

Running Head: PATIENT AND PHYSICIAN VIEWS OF SELF-TESTING

Patient and Physician Views of Self-Testing: Blood Glucose Monitoring

by

Sana Iqbal

A Thesis Submitted in Partial Fulfillment
of the Requirements for the Degree of

Master of Health Sciences in Community Health

in

The Faculty of Health Sciences

University of Ontario Institute of Technology

©Sana Iqbal, 2017

PATIENT AND PHYSICIAN VIEWS OF SELF-TESTING

Certificate of Approval

PATIENT AND PHYSICIAN VIEWS OF SELF-TESTING

Acknowledgements

First and foremost, I would like to thank my research supervisor, Dr. Brenda Gamble. You have guided my academic journey with constant positivity, words of encouragement and support. Your direction and mentorship have been invaluable to me over the last two years.

Thank you to Dr. Gail Lindsay for introducing me to qualitative research and for helping me to frame my perspectives. Your guidance, especially in the Qualitative Research Works-in-Progress workshops were greatly appreciated.

I would like to extend a special thanks to Dr. Hilde Zitzelsberger. Thank you for inspiring my research within the qualitative realm. Your expertise and shared enthusiasm in my area of research has been instrumental in shaping my study. I also thank you for your time, patience and kindness in helping me to acknowledge who I am as a qualitative researcher.

I would also like to extend a special thanks to Dr. Milly Ryan-Harshman. I am so appreciative of your passion in academic writing, as I share the same zeal for writing as you do. Thank you for so thoroughly editing my work and encouraging me to become a more capable writer.

I am especially grateful to Dr. Edward Osborne and Dr. Mike Ward. Your mutual passion for academia and desire to improve patient care turned this research endeavour into a reality. I would not have been able to conduct this research without your support.

I would like to acknowledge the staff within the offices of the Bowmanville Health Centre and Newcastle Village Medical Associates for their roles in the research study.

I would like to extend a sincere thank you to all of my research participants. Thank you for sharing your time and letting your voices be heard. I am deeply grateful and appreciative that you shared your experiences for this research endeavour.

Finally, I would like to thank my colleagues and friends, and most importantly, my family. Your unwavering support, patience and understanding through this entire process has helped me to achieve all of my goals.

PATIENT AND PHYSICIAN VIEWS OF SELF-TESTING

Dedication

I would like to dedicate this thesis to my loving mother.

You took great interest in my work, and encouraged me every step of the way.
Thank you for your support and endless motivation.

You are the epitome of selflessness. Your heart exudes an overwhelming amount of unconditional love and affection, and I aspire to one day be as strong and as resilient as you are.

Ami Jaan, you are my greatest blessing!

PATIENT AND PHYSICIAN VIEWS OF SELF-TESTING

Abstract

Medical laboratories deliver an invaluable healthcare service by providing laboratory results to aid in the diagnosis and monitoring of disease states. Point-of-care testing (POCT), a sub-sector of medical laboratory services, is completed at the patient's bedside with the goal of providing clinical laboratory results in a very short time frame to assist caregivers in clinical decision making (Ehrmeyer & Laessig, 2007). The technology within this sector of laboratory sciences continues to grow rapidly, making Point-of-Care (POC) tests more accessible for use in a variety of settings, essentially decentralizing laboratory testing. This represents an important shift in healthcare culture as it provides healthcare practitioners and patients alike, the opportunity to perform an ever-growing number of laboratory tests, anywhere and at any time. Through the use of semi-structured interview questions, this qualitative research project utilized a case study informed methodology to understand the role of patient autonomy in self-testing (ST) and the function of accountability as it relates to POCT, when testing occurs in an unregulated environment. Findings suggest that ST and self-care behaviours in diabetes that are autonomously initiated result in positive outcomes, as patients are more likely to be active participants in their own healthcare. The principle of patient autonomy was highlighted in the research by the need to build strong patient/physician relationships in order to facilitate dialogue that promotes informed decision-making, an important aspect of patient care. Patients also felt that participating in ST provided them with a greater sense of control over their health, and that an increased frequency of ST could be seen only in a positive manner, regardless of which self-test was being performed. Conversely, the cost and the possibility of encountering difficulties in the interpretation and troubleshooting of self-test results were seen as negative aspects of ST. Through this research endeavour, the necessity for greater measures of accountability were also made evident, as patients and physicians discussed how self-testing could impact patient care. Short-term and long-term goals are provided as recommendations to strengthen accountability in POCT within unregulated environments.

