory's test result does not meet its specimen handling or test reporting standards. Between 2011 and 2016 the

average testing error rate was below 1%, which IQMH considers satisfactory. Non-conformances are also a collected measure, and are considered as any instance where a lab's policies and procedure do not conform to the requirements outlined by IQMH. Between 2012 and 2016, the overall conformance rate was 97%, which is considered high and satisfactory [4]. Quality management encompasses both accreditation to ensure the quality system that is set up in each lab meets the requirement, and the proficiency testing is available to check the results (GA1). It's important to note that because the same program is used to accredit all labs, the quality standards remain the same for all settings in Ontario that have to comply with IQMH standards.

"So, there's no difference in any of the settings – same requirements for all tests on a variety of different standards, which includes ISO standards" (GA1). Although all labs have to meet the high-quality standards that was set out by the IQHM, as can be expected, variability within labs does exist as some labs go above and beyond the requirement.

"Not all hospitals are probably at the same level (of quality), but the external program through IQHM, the external accreditation and the proficiency testing, ensures that everybody gets to a reasonable bar" (PO2). There is a minimum standard that all labs must meet, but some labs exceed this.

The mandatory accreditation process allows IQMH to assess the laboratory's quality practices and policies that oversee how the labs manage their accuracy, complaints, information system and safety. The full visits and mid-cycle assessments that occur every 2 years focus on the problems that were identified in their major review. These visits provide a snapshot of how the lab policies stack up against the accepted international standards. Aside from the policy assessment, the analytical phase is evaluated by using proficiency tests that provides the labs with three or four challenges that include three samples. Each lab receives the same sample and they must report back with the results, which is a real-time way of telling which labs have difficulty getting the right results. As one lab expert explains,

"So, our program (IQMH) acts as a third-party, independent, early warning system for laboratories who may be having difficulty getting the correct results. And we can give them information that allows them to correct bias…." (PO2).

If accreditation standards are not met, the lab has 90 days to take corrective measures, and losing the license is a consequence of non-compliance [13].

Lab performance as measured by the IQMH has to be reported to the Ministry of Health, and the accredited labs are listed on the IQMH website for the public to be able to access. Although the standards for accreditation are the same for hospitals, community and Public Health labs, the reporting requirements vary slightly in that hospitals' systems do not need to report their results as frequently as the community labs (GA1). The key informant was not aware why there was a discrepancy in reporting requirements between those types of labs. Any accreditation that is beyond that of IQMH that is completed by the labs voluntarily do not need to be reported to the Ministry of Health. In 2019, IQMH and Accreditation Canada announced that they would be forming a strategic partnership to develop "the basis for integration of diagnostic accreditation to broader health system accreditation", although this had not yet occurred at the time of writing [39].

### 5.4.1 Identified drawbacks of IQMH

The key informants that were familiar with the accreditation process through IQMH thought that generally, it was done well and the analytical phase of lab tests was assessed in compliance with standardized regulations (PO2, LMP1 & LM3). There were, however, some areas of concern that were voiced by the key informants, particularly with regards to the assessment of pre-analytical and post-analytical phases;

"…a lot of the errors I have read happen in the pre-analytic phase, that's not something that they (IQHM) are able to capture, although they have recently started to attempt to" (LMP1). One key informant stated that the errors that occur during the collecting of blood and other samples are more difficult to capture because there are limited tests that detect human error of, for example, mislabeling and misplacing samples or during the ordering of tests (PO2). Certain aspects of quality deal with the volumes and although processes may be the same in different settings, they are more demanding in high volume environments. For example, one key informant described an incident when there was a problem at a hospital lab in Hamilton, where a piece of equipment was malfunctioning. It took 3 weeks for the error to be identified and all of the tests performed during that time had to be redone. The key informant thought that if this issue had arisen in a community lab, it would have been picked up within hours because the volume for testing for this particular test was so high in community labs and controls and quality checks occur more frequently (PO1).

Another concern was whether the test was actually completed after it was ordered, and the lack of ability to monitor the rate of test completion. This rate could be tracked because the orders should be registered by the ordering physicians through Ontario Laboratory Information System (OLIS), a database that provides the ordering physicians access to the results of the labs ordered by them. However, a key informant identified the issue of some physicians still using paper methods to order tests, which cannot be tracked by the MOHLTC. One key informant cited the Commonwealth Fund Study [78], stating

"And why it's instrumental is if you look at the Commonwealth study, essentially we have the largest non-completion rate of any jurisdiction in terms of people not getting their tests done" (LMP1). This is due to various reasons that could cause patients not to go for their testing, which is further discussed in section 5.8.1.

Being able to identify the rate of test non-completion was acknowledged as a key performance metric that would be important to have, since frequent test non-completion could leave to detrimental health outcomes for some patients (LMP1 & PO2).

One key informant described the relationship between IQMH and the OMA as being perceived to have a conflict of interest because IQMH is a wholly owned subsidiary of the OMA[5]. As the key expert stated:

"Any definition of quality includes how it's ordered and how the tests are interpreted by doctors, so that has to be delinked. That was a recommendation of the expert panel that I do agree with, it hasn't been acted on to the best of my knowledge" (LMP1). Delinking, or establishing IQMH as a stand-alone entity, could reduce any concerns of the influence the OMA may have on the IQMH for the accreditation processes that involve physicians. There is no public visibility into the results of lab accreditation with respect to the physicians, and there is a concern that this structure lacks the degree of independence required for a transparent accreditation process [5].

### 5.4.2 Internal Quality Measures in Hospital and Community Labs

To answer the thesis question of what are the differences in voluntary quality assurance programs between community, Public Health Ontario and hospital labs, one must describe the processes in each type of lab. As noted in section 3.5, for-profit physician labs are exempt from quality measures instilled by IQMH. IQMH provides mandatory accreditation to each hospital,

public and community lab, but all hospital and community labs have additional internal quality assurance measures. IQMH defines the criteria for quality measures and proficiency testing, and it is up to the labs to set up the processes and administer it properly. Once the test results are reported back to IQMH, the results are analyzed and compared against standards for specimen handling, test analysis and reporting. Each lab has to belong to an external quality assurance network of labs that are able to compare standardized samples. The samples are made up of commercially available material that has been proven to be accurate (LPI). Determining a lab's performance can be completed by inter-laboratory comparisons that use testing material sent out by IQMH.

Subspecialty accreditations are not mandated by the government; however, each hospital has a quality measure they upkeep by mandating additional accreditations. The additional accreditation bodies identified by the key informants as possessed by some hospital and community for-profit labs include the Accreditation Canada, American Association of the Blood Bank (AABB), College of American Pathologists (CAP), the American Society of Histocompatability and Immunogenetics (ASHI), and Clinical Laboratory Improvement Amendments (CLIA). Specialties that require more rigorous quality management than what is offered by the IQMH voluntarily apply with the necessary accreditation body. For example, transfusion medicine has an accreditation through the AABB, which is quite rigorous. Hospitals that perform a lot of transplant histocompatibility would go through the CLIA, as do organ transplant laboratories (LP1). In addition to this, each hospital has its own quality care committee of the board, quality care committee of the hospital, quality assurance, risk reporting, incident reports, and requirements of reporting. Self-examination was a theme found among the key informants, where equipment-specific quality control, had to be completed in hospital and community labs.

The motivation and incentives behind additional accreditation were described to be the same by both hospital lab experts and community lab experts during interviews. The prestige in knowing that your lab has specialized accreditation, specifically in riskier fields such as transfusion, was important to the labs and to patients (LM3 & GA1).

"You want to be able to show that you've got the best testing, and your results are the most reliable" (GA1).

The certification was something that could be relayed to patients to instill confidence in the reliable lab work that was provided.

"…every good lab would have its own set of quality measures that they look at over and above what IQMH looks at" (LMP2).

One key informant alluded to community labs having more of an incentive to receive extra accreditation to demonstrate their superior product because of the perception by the public and Ministry of Health of for-profit labs to be "private, blood-sucking companies" (LMP1).

A theme identified by the key informants was duplication in quality control measures between IQMH and specialized accreditation. One key informant from a major Toronto hospital lab admitted to performing College of American Pathologists (CAP) accreditation, although some of the quality measures that were assessed by CAP were already captured by IQMH. In 2017, The CAP accreditation was discontinued in that particular hospital due to a lack of funding and due to duplication of work (LP1). One key informant described the duplication as: "Organizations can have anywhere from three to five different layers of quality management and that's really based on the level of risk that they see. There are instances, quite frankly, where institutions spend too much time and too much money on quality" (LP1).

## 5.5 The Health Human Resources Involved in the Medical Laboratory Sector

This section explores the health human resources that are the key medical lab providers in Ontario's laboratory sector. It aims to answer the thesis questions about who is allowed to perform and order tests, and how are laboratory professionals regulated. The results show a sector with well-regulated and well organized professionals that are involved in the pre-analytical and analytical phases of testing.

### 5.5.1 Who is Able to Order Tests

The *Laboratory and Specimen Collection Centre Licensing Act* [27] outlines who is able to order tests that are paid for by the SOB-LS, covered by private insurance or paid out of pocket by the patient. This includes medical doctors, nurse practitioners and dentists. Naturopaths and midwives are also able to order tests, but they use a limited schedule of benefits which means that there are less tests that they are able to order than doctors, nurse practitioners, midwives and

dentists. Genetic counselors and geneticists are unable to order genetic tests; however, they collaborate with family doctors, obstetrician or gynecologists and would have access to the results by being copied on the lab reports. If the geneticist or genetic counselor holds an MD, this would allow them to order any laboratory test (PO1).

Nursing staff in hospital labs may order laboratory tests if they have a medical order written by a physician explaining under which circumstances a nurse can order tests on behalf of the physician. This is an uncommon practice and usually occurs in emergency rooms where situations require the test results to be obtained quickly (LM4). There are no nurses that work in community for-profit labs, and although they may work in physician owned labs, the physicians order tests themselves in these settings. An interesting caveat to the regulation of authorization of a lab requisition in a community lab on behalf of the physician is that a physician's employee could authorize and sign the requisition but it cannot be the owner or employee of a community laboratory [71]. One explanation as to why this is specified, is to avoid fraudulent lab requisitions completed by community labs to increase lab testing and therefore increase revenue through the fee-for-service model.

### 5.5.2 Who is Able to Perform and Interpret Tests

Each medical laboratory has an organizational structure that includes the director, a medical doctor/pathologist, laboratory specialists, a manager, receptionist, medical laboratory technologist and medical laboratory technicians [49]. This is not to be confused with specimen collection centers in the community, which have owners, managers, receptionists and phlebotomists. The phlebotomists draw blood samples and prepare other types of samples for transportation to medical laboratories. The terms MLAs and medical laboratory technicians are used interchangeably, to describe unregulated, health care professionals which perform specimen collection at the pre-analytical stage and run the automated machines that produce results from the samples as part of the analytical phase [49]. Once the samples are prepared, MLTs are responsible for running the more difficult tests, analyzing them and providing internal and external quality control measures. They are required to undertake tasks that entail judgement and interpretation, including performing and interpreting complex tests that are outside the scope of the MLAs/technicians. MLTs can oversee MLAs, and in the hospital setting that is usually the

case, as the automated component of testing is completed by MLAs under the supervision of MLTs (LM1). Laboratory specialists usually have a PhD and are able to develop sophisticated tests and oversee technologists who run them, although they might perform the test themselves and interpret them. Their role is not very different from their pathologist counterparts; however, they do not directly see patients. The pathologist is an MD, is usually the Medical Director of the lab and is able to interpret the most complex tests and oversees the clinical part of the laboratory. Most hospitals employ physicians such as medical microbiologists, pathologists and haematologists, which all work to interpret different specimens of testing.

The hierarchical structure of collection to interpretation, from least senior to most senior is the medical laboratory assistants (MLAs)/ technicians, medical laboratory technologists (MLTs), the laboratory specialists, depending on the setting, and finally the pathologist. In the hospital settings, the medical laboratory assistants (MLAs), nurses and sometimes physicians perform the specimen collection, preparation and processing of samples for the laboratories. In community and public health labs, the phlebotomists are mainly MLAs or medical laboratory technicians. Physicians and nurses who work in physician owned labs act as phlebotomists and perform lab tests, mainly point of care testing, as MLAs and MLTs are not employed in physician owned labs (LP1). This is because the expertise of MLAs and MLTs is not required for point of care testing and because there is not enough tests to warrant employing them.

As of 2003, the majority of Ontario's MLTs were employed by hospitals (65%), private for-profit community laboratories (14%) and Public Health Ontario laboratories (8%); the rest were registered as 'inactive' which meant that they weren't working in 2003 [79]. One key informant described the role differentiation between MLA/technicians and MLTs as;

"In chemistry, when you've got these big instruments that just churn out results and automatically downloaded, a technician is allowed to run those instruments. You go over into hematology where you are doing differentials, you're looking at the white cells. A technician cannot do that. Because that is purely interpretive" (LP1). In this description, the MLAs/technicians have a distinct role that is obeyed in hospital, community and public laboratories.

### 5.5.3 Who Can Perform Point of Care Testing (POCT)

As described in 2.1.1, Point of Care Testing (POCT) is described as bedside testing, where a diagnostic test is completed at the site of care. It is more expensive on a per test basis than testing completed through a hospital or community laboratory but it is used for its convenience and speed of results. The staff who perform POCT vary depends on the setting; in hospitals, the majority of staff who administer POCT testing are nurses, and sometimes physicians (MLT1), in physician owned labs it is the physician or nurse. There is no POCT in community for-profit labs. Some POCT is used for screening of certain diseases or conditions; if the result comes back positive, then a more comprehensive laboratory test through the hospital or community lab is performed. An example of this is fertility testing which uses a urine sample for the POCT and can be confirmed by drawing a blood sample to send to a community laboratory. Physicians and nurses who work in physician owned labs perform their own POCT. Community laboratories and Public Health laboratories do not have a need for POCT as they perform traditional collection of samples at SCC and send them to medical laboratories for interpretation.

### 5.5.4 Regulation and Oversight of Medical Lab Providers

As mentioned in Chapter 3.5, regulatory Colleges protect the public, ensure high standards of medical care and regulate professions by developing and maintaining standards of practice, knowledge, and skill for its members [49]. The physicians that operate within labs are members of the College of Physicians and Surgeons of Ontario (CPSO), which is accountable to the public and the MOHLTC. At the clinical level, there are board certification for the pathologists to be properly trained, and the certification may vary depending on the specialization of pathology, haematology, cytogenetics or molecular genetics, etc. (LM2). In this way, the IQMH is not responsible for the professional component of quality maintenance for physicians working in labs, such as pathologists, as this falls into the scope of the CPSO (LP2).

The CMLTO is the regulating body of the approximately 7000 MLTs that practice in Ontario [49] by providing guidance, quality assurance and accountability measures. At the time of analysis, the MLAs/technicians were not regulated by any College; however, the CMLTO is

negotiating with the MOHLTC to include them within the MLT regulatory framework. In 2017, the CMLTO met with MOHLTC staff to further the dialogue regarding possible next steps in the regulation and oversight of medical laboratory assistants and technicians. The rationale behind their regulation in the same legislative framework as MLTs would be to provide greater public protection through the assurance of high quality lab services. With more MLAs and technicians interacting with the public, a disciplinary process should be available to protect the users of labs. Regulation would also ensure standardized educational preparation, as many MLAs and technicians have a diverse educational background when they come to work in labs [49].

At the time of writing, there was no regulation of the laboratory specialists, the PhD laboratory scientists that perform the complex interpretation of lab results. One hospital administrator said that the majority of their hospital clinical chemists were PhDs, not MDs. There was no affiliation with the regulatory body of the physicians; although one key informant suggested that it would make sense since many duties that the PhDs were performing were identical to that of the physicians working in labs. The key informant had knowledge that the CPSO did not embrace the proposed idea of regulating laboratory specialists.

### 5.5.5 Regulation and Oversight of POCT

There are rapidly emerging, new point of care testing techniques that are regulated differently depending on where they are administered. This thesis does not explore the POCT testing that is being directly ordered by patients, such as genetic testing by companies like 23andMe or glucose monitoring for diabetes. Although this is a growing industry, it does not aid in the description of the public and private medical lab landscape of Ontario. Key informants who were familiar with POCT stated that hospitals had good regulation and quality assurance measures for the majority of their tests (MLT1 & LM3).