Key words: accountability, patient autonomy, safety, self-monitoring blood glucose, self-testing

PATIENT AND PHYSICIAN VIEWS OF SELF-TESTING

Table of Contents

Certificate of Approval	ii
Acknowledgements.....	iii
Dedication	iv
Abstract.....	v
Table of Contents	vi
Chapter 1 – Introduction	1
1.0. Background	1
1.1. The Diabetes Epidemic	3
1.2. Focus and Impact of Research Study.....	3
1.3. Purpose of Study	4
1.4. Research Objectives.....	5
1.5. Overview of Research Study	5
Chapter 2 – Literature Review	7
2.0. Introduction.....	7
2.1 Literature Search Strategy.....	7
2.2. Self-Testing: Past, Present, Future.....	8
2.3. Point-of-Care in Healthcare Settings	8
2.4. Quality Assurance Programs.....	10
2.5. Regulation and Accountability	11
2.6. The Shift in Healthcare Delivery	12
2.7. Concluding Remarks.....	14
Chapter 3 – Research Methodology.....	15
3.0. Introduction.....	15
3.1. Research Design and Methodology	15
3.2. Conceptual Framework.....	17
3.3. Participants and Recruitment Strategy.....	19
3.3.1. Patient Inclusion and Exclusion Criteria.....	19
3.3.2. Physician Inclusion and Exclusion Criteria	21
3.4. Sampling	21
3.5. Ethics Approval	21

PATIENT AND PHYSICIAN VIEWS OF SELF-TESTING

3.6.	Data Collection	22
3.6.1.	Semi-Structured Interviews	23
3.6.1.1	Advantages and Disadvantages of Face-to-Face, Telephone and Skype Interviews	24
3.6.2.	Self-Administered Questionnaire	25
3.7.	Data Saturation.....	26
3.8.	Data Analysis	26
3.8.1.	Data analysis of semi-structured interviews	26
3.8.1.1.	Transcription of Semi-Structured Interview Data	27
3.8.1.2.	Coding and Thematic Analysis with NVivo 11™.....	28
3.9.	Storage and Retention of Research Data	29
3.10	Ensuring Trustworthiness in Qualitative Research Methods	29
	Chapter 4 – Results	31
4.0.	Introduction.....	31
4.1.	Description of Patient Participants.....	31
4.2.	Description of Physician Participants	31
4.3.	Data Analysis – Contextual Phase	32
4.3.1	Data Analysis - Contextual Phase for Patient Participants.....	32
4.3.2.	Data Analysis – Contextual Phase for Physician Participants.....	34
4.4.	Data Analysis – Conceptual Framework Phase	35
4.4.1.	Impact of Self-Testing to Chronic Disease Management.....	36
4.4.1.1.	Increased Self-Satisfaction	36
4.4.1.2.	Lifestyle Adjustments.....	37
4.4.1.3.	Physician Perspective on Self-Testing in Chronic Disease Management	38
4.4.2.	Decisions that Influence Self-Testing Behaviours in Patients.....	39
4.4.2.1.	Convenience	39
4.4.2.2.	Increased Participation in Care.....	40
4.4.2.3.	Improved Blood Glucose Management.....	40
4.4.2.4.	Facilitators of Self-Testing	41
4.4.2.5.	Cost as a Barrier to Self-Testing.....	42
4.4.2.6.	Adverse Patient Experiences of Monitoring Diabetes with Self-Testing.....	44
4.4.2.7.	Physician Perspective on Factors that Influence Self-Testing Behaviours ..	44
4.4.3.	Impact of Self-Testing on Patient Safety.....	46

PATIENT AND PHYSICIAN VIEWS OF SELF-TESTING

4.4.3.1. Training	46
4.4.3.2. Perceived Accuracy of Self-Testing Devices	46
4.4.3.3. Physician Perspective: Reliability of Patient Reported Self-Monitoring Blood Glucose Values	47
4.4.3.4. Physician Perspective: Interpretation of Patient Reported Self-Monitoring Blood Glucose Values	48
4.4.4. Impact of Glucose Self-Testing to Healthcare Decision-Making	49
4.5. Significant Themes in Key Informant Interviews.....	52
4.5.1. Motives to Seek Out Other Self-Tests.....	52
4.5.2. Impact of Self-Testing on Education and Counseling.....	53
4.5.3. Impact of Clinical Test Results to Healthcare Decision Making	55
4.5.3.1 Interpretation of Self-Test Results.....	55
4.5.3.2. Personal Electronic Access to Laboratory Test Results	57
4.5.4. Impact of Self-Testing on the Patient/Physician Relationship	59
4.5.5. Impact of Self-Testing on the Cost to the Canadian Healthcare System.....	61
4.5.6. Impact of Self-Testing to Patient Care and Patient Outcomes	63
4.5.6.1. Impact of Self-Testing on Patient Outcomes.....	63
4.5.6.2. Impact of Self-Testing on Patient Care	64
4.5.7. Physician Perspective: Benefits and Challenges Faced with Self-Testing.....	66
4.5.7.1. Benefits.....	66
4.5.7.2. Challenges	67
4.5.8. Ethical Considerations in Self-Testing.....	68
4.5.8.1. Vendor & Merchant Accountability.....	68
4.5.8.2. Consumerism	70
4.6. Summary of Data Analysis	71
Chapter 5 – Discussion of Key Findings	73
5.0. Introduction.....	73
5.1. Role of Patient Autonomy in Healthcare.....	73
5.2. Decisions Which Influence Participation in Self-Testing.....	76
5.2.1. Health Promotion and Community Health.....	78
5.2.1.2. Social Determinants of Health.....	78
5.3. Accountability in Self-Testing.....	81
5.4. Recommendations.....	82

PATIENT AND PHYSICIAN VIEWS OF SELF-TESTING

5.4.1. Looking Ahead: Is a Chain of Accountability Appropriate?	82
5.4.2. Long-Term Goals: Models for Safe and Effective Delivery of Self-Initiated Testing.....	84
5.4.3. Short-Term Goals.....	85
5.5. Directions for Future Research	86
5.6. Study Strengths	87
5.7. Study Limitations.....	88
5.8. Concluding Summary	89
References.....	91
A. Appendix A - Research Ethics Board Approval Notice	102
B. Appendix B - Health Belief Model.....	103
C. Appendix C - Hierarchy of Concepts.....	104
D. Appendix D - Patient Recruitment Poster.....	105
E. Appendix E - Patient Letter of Invitation	106
F. Appendix F - Physician Letter of Invitation.....	107
G. Appendix G - Letter of Consent.....	108
H. Appendix H - Thank You Letter	111
I. Appendix I - Physician Survey of Demographic Information.....	112
J. Appendix J - Physician Interview Guide.....	113
K. Appendix K - Patient Survey of Demographic Information	115
L. Appendix L - Patient Interview Guide	117
M. Appendix M - Research Timeline	120
N. Appendix N - Health Promotion Matrix	121
O. Appendix O - Prevalence of diagnosed diabetes among individuals aged one year and older, by age group and sex, Canada, 2008/09	122
P. Appendix P - Chain of Accountability	123
Q. Appendix Q – ISO and CSA Standards	124
R. Appendix R - National and international requirements for quality management of POCT 128	
S. Appendix S - Demographic Description of Patient Participants	129
T. Appendix T - Demographic Description of Physician Participants	131

Chapter 1 – Introduction

1.0. Background

Clinical laboratory testing is an invaluable tool to many healthcare providers. Laboratory test results can be used to confirm or exclude health conditions, classify and monitor disease states and/or guide treatment options (Badrick, 2013). In Ontario, the laboratory medicine sector is highly regulated. In order to provide services, medical laboratories must be compliant with a number of rigorous accreditation standards¹ and must be accountable to multiple healthcare regulatory agencies. Accountability² in Ontario laboratories is well established in ambulatory and acute healthcare settings. Within the healthcare services sector particularly, Deber (2014) identified three dimensions of accountability: fiscal accountability, clinical accountability and accountability to the public. Three key organizations responsible for ensuring that laboratories and laboratory personnel are held accountable for their actions are Accreditation Canada (AC), The College of Medical Laboratory Technologists of Ontario (CMLTO) and the Institute for Quality Management in Healthcare (IQMH). Although these organizations are all independent from one another, they share a common goal: to ensure that patient safety is always held in the highest regard. The CMLTO, AC and IQMH each outline a set of quality standards which are provided to help direct healthcare institutions in strengthening their accountability and managing risk reduction. This ensures that laboratory services provide highly accurate and reliable test results to physicians, in order to guide therapeutic health interventions and to aid in disease diagnosis.

A rapidly growing sub-sector of laboratory services is Point-of-Care Testing (POCT). It is estimated that central laboratory testing is only growing at a rate of 6-7% annually, whereas POCT is growing at a rate of up to 30% per year, depending on the testing area (College of American Pathologists, 2012). POCT is completed at the patient's bedside with the goal of providing clinical laboratory results in a very short time frame to assist caregivers in clinical decision-making (Ehrmeyer & Laessig, 2007). Three

¹ Some accreditation standards are mandatory, whilst subscription to other accreditation standards remain voluntary

² Accountability: A process in which one takes responsibility for their actions (Emanuel & Emanuel, 1996).

levels of complexity exist for POCT: “simple procedures such as glucose testing, moderate-complexity procedures (including provider performed microscopy procedures), or high-complexity procedures such as influenza testing” (AC, 2013). Although the testing systems themselves may be simple and easy to use, it does not mean there is no chance for erroneous results. Errors may take place anywhere through the testing process if manufacturer’s instructions are not followed, or if the individuals performing the testing are not familiar with the test/testing platform. These errors may adversely impact a patient’s care (CDC, 2015).

In ambulatory and acute care settings, laboratory services are responsible for managing all aspects of POCT, as well as ensuring that all accreditation requirements are being satisfied. Quality assurance³ programs in these institutions facilitate standard operating procedures⁴ to ensure that all accreditation requirements are met and followed. Such accreditation standards transparently provide a system whereby methods to address accountability are well established for laboratories, their staff, other healthcare providers and the general public. This is especially the case when organizations such as the CMLTO, AC and IQMH work in tandem with healthcare facilities to achieve the highest level of patient centered care.

Of note however, the area of POCT continues to develop and expand outside of conventional healthcare settings. With improved technology and better appreciation of the diagnostic tools that laboratories can offer, POCT has widened the breadth of tests available at the point-of-care⁵ (POC). This makes POC tests more mainstream and largely accessible to consumers. Dilts (1998) explained that the evolution of home testing kits would make it commonplace to purchase routine hematology, chemistry and coagulation tests without prescriptions at retail stores. As of 2013, North American countries held the largest share of the global POC diagnostics market, followed by the Asia-Pacific region⁶, Europe and the rest of the world (Markets and Markets, 2014). With

³ Quality Assurance: A set of principles and procedures that guide the laboratory in achieving and maintaining a high level of accuracy and proficiency throughout the testing process (CDC, 2014).