POCT can be accredited by Accreditation Canada, which provides a Biomedical Laboratory Services Standards that is not a mandatory set of regulations for hospitals. The key informants were unaware what would happen if the hospitals failed the Accreditation Canada requirements, since the accreditation is voluntary and is not reported to any regulatory body. The Institute of Quality Management in Healthcare (IQMH) has a component requirement for quality and competence for POCT within its program. The results of this program do get reported

to the MOHLTC and failure to meet quality standards could result in loss of license for that particular test. For example, a key informant who is familiar with a community based hospital in south eastern Ontario described an event where emergency physicians that conducted fecal occult blood testing did not pass the necessary quality assessment during a quality control audit conducted by IQMH. Their POCT license for that particular test was removed due to non-compliance.

The in-hospital POCT quality programs are set up by designating a key liaison person, usually an MLT who is responsible for training other personnel, basic trouble shooting, and testing competency. If recertification is required, this person ensures all necessary personnel undergo education modules. The designated key liaison person also tests the glucometers to ensure the glucometer is producing accurate and reliable results. One example of voluntary regulation and quality management of POCT is the glucometer program at Lakeridge Hospital, which requires annual recertification in order to continue to use the instrument. The certificate is electronically recognized by a badge that is used by personnel to operate the glucometer. If staff do not recertify, they are unable to unlock the glucometer to use it for in-patients.
As mentioned earlier in section 3.5, physicians who perform in-office POCT are exempt from IQMH regulations. The Auditor General Report in 2017 [4] highlighted this as an area of concern and called for revision of this regulation.

### 5.5.6 Variability of Medical Lab Provider Roles within Different Lab Settings

The hierarchy of medical lab professionals described above have distinct roles, educational backgrounds and paygrade, which are set out by the CMLTO and the OMA. One of the questions that was explored during the key informant interviews was the possibility of changing the roles of MLAs and MLTs depending on the setting of their work. It was interesting to explore if hospital, community and public health laboratories changed the roles of their medical lab professionals in order to cut costs and avoid having to retrain new health human resources. All key informants agreed that the hospital, community and public health labs hired staff with the desired knowledge for the correct scope of practice and did not use technicians for technologists' duties or vice versa. One key informant said that the CMLTO would not allow this if they found out and would complain to the violating laboratory (GA1). The medical director

signs off on individuals who operate at each capacity and would be expected to report any staff performing work that they are not properly trained or certified for. MLTs may extend their professional practice beyond their scope through delegation from the medical director using a medical directive [49]. The CEO of one of the large community labs stated that they always use MLTs 'where we have to,' (LMP3) and MLAs/technicians where appropriate. This is done for quality patient care purposes- MLAs/technicians do not have the background or competency for some tasks that are required of MLTs, therefore it would negatively impact patient care if they were assigned duties that required an MLT (GA1).

## 5.6 Overview of Genetic Laboratory Testing in Ontario

Genetic testing has been a growing part of the medical laboratory sector as the demand for new tests and personalized medicine grows [5]. The majority of genetic tests for Ontarians are used for the diagnosis and treatment of cancers and identifying genetic disorders in fetuses [4]. The MOHLTC is looking at developing a strategy around how to provide access and licensing for the variety of genetic testing that are now available in other developed countries but are still not readily available for Ontario residents to be performed in Ontario (LM2). This chapter explores the current landscape of genetic testing in Ontario and how the institutions are licensed, funded and how the testing is made accessible to patients.

### 5.6.1 Licensing and Oversight of Genetic Testing

The Laboratories and Genetics Branch of the MOHLTC was established in 2015 as an oversight body for all laboratory and genetics services in Ontario [4]. The Ministry provides licenses, which state where genetics testing can be done, and historically hospitals have been receiving the majority of the licenses, with a few community for-profit labs performing a limited number of genetic testing. PHO labs and physician owned labs do not perform genetic testing. At the time of writing, 14 hospitals in Ontario are able to provide genetic testing, but not the entire spectrum of genetic tests is available in all 14 hospitals (LM4).

Some community labs have been licensed to perform a few genetic tests for non-Ontarians in order to help private labs to develop their capabilities without impacting hospital funding and testing volumes. The rationale behind this decision was to avoid removing too much

volume from hospitals which might impact their expertise and skill in accurately performing tests. This agreement is being reviewed as the Ministry continues to develop its genetic strategy. It was noted by a government expert that each hospital was managing its genetic testing separately, with no overarching strategy by the government. The lack of one overarching governance body for the province causes difficulties, such as slow uptake of adopting processes that benefit patients and the health care system (GA1). Some sources found that different branches within the Ministry were managing the delivery of genetic services, which resulted in a lack of co-ordination and increased redundancy (LM4).

The need for integrated leadership to drive genetic system improvement has been identified with an emphasis on overall governance, funding and coordination of the service system. The Ministry was working with genetics experts and advisory groups, such as the Genetics Advisory Committee at Health Quality Ontario, which was created in 2014. Their mandate was to conduct evidence-based evaluations of new genetic tests for validity and utility. Some of the committee members included neurogeneticists, pediatricians, medical biochemists, health economists and health policy experts [80]. This was part of the larger, more comprehensive Genetics System Framework which builds on the Ministry's efforts to increase the number of genetic tests and broaden the spectrum of lab tests available in Ontario (LP1). The Advisory Group was then disbanded in 2017, presumably because their mandate was fulfilled. At the time of writing, there was still no clear process that assesses and approves new genetic tests.

### 5.6.2 Funding for Genetic Testing

The main funding source for genetic testing within Ontario is the Ministry of Health and Long Term Care, which provides funding to all hospitals' budgets [4]. The Ministry also pays for genetic testing that is performed outside of the country through the Out-of-Country Program Exceptional Access program. Between 2011/12 and 2015/16 the number of specimens sent out of the country for testing almost doubled and the associated costs increased by approximately 80%. That being said, 46 genetic tests that were previously performed outside of Ontario were repatriated into Ontario in 2017. One of the most commonly performed tests in the United States on specimens that come from Ontario is a genetic test that determines the treatment to prevent breast cancer recurrence [4].

Not all tests are paid for by the Ministry. As one respondent pointed out, Sick Kids has developed a group of molecular genetics tests internally for their patients. At the time of writing, the Ministry had not agreed to cover these tests but our key informant told us that physicians find them useful for some patients. Performing these tests accordingly creates a financial pressure on Sick Kids' budget, as no extra funding is being provided by the government. Patients are not billed for the tests either, in part due to Sick Kids' commitment to provide all care that they believe is medically necessary.

Ambiguity around who pays for what also occurs with funding for genetic tests when tests are sent from different institutions to hospitals because the hospitals accepting the genetic testing samples themselves do not have the means or funding to perform that test (LP1). As described in section 5.2.1.1, hospital labs do not have to accept community patients and can ask them to visit community labs to have their lab tests performed. However, genetic testing is different since community labs are not authorized to perform the majority of these tests. In this instance, community labs will collect the specimen and send it to a hospital lab. The hospital lab then will send a bill to the community lab for the test performed. Although the community lab was unable to perform the test and therefore receive funding for that test, it is still responsible to pay the hospital for the test as community labs have a responsibility to service community patients. This is seen as a loss leader, and community labs absorb these costs (or expenditures, as the community lab has to pay the hospital lab); however, it is seen as 'the cost of doing business in Ontario' (LP1).

An example of the ambiguity described earlier around who should pay for community patients is the Sudbury hospital that is able to do some genetic testing but not the entire spectrum. The Sudbury hospital has sent their specimens to UHN for analysis, but UHN cannot bill the Sudbury Hospital for it because, unlike community labs, the Sudbury Hospital does not feel it is their responsibility to provide the testing for a community patient. Covering the cost of genetic testing that is unavailable at the hospital for community patients is not seen as a requirement of the hospital. The hospital would be deemed necessary to pay for the test if it was an inpatient's test or a patient that belonged to a rostered physician of the hospital. Hospital lab budgets are not mandated to cover the cost of tests done elsewhere for community patients, but this has been an unclear area of cost transferring (LP1). Approximately 85% of Sick Kids'

molecular genetic testing volume is from patients that are community patients, and the majority of the funding is covered by the Ministry through the hospital global budget (LP1).

The University Health Network (UHN), a group of teaching hospitals located in Toronto, receives many referrals for genetic testing but they are unable to keep up with the volume because many of the requested tests are not covered by the Ministry through separate programs or are not considered repatriated work and would have to be covered by UHN's own hospital budget. As one hospital executive put it,

"Currently, there is a genetic mismatch between patient flow and funding flow" (LP1).

Genetic counselors that need to send patients for testing cannot send them directly to the hospital because the hospital has to bill the institution that is requesting the test. Therefore, patients get sent to a community lab, where the sample is drawn and sent to the hospital. The hospital then sends back the results to be disseminated to the referring physician and genetic counselor and a bill for the community lab to pay.

The genetics laboratories in the community receive some licenses from the MOHLTC for tests that are covered under OHIP, such as retinoblastoma testing and noninvasive prenatal testing. Some are repatriated tests that used to be sent to the United States but were brought into the province so that patients did not have to travel to receive them. However, the majority of the molecular lab tests are paid by patients' individual insurance plans or by the patients themselves. Patients outside of Ontario that require specialized testing to be conducted in Ontario labs would also pay out of pocket and may be reimbursed by their respective countries or provinces (LMP3).

Two hospital lab experts agreed that genetics is an area of lab services where the Ministry has not kept up with the types of tests that should be provided, the growing volumes or associated funding models for hospital and community labs (LP1 and LM4). One can conclude that funding for genetic testing is not only determined by where the service is delivered but also by the type of patient. In the case of the outpatient who requires genetic testing which is performed the hospital, funding is provided by the community labs.

### 5.6.3 Delivery of Genetic Testing

A large amount of testing is still being sent outside of the country, as is evident from the US$31 million the MOHLTC spent in 2015/16 on specimens sent outside of the country, compared to US$64 million that hospital labs spent on performing genetics testing [5]. At the time

of writing, there was an effort in place to bring out-of-country tests to Ontario by providing funding to mainly hospitals to have the tests repatriated (GA1). In 2015, the Ministry put out an RFP in order to select laboratories that would perform genetic tests that at the time were being sent to the United States. The tests had to be performed at a lower price than in the United States, with specific quality standards and appropriate turn-around time. The hospital labs that had won the RFP have to meet the clinical criteria in order to continue providing the tests. The key informants were unclear about who oversaw the genetic labs to ensure the clinical criteria was being met (LP1).

A key concern expressed by 3 respondents (LP1 & LM4 & LM5) was the lack of planning for the delivery of future genetics testing, and the lack of the patients' benefit in mind. As one respondent put it,

'But there is no real plan (in Ontario) to see whether genetic tests that are now being done in every other jurisdiction, some well and some not so well, will be there to benefit Ontario patients' (LMP1). When decisions are being made with regards to delivery of genetic tests, urban and rural patients experience different challenges that are not addressed in the government's strategy. An example of this is the Ministry's Maternal Serum Screening (MMSS) Program that funds 7 hospitals in Ontario that perform prenatal laboratory tests for pregnant women to detect genetic disorders [4]. Patients can also go to community lab and receive the same test, but they would be considered outside of the MMSS program and would not be covered. This would not be an issue if the community labs were part of the MMSS program, and were funded just like the 7 hospitals to perform the testing [4].The key informants indicated that for the most part the volumes were not great enough for community labs to invest in the necessary equipment, therefore community labs may not even.

Although the majority of genetic tests are performed in hospitals, some genetic tests are performed in specialty labs that are characterized as molecular genetics labs and are owned by private, for-profit companies such as Dynacare. These facilities receive specimens from hospitals, community labs and from centers around the world, depending on the type of tests that are required. Some molecular genetics partners, such as the one owned by Dynacare in Bowmanville, specialize in certain tests that are not performed in hospital or other community labs due to the complex nature of the required experts and materials, such as retinoblastoma identification. Dynacare and LifeLabs also received the license to perform noninvasive prenatal

testing that is conducted on most pregnant women in Ontario now. That was a competitive decision made by the MOHLTC because of the community labs' ability to have a wider breadth of capacity due to established infrastructure that these labs have across Ontario (LMP3). This provides faster turnaround time because the transportation methods and collection facilities' logistics of moving specimens around are well established. Some tests are time sensitive since decisions that impact the fetus have to be made quickly, and the model of care using community labs ensures the turnaround time for testing is acceptable (LMP3).

## 5.7 Overview of the Modernization of the Regulatory and Funding Framework in Ontario's Laboratory Sector

As the key informants delved deeper into the regulatory framework of the Ontario lab sector and why it functions the way it does, a common theme that emerged was the impact of current changes and modernization of the legislation on the delivery, funding and regulatory models of labs. These key factors appeared to lay the groundwork for the current debates about the future of care provided to Ontarians. The need for modernization of a system that has seen little change in community labs' market share, test prices and delivery services was expressed in many documents during the literature review. This is in line with the government's goals of better value, access and quality in health care [5]. Bill 87; *Protecting Patients Act 2017,* [81] which was drafted to come into effect in 2017/18, includes amendments to three statues within them to expand the definition of community laboratory services to include hospitals and change the community lab funding models [82].

### 5.7.1 Legislation Modernization

The Ministry of Health and Long-Term Care licenses and regulates Ontario's labs under the *Ontario Laboratory and Specimen Collection Centre Licensing Act* since 1990 [27, 76]. At the time of writing, as noted in section 3.4, for-profit and not-for-profit suppliers must apply to the MOHLTC in order to receive licenses to operate specimen collection centres and testing facilities. Adding tests to existing licenses also requires labs to submit a proposal to the Ministry of Health, in order for a Public Interest Evaluation (PIE) to be conducted. This evaluation looks at parameters such as the volume of the proposed test, cost and feasibility (GA1). Moving the license requires an application and approval from the MOHLTC. The ability to open and shut

down specimen collection centers also falls under the regulation of the Ministry of Health (LP1). The license must be renewed annually and include information such as the lab's staff number, staff qualifications and laboratory equipment. As noted earlier, Bill 87 *Protecting Patients Act* has proposed amendments to the *Laboratory and Specimen Collection Centre Licensing Act* and the *Health Insurance Act* which will allow the Ministry of Health to be more flexible in regulating and funding the community labs [81]. Receiving Royal Assent in May of 2017, among the many changes included in the Schedule 3 of the *Protecting Patients Act* were propositions that would achieve better value for money by updating fee codes, deleting obsolete codes, revising preambles and adding new clarifications if necessary [47].

One report submitted by the Minister of Health to the Cabinet in 2016 noted that 'for the past 18 years the (community laboratory) funding model has been provider-centric and volume-driven, instead of patient outcomes-based service delivery. Service quality for patients has been defined by the supplier' [4]. Changes to the *Public Hospital Act* under Bill 87 will expand the definition of community laboratory services to include hospitals which can provide lab services to community patients, or those that are neither inpatients nor outpatients of the hospital [82].

A new section was added to the *Public Hospitals Act* and passed, that gives the Minister of Health the ability to designate hospitals to provide incremental volumes for community lab testing with any conditions or requirements that are outlined by the Minister. Section 11, Clause 2 (2) of Bill 87 allows the Minister of Health to enter into arrangements for payment of remuneration with health facilities. At the time of analysis, this model was only available for physicians and practitioners but with the amended changes to the *Health Insurance Act* through Bill 87, community labs will be able to negotiate a transfer payment agreement with the Minister, instead of a fee for service plan [82]. This kind of agreement is in effect and will ensure there is a single core funding envelope for community labs, combining segregated funding envelopes into one.

The funding caps were also revised in 2018 [4]. This will establish a competitive bidding system for community labs, with regions that are unsuccessful in the bidding process having lab services provided by hospitals. The Act vaguely describes the funding model for lab tests completed for community patients in hospitals, stating that it will provide hospitals with 'new specimen collection fee codes to incent access' [81]. Some experts have voiced their concern about this funding model, stating that hospital budgets are already stretched and could not

accommodate providing lab services for community labs [82]. The impact on patient accessibility to medical labs for patients living in rural areas is examined in Chapter 6.

As mentioned earlier, physician-owned labs are exempt from the *Laboratory and Specimen Collection Centre Licensing Act*, however Bill 87 has removed that exception in 2018. The possible effects of this change on physician owned labs is unknown, and one key informant noted:

"Their (physician owned labs) payments were not capped, and their spending has increased fivefold until it was cut back last year (2017), just because it was not being regulated. Maybe Bill 87 will influence that" (LM2).