⁴ Standard Operating Procedure: a written set of instructions which describes how to perform a task safely and correctly

⁵ Point-of-Care: at or near the patient

⁶ Asia-Pacific Region: Japan, China, India, and the Rest of Asia-Pacific (Markets and Markets, 2014)

rate of self-testing (ST) skyrocketing, it is anticipated that ST will contribute to an estimated global market of \$27.5 billion by the year 2018 (Markets and Markets, 2016).

1.1. The Diabetes Epidemic

Testing blood sugar levels at the POC has an estimated market of \$8 billion dollars worldwide (Rajan & Glorikian, 2009). The diabetes epidemic is currently a strong driver of the POC blood glucose market (Markets and Markets, 2014), and it is anticipated that testing blood glucose levels will continue to represent the majority of the POC market for the foreseeable future (Rajan & Glorikian, 2009). As a result, diabetic patients using glucometers represents the most homogenous population of end-users for POC tests. Glucometers were amongst the first devices to be introduced to the POC market in the late 1980s, as a method to support diabetic patients in managing their blood glucose levels (St John & Price, 2014). Over a period of years, every new generation of glucometers became more improved than the previous, and eventually glucometers began to find their way into hospital-based settings. These devices have been shown to improve patient outcomes whilst reducing hospital complications and mortality rates in diabetics and non-diabetics alike, by contributing to improved disease management and tighter glycaemic control (Lewandrowski, 2009). Glucometers are now amongst the most common POC devices on the market due largely in part to the number of diabetic patients who are required to monitor their blood glucose levels (St John & Price, 2014).

1.2. Focus and Impact of Research Study

Lifestyle choices can be important contributors impacting health conditions. More recently, government and healthcare agencies have come to acknowledge the role of lifestyle factors in contributing to poor health, and thus are stressing the need to maintain good health to reduce the health problems directly caused by lifestyle choices (Kricka & Price, 2009). Therefore, offering more choice to patients has been largely in part due to a shift in healthcare culture. The concept of patient autonomy⁷ in self-management continues to be an important healthcare debate. In healthcare decision-making, patient

⁷ Patient Autonomy: In biomedical ethics, autonomy is considered to be a principle of respect whereby patients are supported in making decisions about which healthcare interventions they will or will not receive (Entwistle, Carter, Cribb & McCaffery, 2010).

autonomy suggests that self-diagnosis and ST are considered tools that aid individuals in taking a more active role in their own health (Grispen et al., 2010). It must be noted however, that despite good intentions, even the technological tools such as the POC tests now commercially available to patients, can potentially have adverse effects. Between 1992-2009, the U.S. Food and Drug Administration reported one hundred fatalities due to inaccuracies with glucometers, and another 12 672 serious injuries⁸ were reported between 2004-2008 (Walsh, Roberts, Vigersky & Schwartz, 2012). Considering the rate of adverse events linked to inaccuracies with glucometer usage, it would not be incorrect to posit that adverse events occur with other POC tests as well, and must be more widely publicized. It is important to reflect on this data since ST is on the rise. Much of the existing research on POCT focuses on its usage within formal healthcare environments, as well as the convenience and satisfaction with POCT in home care environments. However, the literature does not address the full role of patient autonomy as a driving factor for ST, when considering the shift of routine laboratory tests into home care environments; therefore, this research presented a unique opportunity to examine the gap in the literature. This research study seeks to explore the value of patient autonomy in self-directed healthcare. In addition, the study examines the implications involved with ST and the production of lab test results that are used in clinical decision making and therapeutic health interventions, when testing occurs outside of regulated healthcare facilities.

1.3. Purpose of Study

The purpose of this study is to understand the role of patient autonomy in ST and to examine the key decisions that influence patients to engage in ST. More specifically, the research examines patient autonomy from the perspective of patient participants who have diabetes. The study explores how patient autonomy, or the ability to self-monitor and self-manage a health condition, affects healthcare decision-making for both the patient and the healthcare provider. Finally, the research seeks to explore who is ultimately responsible for following up with the results of self-testing. In this qualitative

⁸ Serious injuries: includes, but is not limited to treatment with medication(s), hospitalization required, therapy/non-surgical treatment, hypoglycemia/hyperglycemia, loss of consciousness, shaking/tremors, dizziness (Harper, n.d.)

research study, six patients and six primary care physicians participated in semi-structured interviews to discuss their experiences with POCT, the resulting impact of ST to one's health, and the impact of ST on the doctor-patient relationship dynamic.

1.4. Research Objectives

In order to explore the focus of the aforementioned research, the researcher created a specific set of research questions:

- 1) What is the role of patient autonomy in healthcare? How does patient autonomy or ability to self-manage a health condition with a self-test affect healthcare decision-making for both the patient and healthcare provider?
- 2) What influences patients to participate or not participate in self-testing?
- 3) Who is responsible for following up with self-test results?

To fulfill the purpose of this inquiry, the researcher developed a qualitative research study, that employed a set of semi-structured interview questions to engage the patient participants in discussions about elements of ST that impact their autonomy and healthcare. Data collection from physicians helped to produce a more comprehensive understanding of the impact of ST on patient care and to the broader healthcare system. In addition, the researcher collected brief demographic data from both patients and physicians through self-administered paper/electronic questionnaires, for additional data analysis.

1.5. Overview of Research Study

In summary, this chapter presents a brief background on the medical laboratory sector and the emergence of a new sub-sector known as point-of-care testing. The research questions are framed by providing an overview of existing accountability standards within the medical laboratory sector as well as highlighting how the shift in healthcare delivery has influenced patient autonomy in ST healthcare self-management.

In Chapter 2, the researcher will discuss the literature review, and will focus on the gaps in the literature that make this research necessary. Chapter 3 will focus on the methodological approaches, including research design, participants and recruitment strategies, ethics review and data collection. Chapter 4 presents the results and data analysis of the study from patient and physician participants. Chapter 5 discusses the

findings of the research study, presents study limitations and concludes with recommendations for policymakers and suggested areas for future research.

Chapter 2 – Literature Review

2.0. Introduction

This chapter will provide a brief overview of the literature search strategy, review the development of POCT and explore the elements of quality assurance in regulated healthcare settings that ensure POCT does not compromise patient care. In addition, the shift of POCT from healthcare settings to alternative environments and common themes that affect ST, will be examined. The focus of this chapter is to highlight the existing gaps in the literature that makes this research necessary.

2.1 Literature Search Strategy

To perform a search of relevant journals, several health science search databases were consulted. This included CINAHL, MEDLINE via EBSCOhost, MEDLINE via Ovid, Ovid SP, ProQuest Nursing and Allied Health Source and PubMed. These databases were mainly selected as they are considered to be the top databases to contain literature pertaining to health sciences. Keywords selected to perform the search were: point of care systems [MeSH Major Topic], attitudes or perceptions or experience. All searches needed to include point-of-care systems as the medical subject heading or major topic of the article, as the inquiry seeks mainly to gather evidence from this body of literature. Secondly, the researcher had selected ‘attitudes or perceptions or experience’ as the next important keyword in order to find relevant articles that would be capable of measuring or describing experience/attitudes/perceptions related to POCT. The search strategy also included a review of the reference lists contained within appropriate journal articles as a means to obtain other relevant literature. Inclusion and exclusion criteria are as described below:

- Publication date from 2000/01/01 to 2015/12/31 - due to the change in technology in modern times, POC devices have become more advanced and more prevalent in healthcare. Therefore, the researcher chose to look at articles that were published after January 2000.
- Humans – Article must only examine the use of POC devices on humans
- English – Article must be in the English language

Finally, articles were screened based on abstracts provided in the search database. Articles specifically excluded from the search strategy were those which discussed the use of POCT on specimens where capillary or venous blood was not the primary source of sample collected, as this research inquiry seeks to examine the experience of patients who use a POC device to manage their chronic illness using a capillary blood specimen.

2.2. Self-Testing: Past, Present, Future

Historically, urinalysis dipsticks and glucometers were among the very first tests available at the POC. Nowadays, some of the more commonly available POC tests include urine pregnancy tests, screening tests for the Human Immunodeficiency Virus (HIV), fecal occult blood testing, cardiac marker tests, and drugs of abuse testing (Lewandrowski, 2009).

In the 21st century, marked innovations in technology have allowed the field of POC to grow and expand. Outside of traditional healthcare settings, POC tests have become commercialized for personal in home use, and have unique applications for use in transport vehicles⁹, prisons and military operations. Furthermore, they have proved to be especially useful in remote areas or in parts of the world where disaster and medical relief is required, or where the infrastructure may not be able to support a central laboratory (CAP, 2012).

The widespread availability of these tests has introduced the concept of ST to many individuals; instead of having to consult a physician to obtain a lab test result, many patients are now turning to ST, further engaging their role as autonomous patients. Free and Free (1984) describe ST to be an activity in which a lay person (one who lacks the resources of a laboratory, nor possesses the technical, medical or scientific training usually involved in the testing process) produces a clinical laboratory measurement.

2.3. Point-of-Care in Healthcare Settings

In a healthcare services setting, a POC test is often initiated by a physician's order, a medical directive or a medical protocol, whereby the physician caring for the patient ultimately needs to take responsibility for the diagnostic value produced by the

⁹ Transport vehicles: ambulances, helicopters, airliners

POC test. In the event that a questionable POC laboratory result is manifested when testing is conducted at the bedside, healthcare practitioners are able to verify the validity of questionable results by ordering a superior quality venous blood specimen for collection¹⁰, and referring the specimen directly to the laboratory for high quality testing, and ultimately, suitable clinical action if required.

Of consideration is the abundant quantity of literature available that focuses on POCT and its use within well-established healthcare settings. Particularly of concern is the amount of research in this area which suggests that the decentralization of laboratory testing can have very serious consequences. Studies demonstrate that when non-lab personnel are involved in laboratory testing, patient care can be compromised, highlighting the necessity for quality testing at the POC (Plebani, 2009; Lippi, Guidi, Mattiuzzi, & Plebani, 2006). Poor operator training may compromise diagnostic values obtained from a POC test, if operators do not use the correct type/volume of sample, or if there is improper physical application of specimen to the testing surface/chamber of the device. The quality of specimen also can be affected by collection of insufficient sample, incorrect sample type or inability to detect interferences that may be present in the sample. Trained laboratory personnel would easily identify these sources of error in the pre-analytical phases of testing, and would act accordingly as it may affect the end result. Studies indicate that the lack of standardized protocols for procedures in specimen collection contributes to errors that occur in the pre-analytical phases¹¹ of laboratory testing (Rana, 2012; Lippi et al., 2006). In addition, since most POCT does not occur under the direct supervision of laboratory personnel, there is great difficulty in monitoring all of the pre-analytical variables that could affect testing, hence the lack of process improvements in this particular area (Lippi et al., 2006).