### 5.7.2 Modernization of the Schedule of Benefits-Laboratory Sector

At the time of writing, there was no formal process in place to regularly update Ontario's Schedule of Benefits-Laboratory Sector [5]. The current prices are not updated, tests are not delisted according to appropriateness and new tests are not added regularly. As one key informant stated;

'It's been an evolution of a system that hasn't modernised itself in a very long time. And that's what the government is actually in the process of doing. They're changing our whole funding model' (LMP2).

At the time of writing, the government was in the process of establishing a formal means to evaluate new lab tests, recommend the tests to be added to the Schedule of Benefits and have a regularly updated test list using evidence-based evaluations [4].

The cost of a lab test must consider the 3 phases that make up the test in its entirety; the pre-analytical phase, analytical and post-analytical [13]. All phases must be considered when the cost of a test is being discussed, including new automation and technologies that may dramatically reduce the cost of performing the test (PO1). Although it appears the current test costs should be driven down significantly due to aggressive automation that has transformed the lab sector in recent years, other costs such as transportation might offset some of the cost savings the automation brings (LM1). One key informant described the variability in test pricing as such;

'New technologies come into place that have allowed certain tests costs to be lowered. Other tests are more labour-intense. The technology is more sophisticated and costlier. So, we want to get the schedule more in balance to reflect the reality of today's environment.' (PO1)

At the time of writing, there was no process in Ontario that analyzes each test in the Schedule of Benefits to adjust the price of tests to reflect changes to the lab sector. The Deloitte report completed in 2015 suggested that the prices of current tests listed are generous and provide significant profit for the community lab service providers [5]. The Auditor General Report in 2017 stated that the government was planning to establish a utilization committee by late 2017/18 that would be responsible for regularly evaluating the price list of the Schedule of Benefits. This was a recommendation made by the Expert Panel Report in 2015. A lab test fee price list that was drafted by a consulting firm funded by the MOHLTC in 2016 was compared to the current SOB-LS. It showed a significant price difference, with some common test prices falling significantly lower from the current SOB-LS list. This suggests that there has been overpayment from the MOHLTC to community labs with the current SOB-LS.

### 5.7.3 Delisting and Adding Tests to the Schedule of Benefits-Laboratory Sector

One of the greatest weaknesses that two key informants identified while speaking about modernizing the Schedule of Benefits is the lack of elimination of tests that are demonstrated to show no added value (LM2&PO1). At the time of writing, there was no process or committee to ensure tests that are not beneficial to patients are delisted. There are no revisions that identify tests that would be useful to some patients but not others. There were episodes of delisting activities that were triggered for various reasons, but there is no regular review. One key informant spoke of a negotiation between the OMA and Health Quality Ontario (HQO), where HQO identified a few tests that were overused and whose usefulness was in question. Studies have shown that tests that do not appear on requisition forms are ordered less by physicians [83]. It was suggested to remove the tests in question from the requisition forms in order for physicians to order fewer of those tests. This would translate into cost savings, and the millions of dollars in savings would be shared among the community laboratory sector. In anticipation of the cost savings after implementing the requisition form changes, $22 million was removed from the lab budget by the MOHLTC in 2016. However, there was no reduction in ordering that was seen within the OMA. No one was responsible to monitor and ensure the reduction in test use occurred. The pilot was deemed a failure and the requisition forms used for the community lab tests were instated (PO1).

One of the most prominent examples of delisting that actually did occur was Vitamin D testing in the early 90's. The Ontario Association of Medical Laboratories brought the issue to the attention of the Ministry of Health, with a lab policy reform committee presenting the large growth of Vitamin D testing in community labs with no evidence that this testing was useful. The Ontario Health Technology Advisory Committee (OHTAC) is an agency that works within Health Quality Ontario and makes recommendations to the Ministry of Health about which health care services should be insured. It conducted an analysis and agreed with the OAML to remove Vitamin D testing from the SOB-LS as an insured service unless there is a medical condition that exists for which such testing has been demonstrated to be valuable. The community lab requisition forms were changed for physicians to have to include the pre-existing conditions before ordering the test and the number of Vitamin D tests ordered declined. However, its use is creeping up again and the key informants could not pin point why that was. One participant noted,

"There are a number of tests like that that had certain criteria the doctors have to check off to determine whether it's insured or not insured. And doctors are not applying the criteria appropriately most of the time" (PO1). The emphasis that is placed on community labs to educate referring physicians to use appropriate testing practices was discussed in section 5.2.5.

At the time of writing, the last test that was added to the SOB-LS was approximately in 2005, and it was the liquid-based cytology test (LMP2). In comparison, Quebec had added 34 tests since then to keep up with the demand by patients and physicians for medically necessary tests. When asked why tests were so rarely added to the SOB-LS, key informants suggested that the Ministry of Health has good control over tests and expenditures in this way. Adding new tests leaves an unknown factor of increased cost to the government, especially new tests whose potential volumes are unknown, such as genetic tests (LM3). At the time of analysis, OHTAC had a list of tests that are under review to be added to the SOB-LS, but the reviews occur by priority and the laboratory tests are low on that list (PO1). Some of these lab tests are covered in other provinces but not in Ontario. In 2016, a health care consulting firm identified 16 lab tests that were deemed as medically necessary and covered in other provinces, but were not part of the SOB-LS [4]. It is important to note that these tests were covered in Ontario hospitals for inpatients, but were not insured in community labs for those seeking testing outside of the hospital setting. At the time of writing, there were no plans to add these tests, although the Ministry of Health

under the Liberal government indicated that it plans to roll out a New Tests and Technology Fund in 2018 for community labs to better adopt new tests that would be added to the SOB-LS and would improve patient outcomes. This was mentioned in the Auditor General Report in 2017, and no key informants were able to elaborate on this Fund or the details in which this would be incorporated with a process for adding new lab tests.

The key informants were unaware of what processes existed in other provinces to add laboratory testing to their list of insured services. A document created in 2012 titled Options for Laboratory Transformation in British Columbia surveyed health providers about the current state of the British Columbia private and public lab sector. When asked if an introduction of an evidence-based, objective process for adding new tests and new technologies was necessary, 77% responded Agree or Strongly Agree [84]. This demonstrates the recognized need for such a process in other jurisdictions, including Ontario, which would be beneficial for patients and practitioners to regularly have an updated Schedule of Benefits.

New tests added to a hospitals' roster of lab tests have different challenges. New tests are developed by lab experts in each hospital separately, depending on what the hospital's patients need are. The hospital does not have to add new tests to their test lists; however, in order to improve patient care, this is necessary. Hospitals undergo an exhaustive development of new test procedures which include validation exercises and a creation of criteria for when this test should be ordered. This is then certified by the Institute of Quality Management and Healthcare. The Ministry's role in adding the new test to the hospital's test list includes organizing expert panels that discuss feasibility and methodologies of the test, adding the test to the license, and agreeing on funding the test. Hospital labs usually create tests that are used in research or teaching, and would not be adapted by all other hospitals in Ontario. A good example is a genome diagnostic lead at UHN that develops genetic tests for certain types of lung cancers (LM2). The challenge lies in the funding, although a test may be approved by the Ministry to be added to the hospital license, they may not agree to add funding to the hospital's budget for the test. In some cases, which were described by key informants, the Ministry insists that new tests must be done within the financial means of the hospital. Another challenge discussed by the hospital experts was the time it took to get new tests, especially tests for new genes and panels, added to their license. It was described as very 'rate limiting,' taking anywhere from three to

nine months, depending on the Ministry's ability to tap into the right expertise to assess if what the hospital is requesting is legitimate and useful (LM2).

## 5.8 Overview of the Role of Regional Coordination and Partnerships among Ontario Labs

A theme that emerged from the key informant interviews was the availability and accessibility of medical labs to all Ontarians. Access to labs and types of tests available at each location varied significantly depending on where Ontarians lived. Although this is not a novel revelation, particularly in the vast province whose geographical distance to services makes access a challenge, certain policies and regulations made it more difficult to access labs. In order to remedy this, partnerships and regional coordination agreements have been created in certain parts of the province. This section explores the current accessibility challenges to community labs and what role the partnerships between hospitals and community labs provide in ensuring patients can get their lab work done as close to home as possible and in a timely fashion. At the time of writing, the only partnerships that had formed were between hospital labs with other hospital labs, and hospital labs and community labs. Public Health Ontario labs and physician owned labs had not been involved in the development of coordinated care among laboratories.

### 5.8.1 Access to Specimen Collection Centres within the Community

At the time of writing, there were no regular assessments by the MOHLTC to identify underserved areas in Ontario. As of 2011, approximately 16% of Ontarians lived in rural Ontario [85]. One target for availability of an SCC identified the need for 90% of Ontarians living in rural parts of the province to be a half hour drive from an SCC. That has been met according to the Auditor General Report; however, an adequate number of blood drawing stations within each facility or low wait times have not been made a requirement in community SSCs. Community labs report the total number of lab tests performed annually, but do not have to report the number of patients served or specimens collected by each SCC. This data is crucial for understanding if the current capacity of SCCs is sufficient to meet patient data (Office of the Auditor General of Ontario, 2017, 3951).

The location of specimen collection centres is controlled by the companies that own the community labs and can be moved, opened and closed at the discretion of the community labs,

although technically they are regulated by the MOHLTC. Interestingly, a hospital key informant informed the interviewer that community labs could not simply close down their SCCs if they were not making enough money (LM3). Ontario has relatively few specimen collection centres per 100,000 people, as compared to other provinces, with the SCC rate for both hospitals and community for-profit labs. Ontario has four SCCs per 100,000 people, compared to five, six, and fifteen for Alberta, British Columbia, and Manitoba respectively [4]. In the opinion of the key informant, the largest 3 lab providers worked together to impact access, by looking at which company had the largest footprint in what location in Ontario, and had the other labs located nearby close (LM3). This kind of cooperation would benefit the individual community lab companies in that their lab becomes the only available specimen collection centre in the region, which would increase patient volumes and revenue for the lab. Closing down SCCs to decrease costs, even though it negatively impacted access for patients, was a concept the key informants seemed to disagree on. Two key informants described it as 'smart business management' (LMP2 & LM3) while other key informants noted it was negatively impacting patient care. Another key informant described the closing of collection centres as a smart move that consolidates the number of collection centres but increased the capacity of each one. He argued that the new facilities are upgraded and modernized, and each facility is able to accommodate more blood drawing stations and more staff to support them. Although patients might have to travel longer to get to a specimen collection centre, the experience is better and wait times are shorter at the new facilities due to a higher number of phlebotomists. The Ministry's decline in funding in 2015, which removed $50 million from the community labs budget [5], was described also as a factor in the decision of closing multiple SCCs and opening fewer, larger ones which could consolidate staffing and supplies (PO1). A fourth key informant stated that the closing of labs indeed has a negative impact on the population as described by objective data collected by the Ministry, although the expert did not disclose what this data collected (LMP1). Another example is that Belleville has one specimen collection centre and Guelph, which is the same sized community, has six. LifeLabs was the predominant lab in Belleville; it had a 'monopoly' in the region, and shut down its other SSCs for reasons unknown to the key informant. This increased wait times to approximately three hours, but according to the key informant, the Ministry had not allowed for another community lab, that competed with LifeLabs or Dynacare, to open up specimen collection centre in the region (LMP1). This decreases competition and any benefit that

competition might have brought to the regions, with patients ultimately suffering longer wait times. Taking a blood sample takes 4 minutes, another expert explains, but in some parts of the province people are waiting 2-3 hours because community labs had closed down SCCs that they felt were redundant.

"And what they (patients) don't realize is that's not a government decision — that's not because of cutbacks: it's simply because a private organization has made a decision about how much [service] they should get" (LMP2). Two community lab experts denied closing their doors once their funding cap was reached as a means to save on costs, although they did say a strategy to save funding was to decrease hours at their specimen collection centres (LMP2).

An issue identified by two of the lab experts was the access community labs have on the ability and motivation of patients to return for frequent lab tests. An average requisition as paid to the labs costs the MOHLTC $36, but missing a test that is required by a physician due to an inability to get to a lab or due to the anticipation of waiting for a few hours is much more expensive for the health care system. This is because the results of the lab test could lead to a diagnosis that requires treatment promptly, and not receiving treatment could deteriorate patients' health and potentially cause complications. The repercussions of that can be much more expensive for the health care system, than if the patient had completed the lab test in good time and received treatment in a timely fashion. When looking at the cost breakdown for the health care system, it is more beneficial to allow for ease of access to labs so patients can get all of their required tests done. It is difficult to quantify the frequency of this issue or the impact on the health care system, and it has not been well documented in the literature; however, this was noted by the experts as a potential consequence of specimen collection centres closures. As described by one key expert,

"If there is no lab or no access, there are a whole bunch of things that happen. People don't get diagnosed because there is no place to go. People who are sick who have been discharged and are home and, maybe, don't have a car or don't have somebody to drive them, they don't go and have their lab work done, or they are disabled, mental acuity problems, a whole host of issues. We go to Emergency. We get admitted. How much does all that cost for a $3.00 to $25.00 test? It's ridiculous" (LM2). An example of deteriorating accessibility to labs in the past few decades as described by two lab experts are home services by physicians and other health providers which were able to collect blood samples from patients in the comfort of their homes (LMP1 &

LM2). In the early 2000's, the OML estimated approximately 6,000 practitioners provided in-home services including specimen collection; as of 2013 it's 2,000 physicians that provide the service. This is an outcome of the lack of government intervention in the matter by allowing labs to be able to remove useful services that are too expensive for the community labs to provide. "…Home services can be rendered without charge, it's just the expectations and the enabling of that isn't there on the part of government" (LM2). In 2018, LifeLabs charged $30 per visit to the patient for their Mobile Laboratory Services, an in-house blood collection and specimen pick up service that requires a health practitioner requisition[88]. This service used to be offered free of charge to patients who were not able to attend specimen collection centres, but are now required to pay the full amount. If the patient has private insurance, it could be submitted for reimbursement. The key here is the issue around what is considered a medically necessary service, and if in-house blood collection is indeed medically necessary, then it should be provided free of charge to patients. Therefore, this can be interpreted and defined differently by various health care providers and policy makers. Lab experts may see home services as medically necessary, but this is not a required service in Ontario, and the MOHLTC has not deemed it as medically necessary.

"So, what we have is actually a medically necessary service subject to a fee and a fee that some labs won't perform unless you have the cash or credit card. It happens as well in seniors' residences" (LMP1). As pointed out by one key informant, these services are being removed by community labs without the intervention from the government.

### 5.8.2 Benefits of Regional Coordination of Laboratory Services in Hospital and Community Labs

Many hospitals and community labs do not have the full range of testing at their facilities, depending on what the license allows them to perform. Hospitals and community labs may make the decisions to only provide some tests due to the requirements to maintain quality; a certain number of procedures need to be performed per year to become proficient, efficient and maintain expertise (LM3). Another reason for a smaller menu of tests is to centralize tests to certain facilities in order to achieve cost savings and not to duplicate services within a region [4]. This may benefit the patient and health care system in several ways, both because lower fees may be achieved for equipment and staffing if centralization leads to economies of scale, and if more

operational uniformity leads to more accurate results and the ability to maximize the use of equipment and expertise. At the time of writing, provincial lab networks among hospitals existed in 6 of the 14 LHINs, and this is coordinated amongst the hospitals themselves, without any intervention from the government. Although the hospital labs are operated by individual hospitals, which are accountable to the LHINs, there are no regulations provided by the LHINs to ensure standardized practices or inclusion of all hospitals [4]. One key informant noted that there was no centralized management structure within the lab sector, which is why there is a patchwork of partnerships and arrangements that have formed on a per need basis (LM5).

Smaller hospitals in rural areas only perform the limited, basic tests and require the specimens to be moved to local community laboratories or larger hospitals to analyze the remainder of the tests. These hospitals can't afford the level of subspecialisation or have the critical mass that some of the larger hospitals have. There are arrangements and agreements between hospitals, community labs or Public Health labs, which ensure patients can have their tests analyzed. The key informant agreed that the process benefits the patient in the sense that all specimens are collected in one centre, then the blood samples are distributed to the appropriate facility. This ensures the patient does not need to go to different specimen collection centres to get blood drawn for different tests (LM4). The smaller hospitals, where the patients have their samples collected, pay for the collection of samples, and each agreement outlines who is responsible for the costs associated with the rest of the tests.