¹⁰ High quality venipuncture samples are often collected by laboratory personnel, or other healthcare practitioners that are qualified to perform the procedure.

¹¹ The pre-analytical phase of laboratory testing begins at the moment when a laboratory test is ordered. It encompasses specimen collection from the right patient, at the right time, ensuring that an optimal specimen is collected, as well as following through with the correct steps for handling and processing specimen.

2.4. Quality Assurance Programs

Quality assurance programs enforced by laboratories in accredited healthcare facilities ensure POC regulation through mandatory quality assurance processes. This ensures that the laboratory values produced through POCT are validated by daily quality control assays, correct calibration of devices, correct lot number of in-use reagents and proper storage of reagents involved in the use of the clinical diagnostic tests.

Additionally, quality standards within healthcare settings forces analytical methods to be evaluated by external quality assessments and proficiency testing. However, research continues to indicate that non-laboratory personnel do not have the same capability of performing and assessing the result of a diagnostic laboratory test, as they may not have the same level of understanding and appreciation of a quality management program within a diagnostic testing system (Ehrmeyer, 2011; Jones & Meier, 2005). There is currently no existing quality assurance framework in effect for POCT outside of regulated environments, and thus POCT conducted in personal homes are not subjected to the same level of scrutiny pertaining to the quality of test results obtained in a laboratory. This is a significant element pertaining to the safety of the testing process for patients. There are no external organizations monitoring personal POC devices or scrutinizing an individual's testing technique/method to ensure that testing is being performed correctly. Furthermore, the International Organisation for Standardisation (ISO) and the Canadian Standards Association (CSA) detail specific standards for the safe and effective usage of POCT within healthcare environments; however, these standards specifically exclude ST that occurs in home or community settings (CADTH, 2014; Appendix Q).

Additionally, medical laboratory technologists, those who perform, analyze and report laboratory test results, represented <1% of the total labour workforce in Canada between 2011-2013 (Service Canada, 2015). This means that a significant portion of the general public may not fully appreciate the need for quality in POC as they may be incognizant in the area of POCT. Hence, the majority of end-users performing POCT in their own home may not be fully aware of the ramifications that may arise as a result of performing testing without a quality framework in place, which would essentially serve to promote their best interests. As POC is a fairly new area that continues to rapidly grow

outside of clinical care settings, it is not surprising that standardization and regulation is still lacking. As a flaw-free system for POC in established healthcare settings has yet to be achieved, it is important to reflect on the likelihood that encountering challenges in alternative environments exist as well.

2.5. Regulation and Accountability

Systems of accountability for healthcare institutions and healthcare providers alike are well established within the province of Ontario. These mechanisms are in place in order to ensure that healthcare practitioners and healthcare institutions are accountable for their actions. On an individual level, many regulated healthcare practitioners are governed by, and answerable to, their respected regulatory colleges for all actions that may be related to patient care. On a much larger scale, in Ontario's healthcare system, service accountability agreements are prescribed. These agreements contain a set of performance indicators to be met for those who plan, manage and deliver healthcare services in order to monitor financial and organizational health, as well as quality of care (OHQC, 2008). Finally, on an organizational level, quality assurance programs managed by laboratory services ensures that delivery of POCT is reliable. This includes but is not limited to ensuring that all non-laboratory personnel involved in POCT are trained to execute POC tests appropriately, ensuring there is satisfactory cross-correlation of POC tests with those offered at the central laboratory, and participating in external assessments¹². The IQMH, AC and CMLTO further serve to promote accountability within Ontario laboratories. Laboratories work with these accreditation bodies to ensure that they are meeting benchmark standards and that reliable laboratory test results are being produced.

The area of POCT continues to develop and expand outside of conventional healthcare settings. Decentralizing laboratory testing into such environments may have very serious consequences to patient care, considering the lack of standard operating procedures, regulation and accountability. Clearly, the implications of patient initiated ST need to be more closely examined.

¹² Refer to [Appendix Q](#) and [Appendix R](#) which detail ISO standards as well as national and international requirements for quality management of POCT.

2.6. The Shift in Healthcare Delivery

There is a changing dynamic in the delivery of healthcare services – from inpatient to outpatient care settings, from provider-centered care to patient-centered care, and more recently in the delivery of home healthcare (Friedman & Mitchell, 1993; Park, 2006). The shift in healthcare culture, notably in health promotion programs, emphasizes the concept of empowerment, particularly in relation to health and community participation (Robertson & Minkler, 1994). Generally, community empowerment is defined as the approach taken by individuals to involve themselves in a greater capacity in decisions that could affect their overall health and wellbeing (Laverack & Labonte, 2000), and may sometimes be an explicit goal of health promotion programs. By focusing on increased control over health behaviour changes, or on the underlying health determinants¹³ that influence health and wellbeing, individuals become more actively involved in decision-making that ultimately affects their own health.