Sharing of resources among the different hospitals and community labs is a major benefit of the regional partnerships that are created in Ontario's labs. The level of expertise and technology acquired within each hospital and community lab is quite heterogeneous, and these partnerships ensure each facility can tap into each other's resources. For example, a molecular genetics lab owned by Dynacare partnered with London Health Sciences to allow for more people to access a genetic test for epilepsy that was created by London Health Sciences and was only provided to patients in London's immediate catchment area (LMP3). By partnering with Dynacare, the test and clinical expertise can be offered to a much larger region. Another example of regionalizing multiple lab services is the Eastern Ontario Regional Laboratory Association (EORLA) which is a partnership among 16 hospitals, including teaching hospitals, in the Champlain LHIN located in southeastern Ontario. EORLA uses its buying power to purchase

supplies and equipment in bulk, centralize certain lab tests to only one hospital within the network and move staff around the different labs depending on staffing needs [4].

A very important partnership exists between The University Health Network (UHN) and the Timmins Northeast Cluster, which includes 10 hospitals in northeastern Ontario, approximately 700 km away from Toronto, which receive oversight by UHN. Resources and medical expertise are leveraged through this agreement to provide optimal service to rural regions in Ontario that would otherwise would not have access to specialized personnel and test options. The contracts that bind all nine hospitals outline the collaboration and payment terms, with the majority of the funding for the tests done by UHN for other hospitals coming from the rural hospitals' budget. Three out of the four weeks in a month, UHN rotates a pathologist to one of the northern hospitals to help support the interpretation of lab tests. Slides are transported to UHN for interpretation daily as well (LM5). UHN also has a partnership with LifeLabs that perform some of the more routine testing, which offloads the work from UHN, and allows it to concentrate on the more complex testing (LM5). UHN has worked with Lakeridge Health, located in the eastern part of the Greater Toronto Area, for the past 7 years to oversee their pathologists, who perform the majority of reporting but are credentialed by the UHN program Medical Director.

Lifelabs is contracted out to transport specimens between four hospitals that are part of UHN; Toronto General Hospital, Toronto Western Hospital, Princess Margaret Hospital and Toronto Rehab Centre. This partnership has been in place for a few years and uses LifeLabs' well-established transportation system to move specimens and is described by one hospital expert as a process that works like a 'well-oiled machine' (LM3). Hospital labs may send complex tests for infectious diseases to Public Health Ontario labs, and these interrelationships help offload some pressure from hospitals. The PHO labs have raised some concern with the Ministry in 2016 as they have received a significantly higher number of requests from hospitals to provide testing for patients with viral or bacterial infectious disease [4]. They felt that these tests could be performed in the hospital and the hospitals were taking advantage of their ability to offload these test to PHO labs.

Inter-hospital and inter-community lab partnerships encounter challenges due to the autonomous governance structures of hospitals that inherently operate by prioritizing their own programs and patients. Some partnerships fall apart as each entity negotiates services that benefit

them and are unable to compromise financially (LM2). One such partnership formed in the 1990's between Dynacare and Sunnybrook Hospital, a teaching hospital in Toronto, had the idea to leverage the efficiencies of a private lab and maximize the effectiveness of an academic health lab. It was set up to market its services to other institutions, and any profits that were gained from that were shared equally between the two partners (LM3). It did not end up working out, and as one hospital expert described it,

"There is a well-known phenomenon about culture clashes between partners and certainly, that came into play, with different political agendas between the two organizations. The concept was sound, but you have to have the right partners, and so without implying any criticism for either one of the partners, in my estimation, it wasn't a cohesive partnership, and so then they struggled" (LM5).

One public-private partnership as reported by Gamble in 'Quality in Medical Laboratory Services: What's the bottom line?' examined the move of lab test provision from a hospital lab to a private for-profit community lab of tests in order to achieve cost effectiveness. The results were difficult to analyze due to a lack of transparency from the private for-profit lab and it was unclear whether the shift was indeed cost-effective. Gamble concludes that it is important to take into consideration not only economic efficiency, but also technical and clinical proficiency and the impact on the health care system when analyzing public-private partnerships in labs [17].

### 5.8.3 Funding Regional Lab Networks

Contracts for regional lab agreements are unique to each partnership, with the majority of hospital agreements using their global budgets to pay their partner for services that are provided to the hospital. For example, UHN receives specimens from 250 hospitals in Ontario and abroad, including the hospitals mentioned in 5.8.2, and the hospitals are billed for those tests. One caveat to this arrangement are primary pathology consults that get billed to the hospital but the secondary pathology consults, if a second opinion is required, will get billed directly to the Ministry of Health. This is an extremely rare example of hospitals billing the MOHLTC for interpretation of tests (LM4). Hospitals will not accept community lab material if there is no agreement in place, as they are unable to charge the community lab for the work done. It was estimated that the consolidation of testing by the EORLA program decreased staffing

expenditures by approximately $1 million from 2012/13 to 2016/17 [4] which is exactly the kind of efficiencies these partnerships could be providing for the hospitals, and ultimately the MOHLTC. One of the themes that is revealed in this thesis is the continuation of formation of public-private partnerships between labs in Ontario. As Gamble's paper suggests, the decisions to implement these partnerships are made with an anticipated cost savings that may not yield the efficiencies and economies of scale that are claimed by them. There is a debate in what should be done with the achieved cost savings as well, and it has been suggested that one option is to reinvest the cost savings into a business venture embedded in the partnership [86].

A common theme that came up among the interviewees was that the funding model of these partnerships should require the money to follow the patient, meaning that the facility that is performing the test should receive the funding. At the time of analysis, that process was quite complex. When patients with a requisition go into a hospital setting and their physician is not affiliated with the hospital and no partnership has been set up, the patient could be turned away. The patient could then go to a community lab and if the test is not performed by the community lab, the sample would be taken and sent to a hospital lab, and a bill would be sent to the community lab. The adoption of this kind of model, where the community lab is billed if they send the specimen for a patient whose testing cannot be done in their own facility, is extremely convoluted (LM2 & LM3).

At the time of analysis, the MOHLTC was not collecting any test volume numbers performed by hospitals on behalf of other hospitals or fees charged by hospitals to their partners. Without this information, it is difficult to know the actual cost of operating hospital labs. This may become important in the future for the MOHLTC to allocate funding to hospitals appropriately [4]. The following chapter discusses the findings and results of the thesis and their relevance to the thesis questions.

# CHAPTER 6 DISCUSSION

## 6.1 Introduction

As noted in Chapter 1, this research was conducted to obtain a better understanding of Ontario's medical laboratory sector. This chapter will analyze what the findings tell us about the potential impact on the four categories of labs by looking at the ownership structure, funding model, and quality assurance mechanisms. It uses the key research questions to help guide the discussion, with the theme of for-profit and not-for-profit delivery of lab services underpinning the analysis. Understanding the implications of different models of funding and ownership may be useful to policy makers in order to make more informed, sound decisions. This chapter will accordingly discuss the results from Chapter 5 and the implications of the findings described by key informants.

## 6.2 The Implication of Ownership Structure on Providing Publicly Funded Lab Services

This section discusses how the for-profit or not for profit nature of the labs (their ownership structure) may affect the care that is provided to patients. The ideal lab set up would provide timely access to high quality care with a reasonable cost to payers (whether this is the taxpayer or private payers). Due to the undisclosed nature of how government funding is disclosed in for-profit labs, and at times conflicting objectives of a for-profit company, the ideal lab set up has proven to be a challenge for private, for-profit labs. The concept of production characteristics is used when comparing the type of tests that for-profit and not-for-profit labs appear best suited to perform, as well as how transparency and accountability to the MOHLTC vary by ownership structure of the different types of labs. The key informants described the mechanisms that are available to ensure that private for-profit labs adhere to societal goals and act for the best of broader public objectives.

### 6.2.1 Production Characteristics of Tests Performed in For-Profit and Not-for-Profit Labs

Private, for-profit labs are well positioned to perform routine, highly automated tests in the community due to the substantial economies of scale which creates quasi-monopolies in the

community lab sector. As noted previously, in Ontario, there are two for-profit laboratory companies that perform more than 95% of the province's community testing; the resulting high volume of tests within each of these labs lends itself to achieving cost savings and efficiencies through bulk purchasing and sharing of best practices. Many high volume, low complexity tests have become automated, which has driven costs down.

The literature and key informant interviews suggest that there is room for for-profit corporations to provide health services, particularly if the services have high measurability [8]. The analytical phase of testing is considered highly measurable, with the ability to monitor the test outcomes by testing reagents, calibration of instruments and sample handling. The analytical phase has a low error rate and well established quality assurance procedures that ensure the tests are completed appropriately. There was agreement among the key informants that quality assessment of the pre and post-analytical phases was still not as measurable and properly documented as the analytical phase, but processes were improving (LM1).

When health care services become difficult to measure, the literature suggests that not-for-profit delivery is usually a superior method [8]. One reason is that when it becomes more difficult to measure performance, it is more difficult to monitor the extent to which for-profit corporations will pursue such goals as maximizing return on investment to shareholders, at the expense of quality outcomes, particularly when one seeks to avoid unnecessary testing. High quality outcomes of lab testing are defined as tests that produce reliable, valid results for the best cost to the health care system. In this way, not-for-profit labs are also well positioned to deliver lab services in the community. Historically, when the medical labs moved out of the hospitals after the introduction of Medicare in the 1960's, government policies created a market for private for-profit lab services in the community [87]. The community labs service a somewhat different (and less sick) population than do hospital labs. The routine tests provided in the community are easier to automate, which enables for-profit labs to diversity and increase profit and market share[29].

A proposed solution to the high cost of complex tests, lack of economies of scale and underutilized staff and equipment in hospitals has been to amalgamate labs. However, this solution can be difficult to implement if certain lab tests that are required urgently are only performed in a particular facility and are not available for emergency patients at the right place and at the right time. The highly complex nature of labs and the coordination of services that rely

on labs has made it difficult for labs to amalgamate such services in order to reap the benefits described above, although they have been able to do so for tests than are less urgent.

Because Ontario labs have a high degree of measurability and complexity and a low degree of contestability (definitions of these concepts can be found in section 2.4), findings through key informant interviews and document analysis suggest that tests are generally accurately performed and results are interpreted in a timely fashion [7]. The highly complex nature of labs, which integrate them with other labs by resource sharing, allow for tests to be interpreted quickly, as with the example of the partnerships between UHN and rural hospital labs. The sharing of physicians that are able to interpret tests remotely decreases the time patients living in rural areas have to wait to receive their results. The analytical phase of labs are highly measurable, which means errors are detected easily, and ensures tests are accurately performed. The high barrier to entry of labs due to regulations, high sunk cost and monopoly market power has helped to ensure that only those labs that are truly well equipped to enter the market are able to do so. Low contestability contributes to high quality, highly regulated labs that produce accurate results (in the analytical phase).

### 6.2.2 Transparency and Accountability to the MOHLTC and For-Profit and Not-For-Profit Labs

Some disadvantages of for-profit corporations delivering laboratory services were identified by the key informants. These included the lack of transparency of spending costs revealed to the government and the lack of accountability to the MOHLTC. These challenges have been described in various reports as well and recommendations for improvement and change have been put forth by Sullivan's group in the Expert Lab Report in 2015,[5] as well as the 2017 Auditor General Report [4].

As noted in section 5.3.1, private corporations are not obligated to provide costing information to the MOHLTC. Although the MOHLTC is the main source of funding to for-profit labs, and regular reporting of the costs incurred in order to providing services is required to the MOHLTC by all health care organizations, the exemption is made due to the private nature of their ownership structure. The lack of public disclosure has decreased transparency, accountability and the ability of the government to ensure that fees paid for tests are reasonable. An example of this is the effort in 2016 by the MOHLTC to update the Schedule of Benefits-

Laboratory Sector price list. The hired consulting firm was able to obtain data from lab service providers in the United States and one small for-profit Ontario laboratory. However, the two largest for-profit community labs in Ontario chose not to disclose their cost information. Without the input and cost data of the largest providers of labs, who may have lower costs due to economies of scale, it was difficult for the consulting firm to accurately update the new price list[4]. The lack of disclosure of laboratory costs would not have occurred in Ontario had the laboratories been of a not-for-profit or of public nature. The key informants familiar with the topic were under the impression that for-profit labs were paid considerably more per test than the actual incurred costs were.

It has been difficult to compare costs per test between hospital and community labs due to the lack of publicly available knowledge of costs in private for-profit labs. However, a pilot study in 1997 was conducted, where community labs were paid per test and Muskoka and Huntsville hospitals were paid a lump sum for their community patient lab volumes, regardless of number of tests conducted. The results were not made available to the public for a few years until RPO Management Consultants evaluated the pilot and found that the average costs per test was $22 at the small hospitals and $33 in the community labs [88]. The study made recommendations for the hospital labs to maintain volumes of lab tests for outpatients and use the extra lump sum finances for new equipment and extending lab hours. This enabled the hospitals to reach efficiencies that were translated to lower test costs. Despite the results that were discovered in 2014, the pilot carried out in the Muskoka and Huntsville hospital labs was cancelled and none of the recommendations which came out of the findings described above were implemented. This was one instance where there was a side by side comparison between lab tests performed for community patients in both a hospital lab and private for-profit lab setting, and the cost per test to perform it was lower in hospital labs.

The literature has shown that the ownership structure of labs affects who they will be accountable to [29]. There are commonalities in accountability between not-for-profit hospital labs and for-profit labs such as accountability to their patients, licensing and accrediting bodies and health care providers. In terms of administrative accountability, for-profit labs feel they are accountable to their Board of Directors and shareholders. Not-for-profit labs feel they were accountable to their Board of Directors and to the MOHLTC. This is an important finding

because the literature suggests that the accountability framework influences behaviour of key lab stakeholders, whose decisions in turn impact how they manage labs [29].

The key informants agreed that the MOHLTC was not doing enough to hold the for-profit labs accountable when it came to funding and using taxpayer's money appropriately. As one key informant stated:

'The contradiction is that the private laboratories have all the privileges of not-for-profits like hospitals but none of the accountabilities. And the government has not figured out a regime that is appropriate' (LM1). One key informant noted that the MOHLTC has not completed a proper assessment of the appropriateness of funding to different lab providers or an efficiency assessment by each provider. He believed this type of assessment would reveal patterns and practices within the 4 categories of labs in Ontario that are ineffective and could be changed to achieve cost savings and improve patient care. One example was the point of care testing completed in physician-owned labs, which tend to be more expensive in what is paid to physicians by the SOB-LS as compared to the test that is performed in a community or hospital laboratory, which tests for the same thing. Frequently, POCT requires confirmation of the test results from another lab test, and a lab test must be ordered through a community laboratory to confirm or invalidate the results, which is a redundant practice. For example, a urine pregnancy test performed in a physician-owned lab may be confirmed by a blood test taken at a community lab. A change in practice standards, supported by a change in compensation by the MOHLTC, would influence physician ordering practices and decrease unnecessary testing and associated costs.

One reason proposed by the Auditor General Report of 2017 for the inability of the MOHLTC to provide an assessment of appropriateness of funding is due to the fragmented management of the lab sector. Some tests could be provided at a lower cost and in a different lab facility that could benefit the patient, but the labs are managed by different departments within the MOHLTC.

The Laboratories and Genetics Branch manages community, for profit labs, the Hospitals Branch manages the hospital labs, Population and Public Health Division manages PHO labs and physician-owned labs are managed by the Health Services Branch [4].

## 6.3 Proposed Changes to the Funding Model of the Medical Lab Sector

The next section will discuss the funding model changes by the MOHLTC and their potential impact on the for-profit community labs and hospital labs. An external advisory committee report commissioned in 1994 concluded that in order to effectively oversee the for-profit lab sector, the MOHLTC required 'mechanisms to monitor and evaluate outcomes' related directly to their performance [4]. The key informants discussed how the performance of for-profit labs would be impacted by proposed changes by the MOHLTC to performance based transfer payment agreements and updates to the Schedule of Benefits-Laboratory Sector. The hospital labs will be impacted by the hospital outpatient funding model changes. The proposed changes are described in the Community Laboratory Modernization Strategy [89], a document created by the MOHLTC that describes the changes that are aimed to improve labs' value, access, accountability and quality of service.

### 6.3.1 Performance Based Transfer Payment Agreements

In 2017, the MOHLTC announced changes in the funding models to for-profit labs through performance based, short-term transfer payment agreements (TPAs) as part of the Community Laboratory Modernization Strategy (CLMS). The contracts will be up after 3 years, after which they will have to be renegotiated and signed again. The rationale behind short term contracts is that it would allow changes requested by the MOHLTC to occur more quickly without restricting the ability to change future contract terms. As part of the agreements, the cap that limits total funding for each for-profit community lab will change each year depending on volumes from the first 2 years and in comparison to other community for-profit labs. Not many details were available to describe how the performance of labs will be monitored. The recommendation by the Expert Panel was to establish 7-10 years performance based contracts, in order to ensure permanency in the delivery of lab services. One key informant said; '…we need competition, we need to make these entities accountable but the recommendation, the way to do that, was a 10 year contract. Well, that doesn't make sense. A 10 year contract would preclude competition' (LMP1). The argument is that 10 years was too long of a time to have set contracts and to truly impact behaviour of labs to improve efficiency and quality of tests.

Concerns were voiced by other key informants and senior members of for-profit community labs with respect to the short length of the contracts and determination of future allocation of funds. The funding cap allocation which compares to past years' volumes would increase the incentives for community labs to overstate the number of tests they performed in order to increase their billing estimates for the next year. Another issue of basing new test volumes on previous years is that this would encourage providers to compete in large population areas in order to gain market share from other labs. This would not solve the problem of improving access to patients living in rural regions, where test volumes are lower. One key informant predicted that the two largest for-profit lab corporations will be at an unfair advantage when competing for the contracts due to their numerous SCC, extensive transportation network, and economies of scale. Smaller labs will find it difficult to grow their market share if future caps are based on past test volumes (LM2). Short-term contracts will not provide incentives for labs to purchase new equipment and technologies, since the uncertainly of short term funding agreements will deter them from investing in lab equipment. The life span of most pieces of equipment are five to seven years, and the insecurity of profitability under the next short term agreement would deter labs from purchasing them.

### 6.3.2 Updates to the Schedule of Benefits-Laboratory Sector

The funding changes by the MOHLTC to the SOB-LS directly impacts funding amounts to the community for-profit labs. As discussed in Chapter 5, the modernization of the SOB-LS was a main concern for key informants, as test prices, delisting of obsolete tests and addition of new medically necessary tests have not been updated in many years. After data collection was complete for this thesis, the Laboratories and Genetics Branch of the MOHLTC announced that it will be making changes to the SOB-LS as part of the Community Laboratory Modernization Strategy. The changes reflect improvements in technology, amendments to existing services and fee values as well as updated preambles and revised commentary sections [89]. One change is the differentiation in specimen collection that occurs in different geographic areas of the province in order to account for the higher transportation costs in rural regions. In urban regions, community labs will be compensated $10.76, in rural areas $12.76 and in Northern Rural regions $14.26. An included reference map described which SCC are designated as urban, rural or northern rural.

Previously, there was no distinction between regions and reimbursement for specimen collection was equal, although it is understood that specimen collection in rural areas is more expensive due to the longer distances to laboratory facilities. Effective April 1, 2018 there were 203 fee codes that were revised. The majority of test fees were decreased, with a range of decrease in fee between 3%-91%. Some test fees were increased, ranging from 3.72%-100% increase. There was no published documentation or explanation as to why a particular test fee was chosen and how the amount of the decrease or increase was decided on. As of April 1, 2018, 110 obsolete test codes were removed from the SOB-LS as they were no longer relevant and were replaced by other methods [89]. There was only one new lab test added to the SOB-LS, a Non-Invasive Prenatal test which could only be claimed by labs that have entered into an agreement with the MOHLTC under the Provision of Genetic Testing Agreement for Prenatal Screening. This test is an insured service only if the patient meets the indications specified by the Provincial Council for Maternal and Child Health (PCMCH) by completing the Prenatal Test Requisition. Patients can still receive the test if they do not meet the criteria but want to pay for it [71]. Genetic testing has been performed mostly in hospitals, and as discussed in section 6.2.1, is a highly complex category of testing that requires oversight and monitoring. It is unclear what the rationale is for modifying who could perform this frequently performed genetic test, particularly since the literature suggests that the not-for-profit sector is a superior model for delivery of difficult to measure services.

The last major change described in the 2018 document released by the Laboratories and Genetics Branch of the MOHLTC is the discontinuation of calculating the Utilization Discount Modifier (UDM). As discussed in section 6.2.2, the use of the UDM is a practice that was recommended by Sullivan and the Expert Panel to be discontinued as it was ineffective to incentivise labs to reduce unnecessary ordering. This recommendation is reflected in the modifications to the SOB-LS. The changes seen in the new SOB-LS have been welcomed, with many obsolete tests delisted, many test fees updated and the availability of genetic testing to be performed in the community. There are still questions around why new medically necessary tests that are covered in other provinces have not been added to the SOB-LS, and the transparency of the decisions made in how the adjusted fees were set.

### 6.3.3 Hospital Lab Outpatient Payments

Hospitals have been under increasing financial pressure over the past several years and as a result have had to find ways to cut programs and costs. The hospital laboratory departments have seen a decline in services provided to community patients or outpatients in response to the financial pressure. Instead, they have been sending patients to labs located in the community for specimen collection and interpretation. Hospitals are not required to provide outpatient services; however, historically they have done so when a physician is affiliated with the hospital or if the hospital is located in a rural area without an alternative lab nearby. The MOHLTC has agreed to provide new provisions that would pay hospitals designated under section 22 of the *Public Hospital Act* for incremental volumes of community lab services [47]. This hospital outpatient payment model would support lab funding and top up any hospital global budget dollars allocated to lab services. The key informants and the literature review revealed little detail on the amount of money that would be allotted for this, which hospitals would receive the funding, and how they would monitor the appropriate allocation of funds. This is an important initiative, which could create an incentive for hospitals to provide care in the most appropriate setting. Cases have been identified by the Auditor General Report of 2017 where certain tests could be performed more effectively by hospitals than Public Health Ontario or for-profit laboratories. An example of this are hospitals performing *Clostridium difficile* testing themselves using their own budget, which saved them approximately $120,000, rather than sending the specimens to a Public Health Ontario lab for testing. The savings came from hospitals receiving test results faster than if they had sent them out of house, which enabled hospitals to diagnose patients more quickly and discharge wrongly diagnosed patients [4]. The hospital outpatient payments may also improve patient care for those living in remote regions, where hospital labs are often closest geographically to the patients. Although some of this may be due to a higher population, increasing the funding may give an increased incentive to test community patients at the closest laboratory, rather than turning them away and requiring them to travel greater distances to find the next closest SCC.

There is a continuing debate on the cost effectiveness of performing tests in hospital labs, community for-profit labs, physician owned labs and Public Health Ontario labs. Some tests can be more effectively and efficiently performed by one type of lab service provider than another.

Money can be saved and patient care improved if some tests are performed by certain lab providers [4]. Some of the cost savings could come from using available resources more effectively. For example, a study in 2008 for the MOHLTC looked at 12 communities in Ontario that used hospital labs for all tests, and found that the hospitals could also process all community lab work in 4 hours per day, using excess capacity of the hospital night shift staff. This excess capacity in hospitals is seen to be necessary to accommodate for fluctuations in demand created by the emergency department; however, if used more efficiently, it could divert tests from the community labs to the hospital [87]. This may be less desirable for hospitals if their funding does not allow for extra tests, and hospital labs are in fact trying to decrease the number of community patients served, as described in the previous chapter. If they are; however, compensated properly for extra community patient testing then these volumes would be welcomed.

Understanding and comparing the costs of performing tests in for-profit labs versus hospital labs, has been difficult and an ongoing topic of debate in Ontario. The first difference which makes it difficult to compare costs between the two labs is the kind of tests each lab provides; hospitals often perform more complex, costly tests which includes labour intensive pathology and microbiology tests. Private for-profit labs perform more routine tests that have recently seen a vast move towards automation, which improves efficiency and lowers cost [87]. This difference can be explained not by the preference of performed testing of each type of lab, but due to the different needs of patients who report to a hospital versus those that are seen in the community. Those patients in a hospital require urgent, sometimes obscure lab tests to rule out disease, while patients in the community receive routine, less urgent lab testing. The second difference in comparison are the added costs that are more difficult to measure intangible services, such as teaching and research performed in hospital labs [90]. Private for-profit labs incur some costs that hospitals do not by operating specimen collection centres which require their specimens to be transported to processing laboratories. The last difference is that the two kinds of labs also use different techniques to measure their workload. Despite these differences of comparing costs in hospital and for-profit labs, experts in the past have attempted to do so. Sutherland summarizes studies that have reported on mixed results when comparing costs in hospital and for-profit labs. The same 2008 study in Ontario mentioned in the previous paragraph[88] has found that hospitals processing for-profit lab work in their own facility cost $22 per test, while the for-profit labs were doing the same work for $33 per test. A different study

completed by the MOHLTC in 1997 (which was then called Ontario Ministry of Health) found that average cost per reported test in a hospital was $7.44 compared to $6.33 in a private for-profit lab. The Globe and Mail reported that Vitamin D testing cost the Ministry of Health $52 per test in for-profit labs, $32 per test in hospital labs, and $17 per test in Saskatchewan's public labs [91]. These comparisons underscore the variability in available cost effectiveness data in hospital and for-profit labs. Returning to the point of the changes to hospital outpatient payments, the data shows that this would be a favourable outcome for hospitals that are already absorbing community test volumes. Assessing other variables such as real test cost in each type of lab and optimal test location for patient should remain a priority in order to ensure that the MOHLTC is using its funding dollars efficiently.

### 6.4 Quality Assurance Programs in the Different Categories of Labs

As described in sections 5.4, IQMH provides adequate oversight of the quality of lab testing in for-profit community labs, hospital labs and Public Health Ontario labs. There are also internal voluntary quality assurance programs that are used for subspecialty accreditation. There are some overlap in the accreditation provided by the extra subspecialty accreditations and IQMH but overall, the processes and policies are followed rigorously by the above-mentioned categories of labs. There is however, a concern, as noted by the Auditor General Report of 2017 that suggested that the MOHLTC was not collecting useful data from IQMH to ensure all labs and SCCs were meeting their required quality targets [4]. A 2005 audit found that the MOHLTC was not receiving regular reports which provided the overall performance of labs. This in turn, does not allow the MOHLTC to provide remedial action if necessary. The reports obtained by the MOHLTC provide a high-level overview of the IQMH's results of the lab inspections but were not aware of the number of errors or nonconformities that were identified for each licensed lab. Another concern with regards to the IQMH accreditation process, is that all labs are aware of inspections by IQMH in advance and could prepare for them. This may not demonstrate an accurate representation of lab processes that occur daily. Unannounced site inspections would identify true errors in the labs and would prove to be more useful than scheduled site visits [4].

The IQMH website did not list the labs and SCCs that did not successfully receive accreditation-only those that did. This was not a transparent way of providing information to the

public about the state of lab accreditation in Ontario. The MOHLTC does not require public disclosure and reporting of details of the assessment results [4]. This means that although a lab can have multiple errors and non-conformances, if the amount is below the accepted number of instances, it will still receive it's certification. The accepted amount of errors is chosen by the IQMH and presumably is consistent with the standards worldwide as defined by ISO; however, this was not known to the key informants and was not found in the document review. There is a large discrepancy between the number of non-conformances received in SCCs and labs for each LHIN. For example, between 2013-2016 the number of non-conformances that occurred in the Central West LHIN, which is close to Toronto, was 8, compared to 28 in the North Simcoe Muskoka LHIN, located in southwestern Ontario [4]. There is no further investigation completed by the MOHLTC with regards to why this pattern occurs or if it is necessary to alert the labs to improve their performance.

The last identified concern through the findings of this thesis was the lack of consistent performance targets that were collected and monitored by the MOHLTC. There were few targets that were collected and they varied by the type of lab. For-profit community labs and physician-owned labs only had to report their test volume as a performance measure to the MOHLTC. Hospital labs reported test volumes, lab expenditure and the amount of time spent on lab testing by staff to the MOHLT. Public Health Ontario labs had the most number of reported performance measures that included test volumes, percentage of certain lab tests completed with target turnaround time and the number of complaints about their products and services [4]. In comparison, Alberta tracks key metrics for hospital and community labs which include patient wait time, test turnaround times and patient satisfaction. This would be a useful practice in Ontario to improve efficiency and hold the labs accountable to patients and to the MOHLTC.

The next chapter draws the conclusions and future research recommendations that would be useful in studying the Ontario medical lab sector.

# CHAPTER 7 CONCLUSION

The Ontario medical laboratory sector plays an important role in the health care system, by providing diagnostic testing that supports and informs diagnosis, treatment, monitoring therapy and disease surveillance. The majority of tests administered in Ontario are publicly funded, with funding models varying depending on the four laboratory types; hospital labs, community for-profit labs, Public Health Ontario labs and physician owned labs. Various aspects of the laboratory sector are regulated by combinations of legislation, licensing bodies, professional associations, and accreditation bodies. This thesis highlighted the current landscape of the medical laboratory sector by focusing on funding models, ownership structures, quality assessment programs, the organization of health personnel and access to different tests in the four types of laboratories. The key findings that answer the main thesis questions are outlined below.

The funding models of each lab type were explored at length, with suggestions made by key informants from for-profit labs, hospital labs and government organizations that it would be valuable to update the Schedule of Benefits-Laboratory Sector prices to reflect actual costs of testing in for-profit community labs, delist obsolete tests and add medically necessary tests. The key informants felt that monetary incentives did not determine utilization or volumes of tests. Ethical and quality decision-making about what is best for the patient is upheld in for-profit community labs and hospital labs, although the key informants were not as familiar with incentives in physician-owned labs and Public Health Ontario labs. Indeed it is worth noting that after the data collection was complete, the recommendations voiced by key informants in their interviews were largely implemented in 2018 when the MOHLTC updated the SOB-LS; these revisions delisted 110 test codes, revised 203 fee codes, updated specimen collection codes to better reflect the true costs of collecting and transporting specimens in rural and urban SCCs, and added one fee code for community labs to perform a genetic test called Non-Invasive Prenatal Testing. Another funding change allowed hospital labs to bill for some tests performed on community patients. Previously, as noted in section 5.2.1.1, hospitals did not receive extra funding for performing certain tests on outpatients. All recommendations by the key informants

noted in this thesis were addressed in these revisions, except for adding new medically necessary tests to the SOB-LS; the changes only added one genetic test to the SOB-LS.

Although this was beyond the scope of this thesis, future research could examine how the new test prices which were updated in 2018 in the SOB-LS were decided on and how accurate the price paid to labs is compared to the actual lab costs. It would also be useful to determine if tests deemed obsolete in the updated SOB-LS were indeed no longer used in practice. If the delisted tests are still used in the health care system but require special circumstances for them to be ordered, it would be interesting to learn if patients are now paying out of pocket for these tests. It would be useful to explore the role of information systems that provide health providers access to lab results and how inappropriate, repeat testing can be avoided by improving information sharing among labs.

The ownership structure of each lab sets the foundation for how that lab will operate and the licensure and regulations that apply to it. The key informants from the for-profit lab sector suggested that there is room for improvement when it comes to transparency and accountability between for-profit labs and the MOHLTC. The key informants believe that increased transparency in what actual community for-profit lab costs are would better inform the MOHLTC what it should be paying the labs for tests. They suggested that there is room for for-profit corporations to perform lab tests, particularly if the tests are highly measurable. It is felt by the key informants that it is the responsibility of the MOHLTC to provide regular assessments and adequate oversight of community for profit labs to improve the efficiency and cost-effectiveness of tests provided.

In terms of quality assurance, IQMH provides a rigorous mandatory process with high expectation of all labs that it accredits-except for physician-owned labs. There are considerable voluntary internal quality accreditation programs within hospital labs and for-profit community labs, with some overlap with accreditation provided by IQMH. The data suggests that more work needs to be completed by IQMH to measure and assess pre-analytical and post-analytical variables, which tend to have a higher error rate than the more easily measurable analytical phase of lab testing.

As noted by the key informants, there appears to be adequate oversight and regulation of health personnel working in the laboratory sector, with an aim to regulate the profession that was not yet part of a regulatory body, the Medical Laboratory Assistants/Technicians.

Access to necessary lab services is being made possible in Ontario through increased repatriation of genetic testing from the United States and into hospital labs and some community for-profit labs. Partnerships that form between hospital labs located in urban and rural regions ensure patients in rural Ontario have their tests interpreted by specialists located in urban settings. There is still variable data on the cost effectiveness of some regional partnership models. Further work needs to be done to better understand the access to specimen collection centres in different regions of Ontario and how it impacts patient access as Ontario continues to have a lower rate of specimen collection centres as compared to other provinces.