‘Telehealth’ is one such model that facilitates home healthcare, which also can be considered an up and coming facilitator of POCT. The telehealth model utilizes a broad variety of methods and technologies to virtually deliver medical, health and education services (CCHP, 2010). Considering that POCT gives patients access to their own test results, the telehealth system could be of benefit if patients needed treatment decision support and assistance. In chronic disease management¹⁴, the telemedicine model has already proven to be quite beneficial when timely healthcare interventions are coupled with health promotion activities (Bashshur et al., 2014). Essentially, the telehealth model works to decrease the burden on the healthcare system by reducing hospital admissions and length of stay, patient visits to primary care physicians, walk-in clinics and emergency departments (CCHP, 2010; Bashshur et al., 2014).

Considering the change in models of healthcare delivery, it is important to understand the current state of knowledge concerning patient and physician views of ST. Much of the existing literature on ST discusses the successes and pitfalls of ST within a

¹³ Health determinants: income, social status, environmental threats, housing, education, gender, employment (PHAC, 2008).

¹⁴ The three chronic diseases included in the Bashshur et al., (2014) study include: congestive heart failure, stroke and chronic obstructive pulmonary disorder

specific clinical context¹⁵. However, few studies have surveyed the attitudes of patients and physicians in a rigorous manner. In two separate studies conducted by Laurence et al. (2010) and Thompson, Ragucci, Fermo & Whitley (2009), patient levels of satisfaction between POCT and routine laboratory testing were examined. Research in these two studies indicated that patients felt more comfortable having a finger prick over a venipuncture to collect blood, that it was convenient to perform testing in the privacy of their own homes and that having immediate result feedback was important to their disease management, as well as strengthened their relationship with their primary care physician. On the other hand, laboratories were considered more hygienic and results were thought to be more reliable, although it was inconvenient and costly to go to a laboratory for the testing procedure. A systematic review of primary care clinicians' attitudes of POCT primarily in European nations, conducted by Jones et al. (2013), identified the major barriers and facilitators to POCT. Facilitators in primary care facilities included a cost/time savings, improved patient convenience, and increased satisfaction and health outcomes of patients. Barriers identified included the time required to use POC equipment, inaccurate results, inappropriate testing, and concerns over reliability of testing. A mixed methods study by Grispen et al. (2010) examined the role of autonomy in decisions to self-test. The study described the use of self-tests in patients who initiate ST by examining decisions to perform ST, as well as the conditions surrounding the execution, interpretation and follow-up behaviours associated with the self-test. However, the literature failed to contextualize patient autonomy in POCT in environments where there is currently no framework for regulation and accountability.

Furthermore, each healthcare decision that a patient makes with the use of a self-test has a considerable related ethical component when ST occurs in the privacy of one's home. For example, Youngs and Hooper (2015) highlight the possible implications for good and harm, when using an at home HIV screening test. The authors indicate that ST can allow for an early diagnosis, thereby improving the patient's prognosis and reducing chances for transmission of the virus. Conversely, false positives may cause undue emotional distress to patients, whilst false negatives may cause the ongoing spread of the

¹⁵ For example, consider studies examining the successes and barriers of self-monitoring blood glucose and anticoagulation status

disease. Additionally, some patients may not even seek healthcare support in the event that they find out that they are positive for the disease, for fear of the stigma associated with HIV. Without clinical guidance from a qualified healthcare provider, patients may be at risk of incorrectly interpreting self-test results. Kearns, O'Mathúna and Scott (2010) argue that ST in the privacy of one's home can negatively impact the individual if they do not have the proper support from a healthcare practitioner that can make sense of the ST results in a meaningful way.

Many of the studies discussed above establish how ST can affect patients both positively and negatively. The research, however, fails to demonstrate why healthcare decision-making as it relates to ST and patient autonomy needs further attention. Evaluating the impact of ST initiated by the patient is still not completely understood, nor are the implications of participating in self-testing clear. Additionally, there is no clear chain of accountability for who is ultimately responsible for self-test results, when testing is initiated by patients. As the technology behind clinical laboratory sciences continues to grow, the need to capture patient and physician perspectives on ST further validates this research.

2.7. Concluding Remarks

The existing healthcare literature draws attention to the fact that no studies have been conducted to evaluate the utility and/or consequently the implications associated with ST in home-based settings, an environment lacking a formal regulatory process to ensure safety and quality testing at the POC. Conducting this research presented an opportunity for an original contribution to the field of POC, from an end-user's perspective, with additional interviews with physicians who acted as key informants on the discussion of POCT within the community. This study allowed the opportunity to actively engage primary care physicians and patients in dialogue with the researcher, to provide rich descriptive qualitative data that will contribute immensely to the ongoing discussion about the impact of patient autonomy on personal health, with the context and impact of ST at the heart of the discussion.

Chapter 3 – Research Methodology

This chapter will discuss the research design and methodology, provide an overview of the data collection and data analysis methods, and will discuss ethical considerations pertaining to the study. A research timeline is included in Appendix M.

3.0. Introduction

Since POCT may fundamentally shift the accessibility of laboratory testing in the future, the scope of the research is to seek out an understanding of the implications of patients conducting self-testing in the community, how it affects patients and healthcare providers, and how it could affect the shape of healthcare in the future. In order to facilitate answering the goals of this qualitative research study, the research study sought out to examine the role of patient autonomy in POCT and chronic disease management, assess its impact to patient care, and to address the question of accountability in ST when ST is patient driven.