While looking at the Ontario lab quality assurance programs, funding models, ownership structures and access to care, this study found that the funding models did not incentivize unnecessary testing, probably because requisitions for testing had to be completed by physicians. The physicians in hospital labs were less likely to order unnecessary tests as compared to practitioners in the community due to algorithms and support in the form of education from hospital laboratory experts. However, community labs were not incentivized to educate community physicians on proper ordering practices. However, there was no data available about ordering practices of physicians in physician-owned labs (where there were possible incentives for unnecessary testing), as none of the key experts were familiar with that part of the lab sector. Key informants suggested that any updates to funding models should allow the money to follow the patient, meaning that the labs that did the test should receive the funding for it. This is evident in the dilemma that hospitals experience when they provide testing to outpatients but cannot bill the MOHLTC for this. Another key observation that pertains to the funding model is the inability of the MOHLTC to provide an assessment of appropriateness of funding due to the fragmented management of the lab sector. Some tests could be provided at a lower cost and in a different lab facility that would benefit the patient, but the different categories of labs are managed by different departments within the MOHLTC.

As noted in section 5.4, quality management encompasses accreditation and proficiency testing. Quality standards remain the same for the three licensed lab types and are generally high. Proficiency testing for the analytical phase is well measured, and efforts are ongoing to capture pre and post-analytical errors such as mislabeling patient samples. One area of concern was variability in the performance targets for each lab type that were collected by the MOHLTC. Public Health Ontario labs had the most number of reported performance measures, followed by

hospital labs and finally community labs. Physician owned labs do not report any metrics. In order to provide high quality care across all labs in Ontario, it was recommended by the key informants that reporting should be standardized and collected regularly.

The key informants described the mechanisms that are available to ensure that private for-profit labs adhere to societal goals and act for the best of broader public objectives. This includes regulation of professionals, maintaining a rigorous quality assurance program, and updating the Schedule of Benefits-Laboratory Sector regularly to reflect true expenses of labs.

Although medical laboratories vary in each province by ownership and funding structures, understanding the lab sector in Ontario can identify leading practices that can inform the strategy and delivery methods in other provinces.

**Appendices: A-G**

Appendix A: Interview Guide

**Preamble:** Thank you for taking the time to meet with me and completing this interview with me. As I described in my introductory email, I'm a Master student at the University of Toronto conducting my thesis research on the privet public mix of the medical laboratory sector. This interview will not take any longer than 1 hour, and at any point if you would like to stop or withdraw, please feel free to do so. If at any point after the interview you wish to withdraw the data your provided during the interview, you can email me and the data will be withdrawn without questions asked, until approximately July of this year. After that, the data will be analyzed and it will be difficult to extract your excerpts.
Did you get a chance to review the consent form? Did you have any questions about the consent form?

I would like to start by learning a little bit about your background. How long have you been working as a _____(insert profession here). How long have you been working in the medical laboratory sector?
Ok great, I will move on to the first set of broad questions pertaining to payment and funding methods.

1) Who pays for what in community laboratories and hospital labs?

Are there tests that are not insured in community labs but are paid for in hospital?

Does the Schedule of Benefits encompass all tests performed in community labs and hospital labs?

Are the same fees paid for both?

How do monetary incentives impact appropriateness of testing practices in each kind of lab?

The second set of research questions aims to answer the kinds of tests that are completed in a for profit and not for profit lab.

2) What are the array of different tests that are done in each type of lab?

Who decides where lab tests can be performed?

How do new laboratory tests get approved for coverage?

Great, I'll switch gears and talk about the quality measures that are required for labs.

3) What are the differences in quality assurance programs between community and hospital labs?

Are there internal quality measures that differ for each lab that do not pertain to the Institute of Quality Management in Healthcare?

The last set of research questions aim to answer about the workforce of the different labs.

4) Who is allowed to perform tests?

Who is able to order tests?

Does it vary by setting?

Closing

In closing, I wanted to ask if you had any questions for me about anything we talked about or the research that I'm conducting?

Would it be alright for me to contact you in the future if I require any clarification or detail about anything that we talked about tonight?
Would you want to have a copy of the final results? If so, what email address should I use to send the final paper?

I want to thank you for your time in answering my questions and helping me understand your experience.

Appendix B: Invitation Letter

**Email Recruitment Script**
**Anna Lvin BSc,**
**Masters Candidate in Science**

**Explaining the Public Private mix of the Ontario Medical Laboratory Sector**

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**E-mail Subject line: University of Toronto Study - Explaining the Public Private mix of the Ontario Medical Laboratory Sector**

I am inviting you to complete an interview with myself which will last no more than 1 hour. As part of the graduate program in Health Services Research at the University of Toronto, I am carrying out a study to better understand the public and private organizational structure of Ontario's medical laboratory sector. I'm interested in learning about the landscape of the lab sector, including quality assurance, funding models, new tests being added to the Schedule of Benefits, among other questions.

*A few options will exist on explaining how this individual was selected:*
I selected your name from an article that you helped write about the Ontario Medical lab sector.
OR
I selected your name after you had spoken in a lecture during a graduate course at the Institute of Health Policy Management and Evaluation.
OR
I selected your name after our brief conversation at X location.
The risks in this study are very limited as you are able to control how much you would like to reveal during the interview. The interview will be conducted at the date, time and location most convenient to you.
You can stop being in this study any time during the interview and afterwards up to July 2017.
This study has been reviewed and cleared by the University of Toronto Research Ethics Board.
If you are interested in participating, please review the attached informed consent form.

I would like to thank you in advance for your time and consideration. If you would like to participate, please let me coordinate a date and time most convenient for you with your administrative assistant staff.

Ann Lvin, BSc
Masters Candidate in Health Services Research

Institute of Health Policy Management and Evaluation
University of Toronto
Tel: 416-230-8394
**Anna.lvin@mail.utoronto.ca**

Appendix C: Consent Letter

**Date**

**A Study about the Public Private Mix of the Ontario Medical Laboratory Sector**


Supervisor:
Dr. Raisa Deber
Institute of Health Policy, Management and Evaluation
University of Toronto
Toronto, Ontario, Canada
raisa.deber@utoronto.ca

Student Investigator:
Anna Lvin
Institute of Health Policy, Management and Evaluation
University of Toronto
Toronto, Ontario, Canada
anna.lvin@mail.utoronto.ca
416-230-8394


**Purpose of the Study:**
To understand the current landscape of the Ontario Medical Laboratory Sector.

You are invited to take part in this study, conducted as part of my thesis, on the private and public mix of the medical lab sector. We are trying to better understand the different funding models that exist in community labs, hospital labs and physician owned labs, as well as the quality assurance measures in place, who is able to order lab tests and how new lab tests are added to the schedule of Benefits.

**Procedures involved in the Research:**
Semi structured in-person interviews will last no more than one hour and will involve myself asking you a series of questions pertaining to the thesis work. I would like to take hand written notes supplemented by an audio recorder in order to comply with standard practices but only with your permission. Alternatively, if a telephone interview is preferred, that can be set up as well. A sample question would be 'Who pays for what in community laboratories and hospital labs? Or 'Are there tests that are not insured in community labs but are paid for in hospital?

You will be asked to answer questions to the best of your ability and knowledge. You will be asked not to mention any names of colleagues or persons within the sector as to protect their privacy. You might be asked questions that you may not feel you can answer, at which point you will not need to.

**Potential Harms, Risks**:
It is not likely that there will be any harms or discomforts from answering the questions. The questions are broad and only seek clarity and information on processes and facts that are

common knowledge but are not found in the current literature available to the public. You do not need to answer questions that you do not want to answer or that make you feel uncomfortable.

**Confidentiality**

You are participating in this study confidentially. I will not use your name or any information that would allow you to be identified. However, since the laboratory community is small, others may be able to identify you from references you make. Please keep this in mind during the interview process.

Every effort will be made to protect your confidentiality and privacy. The audio recorder used during the interview will be kept in a secure, safe drawer with a key which only the student investigator will have a copy of. Once the interviews are transcribed, the encrypted USB will only be handled by myself and one other coder who will only save codes/themes on the encrypted USB key, and perhaps the supervisor. One other qualitative researcher who will be appointed by the supervisor to assist in analyzing and coding the de-identified data will have access to the de-identified transcripts on the encrypted USB. The key to identify participants will be kept on a password protected laptop and will not be accessed by anyone other than the student investigator and supervisor. No hard copy media will be used eg paper transcripts. The NVivo software will only contain de-identified data. The researcher will save all of their analysis on the USB and not save any documents on their personal computer.

**Potential Benefits**

The research will not benefit you directly. I hope that what is learned as a result of this study will help us to better understand the role that privatization plays in the laboratory sector. This could contribute to the exploration of the difference between public and private labs and findings could provide insight into the factors that differentiate private and public labs. These factors could potentially be used as policy levers aiding in future lab sector decisions that determine what role the private lab sector should play in delivering lab services.

**Withdrawal**

Your participation in this study is voluntary and if you decide you no longer would like to be part of the study, you can withdraw from the interview for whatever reason. This can be done after the interview and even after signing the consent form. If you would not like for me to use the information provided in the interview, you can withdraw that information until approximately September of 2017.

This study has been reviewed by the University of Toronto Research Ethics Board and has received ethics clearance. If you have concerns about your rights as a participant or about the way the study is conducted, please contact:

*Social Sciences, Humanities and Education REB*
**Chair:** Professor Matthew Brower
**Research Ethics Manager:** Dr. Dean Sharpe

**CONSENT**

I have read the information presented in the information letter about a study being conducted by Anna Lvin of the University of Toronto. I have had the chance to ask questions and receive any additional details. I understand I may withdraw form this study at any time, up until September 2017.

I agree to participate in the study.

I agree that the interview can be audio record

_____Yes

_____ No

Signature: _____ Date: _____

Name of Participant (Printed) _____

Appendix D: Code Book Used to Code Key Informant Interviews

| Categories | Sub-categories | Description |
|---|---|---|
| Funding models | Hospital labs<br>For profit community labs<br>Public Health Ontario Labs<br>Physician Owned labs | -Uninsured services that vary between setting (hospital vs community lab)<br>-Global budget<br>-Variability in fees paid to labs<br>-Point of Care testing payment schemes<br>-Schedule of Benefits<br>Laboratory Sector Payment<br>-Private out of pocket/insurance |
| Structure and organization of the laboratory sector | Hospital labs<br>For profit community labs<br>Public Health Ontario Labs<br>Physician Owned labs | -Governance<br>-Accreditation processes<br>-Legislation<br>-Licensure<br>-Regulation<br>-Nature of work differs between lab types<br>-Accountability structure<br>-Ownership structure |
| Key Organizations | Not-for-Profit<br>For-Profit<br>Government<br>Regulatory Bodies | -LifeLabs/Dynacare<br>-Hospital labs<br>-Sick Kids<br>- University Health Network<br>-Public Health Ontario<br>-Ontario Association Medical Laboratories<br>-College of Physicians & Surgeons of Ontario<br>- Ministry of Health and Long Term Care<br>-Local Health Integration Network<br>-College of Medical Laboratory Technologists of Ontario<br>-Institute of Quality Management in Healthcare |

| Categories | Sub-categories | Description |
|---|---|---|
| Modernization of the Funding models | Schedule of Benefits Laboratory Sector<br>Global budget Payment model | -Approval for new tests process<br>-Delisting of tests<br>-Cost analysis per test<br>-Impact of technology/automation |
| Public and Private organizations as a provider of health care | Competition<br>Production characteristics<br>Monetary incentives | -advantages/disadvantages<br>-appropriate role |
| Genetic Lab Testing | Hospital labs<br>Community for-profit labs<br>Repatriation of tests | -Bringing tests in-house from out-of-province and out-of-country<br>-Universal coverage of new genetic tests<br>-Strategy for |
| Quality Assurance Programs | Institute of Quality Management in Healthcare<br>Hospital labs and community for-profit lab quality differences<br>Ontario Medical Association | -Internal quality improvement measures<br>-External quality assessment measures<br>-POCT quality measures<br>-Laboratory proficiency measures<br>-clinical<br>-technical<br>-pre-analytical, analytical and post-analytical quality analysis<br>-Ontario Laboratory Accreditation |

| Categories | Sub-categories | Description |
|---|---|---|
| Partnership Programs | -Eastern Ontario Regional Laboratory Association<br>-UHN and Timmins Northeast Cluster | -Impact on access<br>-Specimen collection Centres<br>- Specialists<br>-Variability in agreements province wide<br>-Profit sharing incentives<br>-Challenges of autonomous governance structures in hospitals<br>-Consolidation of equipment<br>-Economies of scale<br>-Sharing of resources |
| | -Past/present failed partnerships | |
| | -Hospital/hospital partnerships | |
| | -Hospital/community labs partnerships | |
| Health Human Resources | Regulated Health Professions Act | - Regulation of HHR<br>- Ordering physicians<br>- Medial laboratory technologists/technicians |
| | - College of Medical Laboratory Technologists of Ontario | |
| | - College of Physicians and Surgeons of Ontario | |

Appendix E REB Application

ETHICS REVIEW APPLICATION FORM FOR

SUPERVISED AND SPONSORED RESEARCHERS
(For use by graduate students, post-docs, residents, external investigators, and visiting professors/researchers)

**Before you start, familiarize yourself with:**
TCPS2
Application instructions
Office FAQs

## SECTION A – GENERAL INFORMATION

### 1. TITLE OF RESEARCH PROJECT

**Explaining the Public Private mix of the Ontario Medical Laboratory Sector**

### 2. INVESTIGATOR INFORMATION

**Investigator:**

| | |
|---|---|
| Title (e.g., Dr., Ms., etc.):Miss | Name: Anna Lvin |
| Department (or organization if not affiliated with U of T): Institute of Health Policy Management and Evaluation | |
| Mailing address: 12 Douro Street Unit 425, Toronto, ON M6K 3M4 | |
| Phone: 416-230-8394 | Institutional e-mail: anna.lvin@mail.utoronto.ca |

**Level of Project:**

| | |
|---|---|
| Student Research: Doctoral ☐ | Masters ☐X |
| Post-Doctoral Research ☐ | Visiting professor/External researcher ☐ |
| Course Based ☐ | |
| CBR/CBPR ☐ | Other ☐ (specify: ) |

**Supervisor/Sponsor (must be a UofT faculty member with research privileges):**

| | |
|---|---|
| Title:Dr. | Name: Raisa Deber |
| Department: Institute of Health Policy Management and Evaluation | |
| Mailing address: 4th Floor, 155 College St, Toronto, ON M5T 3M6 | |
| Phone: | Institutional e-mail: raisa.deber@utoronto.ca |

**Co-Investigators:**

Are co-investigators involved? Thesis committee member Yes ☐X No ☐

| | |
|---|---|
| Title: Dr. | Name: Brenda Gamble |

| | |
|---|---|
| Department (or organization if not affiliated with U of T): Associate Professor Faculty of Health Sciences University of Ontario Institute of Technology | |
| Mailing address: Science Building - Room 3023<br>North Oshawa<br>2000 Simcoe Street North<br>Oshawa, ON L1H 7K4 | |
| Phone:<br>905.721.8668 ext. 2934 | Institutional e-mail: brenda.gamble@uoit.ca |

| | |
|---|---|
| Title: | Name: |
| Department (or organization if not affiliated with U of T): | |
| Mailing address: | |
| Phone: | Institutional e-mail: |

***Please append additional pages with co-investigators' names if necessary.***

## 3. UNIVERSITY OF TORONTO RESEARCH ETHICS BOARD:

Social Sciences, Humanities and Education ☐ Health Sciences X☐
HIV/AIDS ☐

To determine which Research Ethics Board (REB) your application should be submitted, please consult: http://www.research.utoronto.ca/about/boards-and-committees/research-ethics-boards-reb/

## 4. LOCATION(S) WHERE THE RESEARCH WILL BE CONDUCTED:

(a) If the research is to be conducted at a site requiring administrative approval/consent (e.g., in a school), please include all administrative consent letters. It is the responsibility of the researcher to determine what other means of approval are required, and to obtain approval prior to starting the project.

University of Toronto ☐
Hospital ☐ specify site(s)
School board or community agency ☐ specify site(s)
Community within the GTA ☐**X** specify site(s) Participant offices, preferential location as per participant, over the phone.
International ☐ specify site(s)
Other ☐ specify site(s)

(b) For all off-campus research, whether in the local community or internationally, the researcher should consult with the Framework on Off-Campus Safety, Guidelines on Off-Campus Safety, and Guidelines on Safety in Field for institutional requirements.

(c) **The University of Toronto has an agreement with the Toronto Academic Health Sciences Network (TAHSN) hospitals regarding ethics review of hospital-based research where the University plays a peripheral role. Based on this agreement, certain hospital-based research may not require ethics review at the University of Toronto. If your research is based at a**

**TAHSN hospital, please consult the following document to determine whether or not your research requires review at the University of Toronto.** http://www.research.utoronto.ca/faculty-and-staff/research-ethics-and-protections/humans-in-research/ - "Administrative review" heading toward the bottom of the page.

## 5. OTHER RESEARCH ETHICS BOARD APPROVAL(S)

(a) Does the research involve another institution or site? Yes ☐ No ☐**X**

(b) Has any other REB approved this project? Yes ☐ No ☐**X**

If **Yes**, please provide a copy of the approval letter upon submission of this application.

If **No**, will any other REB be asked for approval?

Yes ☐ (please specify which REB) No ☐**X**

## 6. FUNDING OF THIS PROJECT

(a)

| Funding Status | Source and Type | Details |
|---|---|---|
| Funded ☐ | Agency: | Fund #: 4 (6 digits) |
| | Agency: | Fund # :4 (6 digits) |
| Applied for funding ☐ | Agency: | Submission date: |
| | Agency: | Submission date: |
| Unfunded ☐**X**<br>If unfunded, please explain why no funding is needed: As a part time MSc student, all data collection and analysis will be done by myself with the assistance of my supervisor. Funding is not required for any stage of the research as the entire project will be completed on my own time, effort and spend. Participants will not be compensated. | | |

## 7. CONTRACTS AND AGREEMENTS

(a) Is this research to be carried out as a contract or under a research agreement? Yes ☐ No ☐**X**

If yes, is there a University of Toronto funding or non-funded agreement associated with the research? Yes ☐ No ☐**X**

If **Yes,** please append a copy of the agreement with of this application.

Is there any aspect of the contract that could put any member of the research team in a potential conflict of interest? Yes ☐ No ☐**X**

If yes, please elaborate under #10.

(b) Is this a Division 5, Health Canada regulated clinical trial that involves drugs, devices or natural health products?

Yes ☐ No **X**☐ (if so, the application must be reviewed by the full board)

## 8. PROJECT START AND END DATES

Estimated start date for the component of this project that involves human participants or data: February 2017
Estimated completion date of involvement of human participants or data for this project: June 2017

## 9. SCHOLARLY REVIEW:

(a) Please check one:

I. ☐**X** The research has undergone scholarly review by thesis committee, departmental review committee, peer review committee or some other equivalent (Specify review type – e.g., departmental research committee, supervisor, CIHR, SSHRC, OHTN, etc.):
Thesis committee comprised of supervisor and one other committee member that is an expert in the field.

II. ☐ The research will undergo scholarly review prior to funding
(Specify review committee – e.g., departmental research committee, SSHRC, CIHR peer-review committee, etc.):

III. ☐ The research will not undergo scholarly review (Please note that all research greater than minimal risk requires scholarly review)

(b) If box I or II above was checked, please specify if:

☐**X** The review was/will be specific to this application

☐ The review was/will be part of a larger grant

## 10. CONFLICTS OF INTEREST

(a) Will the researcher(s), members of the research team, and/or their partners or immediate family members:

(i) Receive any personal benefits (e.g., financial benefit such as remuneration, intellectual property rights, rights of employment, consultancies, board membership, share ownership, stock options, etc.) as a result of or in connection with this study? Yes ☐ No ☐**X**

(ii) If **Yes**, please provide further details and discuss how any real, potential or perceived conflicts of interest will be managed during the project. (Do not include conference and travel expense coverage, or other benefits which are considered standard for the conduct of research.)

(b) Describe any restrictions regarding access to or disclosure of information (during or at the end of the study) that have been placed on the investigator(s). These restrictions include controls placed by the sponsor, funding body, advisory or steering committee.

No restrictions have been placed

(c) Where relevant, please explain any pre-existing relationship between the researcher(s) and the researched (e.g., instructor-student; manager-employee; clinician-patient; minister-congregant). Please pay special attention to relationships in which there may be a power differential – actual or perceived.

The participants who will be interviewed have no current or existing relationship with the researcher (myself). There may be conflict between the supervising committee and participants, as some of the participants are known to the committee members but there is no formal relationship and no power differential.

## SECTION B – SUMMARY OF THE PROPOSED RESEARCH

### 11. RATIONALE

Describe the purpose and scholarly rationale for the proposed project. State the hypotheses/research questions to be examined. The rationale for doing the study must be clear. Please include references in this section.

The purpose for the proposed project is to better understand the implications of different types of ways in which laboratory services are organized. Using the case example of Ontario, laboratories can be divided into two major categories: hospital labs, and community labs. Community labs can be further subdivided into physician owned labs, and for-profit labs. The funding models differ for these, and hence the incentives to perform tests vary by type of laboratory. One key question is how these different incentives may influence the behavior of the labs, including what tests they do, the volume of services, and the quality assurance activities. This information can in turn contribute to a better understanding of the implications of different ways of funding and organizing health care services. (Madore, Tiedemann, 2005). The research will contribute to the exploration of the difference between different laboratory models (Sullivan, Gordon & Minto, 2015).
The research questions are broken down into four umbrella questions with further probing questions that follow. The first set of research questions are:

1) Who pays for what in community laboratories and hospital labs?

Are there tests that are not insured in community labs but are paid for in hospital?
Does the Schedule of Benefits encompass all tests performed in community labs and hospital labs? Are the same fees paid for both?
How do monetary incentives impact appropriateness of testing practices in each kind of lab?
The second set of research questions aims to answer:

2) What are the array of different tests that are done in each type of lab? Who decides where lab tests can be performed? How do new laboratory tests get approved for coverage?

The third question assesses quality assurance, specifically:

3) What are the differences in quality assurance programs between community and hospital labs?

The last set of research questions aim to answer

4) Who is allowed to perform tests?

Who is able to order tests? Does it vary by setting?

### 12. METHODS

(a) Please describe all formal and informal procedures to be used. Describe the data to be collected, where and how they will be obtained and how they will be analyzed.

Semi structured, face-to-face interviews with key stakeholders from the medical laboratory sector will be conducted to gain further insight into the four research questions outlined above. Interviews will be conducted by me, using audio recording and providing guidance to ensure the discussion is efficient, on topic and does not exceed approximately 1 hour in length. Interview schedules will be decided with the help of the participants in order to better accommodate their busy schedules. The interviewees will be asked about funding models within community and hospital labs, the ability of the current Schedule of Benefits to encompass all lab tests, array of tests done in labs, quality assurance programs within the lab industry and the roles of professionals involved in providing lab tests.

Analysis

The data will be analyzed using a rigorous content analysis process, which is widely used in health-related disciples (Elo & Kyngas, 2007). This method is suitable for identifying, analyzing and reporting patterns recognized within conducted interviews. When using this method, generally there is an idea about which themes might emerge and researchers are able to look for the themes within the data. This will be the case for some of the research questions, where the document review has helped illuminate possible concepts and themes which may be discussed within the interviews. Armed with a good understanding of the topic, the transcripts will be analyzed for patterns using ideas introduced by the website. Research questions that have no starting data mentioned in the document review will solely use the transcripts to look for answers, themes and concepts. Before the coding portion of the analysis begins, a thorough examination of the data will help identify major, broad themes. Coding will be used to 'transform raw data into a standardized form' (Kohlbacher, 2006), and will help reduce text into a unit-by-variable matrix to help group the data and find patterns. Data triangulation will be used where possible, to enhance validity by ensuring the multiple data sources provide a rich and robust data set (Gamble, Bourne & Deber, 2014). Two reviewers will analyze the findings and NVivo software will be used to manage and organize the data.

(b) Attach a copy of all questionnaires, interview guides and/or any other instruments.

(c) Include a **list of appendices** here for all additional materials submitted (e.g., Appendix A – Informed Consent; Appendix B – Interview Guide, etc.):

Appendix A- Initial introductory email
Appendix B- Informed Consent Form
Appendix C- Interview Guide

**13. PARTICIPANTS, DATA AND/OR BIOLOGICAL MATERIALS**

(a) Describe the participants to be recruited list the eligibility criteria, and indicate the estimated sample size (i.e. min-max # of participants). Where applicable, please also provide a rationale for your choice in sample size and/or sample size calculation.

The participants to be recruited are experts in the medical laboratory sector at either the administrative level, teaching or managing level. The key informants to be contacted will include MOHLTC employees working directly with the labs, Quality assurance organizations,

pathologists, community lab CEOs, managers of allied service providers, advocacy groups for lab technologists and advisors on future laboratory strategy committees. The estimated sample size is between 10-12 interviews. This number was estimated based on the literature review experts that could be contacted in Toronto and the GTA for interviews. Saturation of each research question will be a goal, and although the participants have a wide range of occupations, the questions are broad enough that each participant could contribute to the overall scope and depth of answers. The number of interviews intended to be conducted is a flexible number and sufficient time has been set aside in case more interviews are required to reach data saturation.

Where the research involves extraction or collection of personally identifiable information, please describe the purpose, from whom the information will be obtained, what it will include, and how permission to access the data is being sought. (Strategies for recruitment are to be described in section #15.)

(b) The only personally identifiable information collected will be the participants' current occupation/position in the medical laboratory sector. Each participant will be given a unique identifier in order to keep their names anonymous. Participants will be asked not to mention colleagues or names from organizations that would reveal their identity or provide any private information which is not common knowledge among lab experts. However, I may cite identifiable information if it is in the public domain, or if explicit permission is given. Audio recording of participants will be collected for accurate qualitative research measures and will be kept until they have been transcribed and verified by the participant.

(c) Is there any group or individual-level vulnerability related to the research that needs to be mitigated (for example, difficulties understanding informed consent, history of exploitation by researchers, power differential between the researcher and the potential participant)? If so, please provide further details below

It is not believed that there will be any individual-level vulnerability related to the research as they are senior, high level individuals working within medical lab sector organizations.

(d) If your research involves the collection and/or use of biological materials (e.g. blood, saliva, urine, teeth, etc.), please provide details below. Be sure to indicate how the samples will be collected and by whom.

N/A

**14. EXPERIENCE OF INVESTIGATORS WITH THIS TYPE OF RESEARCH**

Please provide a brief description of previous experience by (i) the principal investigator/supervisor or sponsor, (ii) the research team and (iii) the people who will have direct contact with the participants. If there has not been previous experience with this type of research, please describe how the principal investigator/research team will be prepared.

As a Masters student, I have not had previous experience interviewing participants for a research project. I will however be prepared by taking courses prior to the interviews which will ready me for this experience. An Introduction to Qualitative Course at the Institute of Health Policy Management and Evaluation (IHPME) provides graduate students with the opportunity to create

their own research question and interviews. The supervisor of my research has vast knowledge and experience guiding graduate students through MSc and PhDs in both quantitative and qualitative theses. My thesis committee member has a particular interest in public/private sectors in health care and has a thorough knowledge of the Medical Laboratory Sector.

**15. RECRUITMENT OF PARTICIPANTS**

Where there is recruitment, please describe how, by whom, and from where the participants will be recruited. Where participant observation is to be used, please explain the form of insertion of the researcher into the research setting (e.g., living in a community, visiting on a bi-weekly basis, attending organized functions). If relevant, describe any translation of recruitment materials, how this will occur and whether or not those people responsible for recruitment will speak the language of the participants.

All participants will be initially contacted via email from me, with their administrative assistants cc'd if that information is available. An introductory email will provide information about myself and the research being conducted. The consent form will be attached to the original email. The participant will be asked to be interviewed either in person or over the phone. If the telephone interview option is more convenient, a structured key informant interview tool will be used to address the primary questions (Section 4 Key Informant Interviews n.d.). Informed consent for participants who cannot attend the interview in person will be signed by the participant, scanned and sent back to the researcher before the interview occurs. A list of potential candidates was created during the literature review phase of the project to identify possible candidates who have written relevant articles about the lab sector and who live in Toronto or Greater Toronto Area. Participants may also recommend other potential participants whose knowledge and experience may be relevant to the research projects. These participants will also be contacted via the introductory email.

**Attach a copy of all posters, advertisements, flyers, letters, e-mail text, or telephone scripts to be used for recruitment as appendices.**

**16. COMPENSATION**

**Please see U of T's Compensation and Reimbursement Guidelines.**

(a) Will participants receive compensation for participation?

| | | |
|---|---|---|
| Financial | Yes ☐ | No ☐X |
| In-kind | Yes ☐ | No ☐X |
| Other | Yes ☐ | No ☐X |

(b) If **Yes**, please provide details and justification for the amount or the value of the compensation offered.

(c) If **No**, please explain why compensation is not possible or appropriate.

This research project did not receive any funding, awards or grants therefore there is no financial support available for participants. The participants will be made as comfortable as possible during the interview process, with scheduling and timing respecting their busy schedules. As some of them have been contacted in the preliminary research stage and ideas for possible

research questions were discussed, many seemed passionate to share their knowledge and fill the gap in the literature that exists in the Ontario medical lab sector. Not providing compensation will rely on participants' goodwill to complete the interviews to the best of their ability.

(d) Where there is a withdrawal clause in the research procedure, if participants choose to withdraw, how will compensation be affected?

N/A

**SECTION C –DESCRIPTION OF THE RISKS AND BENEFITS OF THE PROPOSED RESEARCH**

**17. POSSIBLE RISKS**

(a) Please indicate all potential risks to participants as individuals or as members of a community that may arise from this research:

(i) Physical risks (e.g., any bodily contact or administration of any substance): Yes ☐ No ☐X

(ii) Psychological/emotional risks (e.g., feeling uncomfortable, embarrassed, or upset): Yes ☐ No ☐X

(iii) Social risks (e.g., loss of status, privacy and/or reputation): Yes ☐ No ☐X

(iv) Legal risks (e.g., apprehension or arrest, subpoena): Yes ☐ No ☐X

(b) Please briefly describe each of the risks noted above and outline the steps that will be taken to manage and/or minimize them.

**18. POSSIBLE BENEFITS**

- Describe any potential direct benefits to participants from their involvement in the project
- Describe any potential direct benefits to the community (e.g., capacity building)
- Comment on the potential benefits to the scientific/scholarly community or society that would justify involvement of participants in this study

I do not believe that the participants will receive any direct benefits from their involvement in the project.
Potential benefit to the community would be the knowledge acquired from the interviews which will give community members a better understanding of how the not-for-profit and for-profit labs in Ontario operate. Health care planning is a common outcome of descriptive research by providing surveillance of health states and descriptions of characteristics of a health care phenomenon (Barratt, Kirwan, 2009). a hypothesis may be generated about the current state of the Ontario lab sector and the roles of the private sector in health care. Although the creation and validation of a hypothesis is not the goal of this proposal, it can aid in the developing of health care policies in Ontario with regards to the lab sector. As the information extracted from the interviews is not common knowledge and is mostly not available from the literature, providing it

to the public could reveal undesirable processes that could be altered. On the contrary, if the collected data divulges data that shows competent, reliable lab processes, then this is also beneficial information for future policymakers.

## SECTION D – INFORMED CONSENT

### 19. CONSENT PROCESS

(a) Describe the process that will be used to obtain informed consent and explain how it will be recorded. Please note that it is the quality of the consent, not the form that is important. The goal is to ensure that potential participants understand to what they are consenting.

A clear and concise consent form will be emailed to participants during the introductory email. At the beginning of each interview, time will be taken to ensure participants understood the consent and did not have any questions before it is signed. For participants who are partaking in phone interviews, the form will be signed, scanned and emailed back to the researcher. Again, at the beginning of the interview it will be reviewed briefly to ensure the participant is comfortable with the consent.

(b) If the research involves extraction or collection of personally identifiable information from or about a research participant, please describe how consent from the individuals or authorization from the data custodian (e.g., medical records department, district school board) will be obtained.

The only personally identifiable information obtained will be the first and last name, occupation, and audio recording.

### 20. CONSENT DOCUMENTS

(a) **Attach an Information Letter/Consent Form**
For details about the required elements in the information letter and consent form, please refer to our informed consent guide (http://www.research.utoronto.ca/wp-content/uploads/documents/2014/10/GUIDE-FOR-INFORMED-CONSENT-V-Oct-2014.pdf**)**

**Additional documentation regarding consent should be provided such as:**

- **screening materials introductory letters, letters of administrative consent or authorization**

(b) If any of the information collected in the screening process - prior to full informed consent to participate in the study - is to be retained from those who are later excluded or refuse to participate in the study, please state how potential participants will be informed of this course of action and whether they will have the right to refuse to allow this information to be kept.

During the screening process, no information was collected other than the participant's name, email address and name of work place.

### 21. COMMUNITY AND/OR ORGANIZATIONAL CONSENT, OR CONSENT BY AN AUTHORIZED PARTY

(a) If the research is taking place within a community or an organization which requires that formal consent be sought prior to the involvement of individual participants, describe how consent will be obtained and attach any relevant documentation. If consent will not be

sought, please provide a justification and describe any alternative forms of consultation that may take place.

From my current understanding, no organizational consent will be required as the individuals speak strictly their opinion and their thoughts do not reflect that of the organization for which they work for. If the information they provide is in the public domain, then that will be cited if necessary. Nevertheless, if any information pertaining to the organization may appear sensitive or may reveal any undesirable information, the participant will be consulted as well as the supervisor to garner their opinion on the matter.

(b) If any or all of the participants are children and/or individuals that may lack the capacity to consent , describe the process by which capacity/competency will be assessed and/or, the proposed alternate source of consent.

N/A

(c) If an authorized third party will be used to obtain consent:

i) Submit a copy of the permission/information letter to be provided to the person(s) providing the alternative consent

ii) Describe the assent process for participants and attach the assent letter.

N/A

**22. DEBRIEFING and DISSEMINATION**

(a) If deception or intentional non-disclosure will be used in the study, provide justification. Please consult the Guidelines for the Use of Deception and Debriefing in Research

Deception and intentional non-disclosure will not be used in this study.

(b) Please provide a copy of the written debriefing form, if applicable.

( c ) If participants and/or communities will be given the option of withdrawing their data following the debriefing, please describe this process.

N/A

(d) Please describe what information/feedback will be provided to participants and/or communities after their participation in the project is complete (e.g., report, poster presentation, pamphlet, etc.) and note how participants will be able to access this information.

The participants will be asked if they would be interested in reading the completed thesis or potential publication, and if they would be interested in receiving a copy via email. If they agree, their email addresses will be confirmed and stored for future reference.

**23. PARTICIPANT WITHDRAWAL**

(a) Where applicable, please describe how participants will be informed of their right to withdraw from the project and outline the procedures that will be followed to allow them to exercise this right.

At the beginning of the interview, in the preamble, participants will be notified that if at any point they decide to stop the interview, there will be no negative consequence. If at any point after the interview they wish to not include their interview in the research, they are able to contact the researcher and all data will be withdrawn without questions.

(b) Indicate what will be done with the participant's data and any consequences which withdrawal may have on the participant.

Participants who no longer wish to participate in the study after the interview is conducted will be removed from the key code, their audio recording will be deleted along with the transcripts.

(c) If participants will not have the right to withdraw from the project at all, or beyond a certain point, please explain. Ensure this information is included in the consent process and consent form.

The only point at which the participants will not able to withdraw their data is after it has been embedded, analyzed and themes have been created within the thesis. All labels have been removed from all quotes at that stage and it would not be possible to identify which participant provided what information.

**SECTION E – CONFIDENTIALITY AND PRIVACY**

**24. CONFIDENTIALITY**

Data security measures must be consistent with UT's *Data Security Standards for Personally Identifiable and Other Confidential Data in Research.* All identifiable electronic data that is being kept outside of a secure server environment must be encrypted.

(a) Will the data be treated as confidential? Yes ☐X No ☐

(b) Describe the procedures to be used to protect the confidentiality of participants or informants, where applicable

The minimum amount of identifiable data will be collected during the interviews including name and current job role. The audio recorder with all recorded interviews will be kept in a drawer which locks with a key. All transcripts will be de-identified and the key will be kept separate in a password protected Excel spreadsheet. The transcripts themselves will be stored on a USB flash drive that comes with encryption.

( c) Describe any limitations to protecting the confidentiality of participants whether due to the law, the methods used, or other reasons (e.g., a duty to report)

A possible limitation to protecting the confidentiality of participants is the misplacement of the audio recording. The information collected is considered not to be highly sensitive therefore a duty to report should not be a necessary encounter.

## 25. DATA SECURITY, RETENTION AND ACCESS

(a) Describe how data (including written records, video/audio recordings, artifacts and questionnaires) will be protected during the conduct of the research and dissemination of results.

The audio recorder used during the interview will be kept in a secure, safe drawer with a key which only the principal investigator will have a copy of. The USB will be encrypted using Windows bitlocker and will only be handled by the principal investigator and one other coder who will only save codes/themes on the encrypted USB. The key to identify participants will be kept on a password protected laptop and will not be accessed by anyone other than the principal investigator and supervisor. The transcripts will be de-identified, and only the key to identify respondents will be capable of identifying the transcripts. This key to identify respondents will be kept until the data analysis portion of the study. A backup of the de-identified data will also be kept on a backup, encrypted USB as a precaution. Only de-identified data will be used in all analysis. No hard copy media will be used eg paper transcripts. The NVivo software will only contain de-identified data.

(b) Explain how long data or samples will be retained. (If applicable, referring to the standard data retention practice for your discipline) Provide details of their final disposal or storage. Provide a justification if you intend to store your data for an indefinite length of time. If the data may have archival value, discuss how participants will be informed of this possibility during the consent process.

The audio recordings will be kept until they have been transcribed and verified by the participant. At that time all interviews on the audio recorder will be deleted and the key linking identity to code will also be deleted. This would be approximately 8 months after data collection. The transcripts will be deleted from the USB key after analysis is completed.

(c) If participant anonymity or confidentiality is not appropriate to this research project, please explain.

It is appropriate and all measures will be taken to comply with confidentiality measures.

(d) If data will be shared with other researchers or users, please describe how and where the data will be stored and any restrictions that will be made regarding access.

One other qualitative researcher who will be appointed by the supervisor to analyze and code the de-identified data will have access to the de-identified transcripts on the encrypted USB to assist with data analysis. The researcher will save all of their analysis on the USB and not save any documents on their personal computer. The researcher will not have access to the key that identifies participants.

**SECTION F – LEVEL OF RISK AND REVIEW TYPE**

See the *Instructions for Ethics Review Submission Form* for detailed information about the Risk Matrix.

## 26. RISK MATRIX: REVIEW TYPE BY GROUP VULNERABILITY and RESEARCH RISK

(a) Indicate the Risk Level for this project by checking the intersecting box

| Risk / Group Vulnerability | Research Risk: Low | Research Risk: Medium | Research Risk: High |
|---|---|---|---|
| **Low** | **1** ☐X | **1** ☐ | **2** ☐ |
| **Medium** | **1** ☐ | **2** ☐ | **3** ☐ |
| **High** | **2** ☐ | **3** ☐ | **3** ☐ |

(b) Explain/justify the level of research risk and group vulnerability reported above:

The participants who will be interviewed are highly educated, knowledgeable experts in the field of medical laboratories. They will be aware of any information that should not be disclosed and will not share that information. They will be deliberate and concise with their answers to ensure no breach of trust or confidentiality within their institution will occur.

**(Please note that the final determination of Review Type and level of monitoring will be made by the reviewing University of Toronto REB)**

Based on the level of risk, these are the types of ethics review that an application may receive:

**Risk level = 1: Delegated Review; Risk level = 2 or 3: Full Board Review**

**For both delegated and full reviews (SSH&E, HS, or HIV)**, please submit one electronic copy of your application and all appendices (e.g., recruitment, information/consent and debriefing materials, and study instruments) as a **single** Word document or a pdf. *Do not submit your entire research proposal.* Please ensure that the electronic signatures are in place and e-mail to **new.ethics.protocols@utoronto.ca**

**The deadline for delegated review (SSH&E or HS) is EVERY Monday, or first business day of the week, by 4 pm. Information about full REB meeting and submission due dates are posted on our website** (SSH&E, HS or HIV).

**HIV REB reviews all applications at full board level but applies proportionate review based on the level of risk.**

**All other submissions (e.g., amendments, adverse events, and continuing review submissions) should be sent to ethics.review@utoronto.ca**

**SECTION G – SIGNATURES**

## 27. PRIVACY REGULATIONS

**My signature as Investigator, in Section G of this application form, confirms that I am aware of, understand, and will comply with all relevant laws governing the collection and use of personally identifiable information in research.** I understand that for research involving extraction or collection of personally identifiable information, provincial, national and/or international laws may apply and that any apparent mishandling of personally identifiable information must be reported to the Office of Research Ethics.

For U of T **student researchers**, my signature confirms that I am a registered student in good standing with the University of Toronto. My project has been reviewed and approved by my advisory committee or equivalent (where applicable). If my status as a student changes, I will inform the Office of Research Ethics.

| |
|---|
| Signature of Investigator: _____ Date: |

***For **Graduate Students**, the signature of the Faculty Supervisor is required. For **Post-Doctoral Fellows** and **Visiting Professors or Researchers**, the signature of the Faculty Sponsor is required. In addition to the supervisor/sponsor, the chair or the dean of the UoT sponsor's/supervisor's department is required to approve and sign the form***

As the UofT **Faculty Supervisor** of this project, my signature confirms that I have reviewed and approve the scientific merit of the research project and this ethics application submission. I will provide the necessary supervision to the student researcher throughout the project, to ensure that all procedures performed under the research project will be conducted in accordance with relevant University, provincial, national or international policies and regulations that govern research involving human subjects. This includes ensuring that the level of risk inherent to the project is managed by the level of research experience that the student has, combined with the extent of oversight that will be provided by the Faculty Supervisor and/or On-site Supervisor.

As the UofT **Faculty Sponsor** for this project, my signature confirms that I have reviewed and approve of the research project and will assume responsibility, as the University representative, for this research project. I will ensure that all procedures performed under the project will be conducted in accordance with all relevant University, provincial, national or international policies and regulations that govern research involving human participants.

| |
|---|
| Signature of Faculty Supervisor/Sponsor: _____<br>Date: |

As the **Departmental Chair/Dean**, my signature confirms that I am aware of the requirements for scholarly review and that the ethics application for this research has received appropriate review prior to submission.

In addition, my administrative unit will follow guidelines and procedures to ensure compliance with all relevant University, provincial, national or international policies and regulations that govern research involving human participants. My signature also reflects the willingness of the department, faculty or

division to administer the research funds, if there are any, in accordance with University, regulatory agency and sponsor agency policies.

| |
|---|
| Print Name of Departmental Chair/Dean (or designate) :<br><br>Signature of Departmental Chair/Dean: _____ Date:<br>(or authorized designate) |

Appendix F: Complete List of Documents Reviewed

| Article/Paper | Background/Historical | Payment Structure | Types of Tests | Quality Assurance | Medical Lab Personnel |
|---|---|---|---|---|---|
| Auditor General Report 2017 | X | X | X | X | X |
| Quality Management Program Laboratory Services(Q MP-LS) | | | | X | X |
| CMLTO Reports and Publications | | | | | X |
| Laboratory Services North East Local Health Integration Network. Integrated Health Service Place | X | X | | | |
| Critical Values Report on Ontario's Community MLS | X | | | | |
| Health Systems in Transition: Canada Health System Review | X | | | | |
| Laboratory Services Expert Panel | X | X | X | X | |
| Schedule 3 Laboratory and Specimen Collection Centre Licensing Act | | | | | X |

| Article/Paper | Background/Historical | Payment structure | Types of Tests | Quality Assurance | Medical Lab Personnel |
|---|---|---|---|---|---|
| Ontario Association Of Medical Laboratories | | | | X | X |
| Bill 87, Protecting Patients Act, 2017 | X | X | | | |
| Schedule of Benefits for Laboratory Sector, 2017 | | | | | X |
| Laboratory Services Review, 1992 | | X | | X | X |

Appendix G: Description of Relevant Key Stakeholders and Concepts in the Ontario Medical Laboratory Sector

| **Name of Organization** | **Description of Relevance to Ontario's MLS** |
|---|---|
| Cancer Care Ontario (CCO) | An agency of the provincial Government of Ontario that is responsible for improving cancer and renal services. |
| Colon Cancer Check Program (CCSP) | Ontario's organized screening program designed to encourage screening participation and reduce deaths from colorectal cancer |
| College of Medical Laboratory Technologists of Ontario (CMLTO) | The provincial regulatory body for medical laboratory technologists (MLTs). Its purpose is to ensure the public receives quality laboratory services by ensuring that MLTs are competent and ethical professionals. |
| College of Physicians and Surgeons of Ontario (CPSO) | Responsible for monitoring and maintaining standards of practice through peer assessment and remediation, developing policies to provide guidance to physicians about regulatory requirements, and investigating patient complaints. |
| Eastern Ontario Regional Laboratory Association (EORLA) | A non-profit organization encompassing 19 hospital based laboratories in the Champlain Local Health Integration Network which provides lab tests to both hospital in-patients and registered outpatients. |
| Health System Funding Reform (HSFR) | A new funding model for Ontario's hospitals which moves away from a global funding allocation and is meant to be more transparent, evidence-based and allows funding to be tied more directly to the quality care. There are two components to HSFR, which are Health Based Allocation (HBAM) and Quality Based Procedures (QBP). HBAM funding allocates a fixed amount of funding for each health service provider based on demographics of patients served. QBP funding is allocated for specific procedures based on a 'price x volume + quality' approach. |
| In Common Laboratories (ICL) | A private, not-for-profit laboratory diagnostic brokerage company. ICL's reference laboratories are primarily hospital-based, and improve the flow of lab tests and results that move through Ontario. |
| | |

| Name of Organization | Description of Relevance to Ontario's MLS |
|---|---|
| Institute of Quality Management in Healthcare (IQMH) | A not-for-profit corporation, and a subsidiary of the Ontario Medical Association, which is funded by the MOHLTC. The role of IQMH is to assess the quality and competence of all licensed labs in Ontario through regulated programs such as the Centre for Accreditation and Centre for Proficiency Testing. These programs are responsible for accrediting and examining laboratories and increasingly now specimen collection centres, which includes looking at processes within all three analytical phases (phase I,II and III). |
| Local Health Integration Network (LHIN) | Are the health authorities responsible for regional administration of public health care services in the province of Ontario, Canada. There are 14 LHINs in Ontario as of 2018. |
| Ministry of Health and Long-Term Care (MOHLTC) | The Government of Ontario Ministry responsible for administering the health care system and providing services to the province of Ontario. In this thesis, the MOHLTC can also be called 'the Ministry' interchangably |
| Medical Laboratory Technologists (MLT) | One of Ontario's regulated health professions, MLTs are responsible for performing lab tests on blood, body fluids, cells and tissues and must be certified by the CMLTO in order to practice in Ontario |
| Ontario Association of Medical Laboratories (OAML) | Represents its members as a unified voice for lab services in Ontario to government, other health service partners and to the public. Their main aim is to promote professionalism, accountability and excellence in the delivery of lab tests to patients. |
| Ontario Health Insurance Plan (OHIP) | The government-run health insurance plan for the Canadian province of Ontario. All Ontarians with a valid Ontario health card are eligible to receive health services that are covered under the provincial plan. |
| Ontario Health Technology Advisory Committee (OHTAC) | A program within Health Quality Ontario which reviews health technology assessments and provides evidence-based recommendations to the Minister of Health and Long-Term Care on which health care services and devices should be publicly funded. |

| Name of Organization | Description of Relevance to Ontario's MLS |
|---|---|
| Ontario Medical Association (OMA) | Membership organization that represents the political, clinical and economic interests of Ontario physicians. Practising physicians, residents, and medical students enrolled in any of the six Ontario faculties of medicine are eligible to be part of the OMA. |
| Public Health Ontario (PHO) | *A* Crown corporation dedicated to protecting and promoting the health of all Ontarians and reducing inequities in health. |
| Point of Care Testing (POCT) | Lab tests that are done at the bedside, or in close proximity, of the patient. POCT is mainly used in hospitals and physician owned labs for results that are needed quickly. |
| Quality Health Ontario (QHO) | The provincial advisor on quality in health care. HQO reports to the public on the quality of the health care system, evaluates health programs in all areas and provides objective advice on how to improve health care. |
| Specimen Collection Centre (SCC) | A facility where patients can provide their samples or specimens for analysis by the medical laboratory . |
| Schedule of Benefits-Laboratory Sector (SOB-LS) | A list of insured community laboratory services, the fees for these services and notes for clarification and details on billing and eligibility criteria that is provided to health care providers and patients enrolled in the Ontario Health Insurance Plan (OHIP). |
| The Hospital for Sick Children (Sick Kids) | Major hospital for the paediatric population located in downtown Toronto. |
| University Health Network (UHN) | A health care and medical research organization in Toronto, Ontario. It is the largest such research organization in Canada and North America. |

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