The researcher's role in this study included (a) establishing liaisons with primary care physicians and primary care facilities to aid in the process of recruitment for research participants; (b) completing formal research ethics application for review by the University of Ontario Institute of Technology (UOIT) Research Ethics Board to conduct research; (c) collecting data; (d) entering data; (e) analyzing data; (f) writing the thesis; (g) presenting and disseminating of findings.

3.1. Research Design and Methodology

This research study was qualitative in nature. Holloway (2005) indicates that qualitative research is important in healthcare to develop or modify existing health or education policies, and that exploring the need for change in health policies can only be effective if the underlying reason for health behaviours are understood. Wiersma & Jurs (2009) clarify that capturing the perceptions brought forth by participants in qualitative research exposes an accurate measure of reality from the participants' perspectives. Therefore, "meaning is as perceived or experienced by those being studied; it is not imposed by the researcher" (Wiersma & Jurs, 2009, pp. 232-233). More importantly, qualitative health researchers provide a voice for individuals to share meaningful stories. In health care research, qualitative studies provide a means to convey how various forms

of illness impact their relationships, work and leisure time, and provides insight into how these individuals choose to manage their future health related outcomes and how this relates to their eventual dying and death (Morse, 2012). Qualitative research can adopt a variety of methods and it involves an interpretive approach to understand the nature of the problem; this can be achieved by examining a range of empirical materials which describe “routine and problematic moments and meaning in individuals’ lives” (Denzin & Lincoln, 1994, p. 2).

In order for the research to address the goals of this research study, the researcher used a case study informed methodology, adopting teachings from qualitative researcher, Robert Yin. This methodology is embedded within the interpretivist paradigm, one in which the researcher offers up a perspective that would help his or her readers to understand a particular phenomenon of interest (Willis, 2007). The interpretivist paradigm seeks to understand the lived experiences of individuals and the meanings that individuals attach to their experiences. Hennink, Hutter & Bailey (2011) explain that since each person’s perception of reality is subjective, numerous perspectives of the same reality may exist. This is just one of the many reasons why qualitative research can be useful to identify areas for improvement in healthcare.

This research endeavour employed a case study informed approach to gain an understanding of a social sciences phenomenon in a comprehensive and detailed manner by extensively exploring a modern-day phenomenon within a ‘real-life’ context, especially when the boundaries between the phenomenon of interest and the contextual variables are somewhat blurred and not noticeably evident (Yin, 2009). This approach is best used in social sciences research that seeks to uncover the “how” and the “why” of a particular phenomenon. Case studies are also known for their strength in being a complementary method to other research methods (Yin, 2009). For example, research methods that involve the use of randomized trials¹⁶ may establish a “cause and effect” relationship, yet lack the ability to explain how/why a given intervention was successful. A case study method could successfully address this sort of a question. Finally, case studies are also considered to be the preferred method to examine present-day issues in a

¹⁶ Randomized trials look to prove causal relationships by observing a control group and manipulating a variable of interest in the other group (Sibbald & Roland, 1998).

setting where the researcher has no influence over relevant behaviours. This involves interviews with research participants and the researcher's direct observations of the events to be studied (Yin, 2009). In this particular research endeavour, a case study informed approach was used as a guide to help the researcher understand how ST is influenced by an autonomous patient decision-making process, from both the healthcare provider and patient's perspective.

3.2. Conceptual Framework

The study design was guided by the use of a conceptual framework, in order to bring a greater focus to the concepts to be studied and the relationships that each has to the other (Maxwell, 2005). It was the researcher's intention to use open-ended and loosely structured questions in an interview style, with probative questions as required, in order to engage in dialogue with the research participants. The researcher used a hierarchy of concepts (Appendix C) in order to organize the research and expose and highlight the links between the different levels of related concepts. Punch (2006) suggests that a hierarchy of concepts is governed by a process of logic whereby the relationships between the concepts are demonstrated by making general concepts more specific at each level of the hierarchy. Clearly indicating the different dimensions of related concepts involved at each level of hierarchy provides further internal consistency, coherence and validity to the research study (Punch, 2006). In addition, the conceptual framework served to direct questions that ultimately helped to address the role of autonomy in POCT, as well as touching on measures of accountability and regulation that should serve to promote the safety of patients conducting self-driven POC tests.

To address the study's research questions, the researcher designed a unique conceptual framework to guide this study. The conceptual framework used in this study merges the concepts from two key models: clinical governance and the health belief model (HBM).

The clinical governance framework is an invaluable tool in healthcare settings as it involves an established process by which patients and healthcare providers can work together to achieve quality at the POC. The framework itself serves to evaluate and explore the role of quality assurance, regulation and accountability in meeting the needs of POC users within the community. Pearson (2006) and Freedman (2002) describe

clinical governance as a quality framework that encompasses risk management, clinical and cost-effectiveness as well as patient outcomes in the medical laboratory sector; it is essentially a systematic approach to quality assurance. Clinical risk management encompasses operator training, as well as education about the phases of laboratory testing, regular audits and competency checks (Pearson, 2006). In addition, management of clinical and cost-effectiveness is an important variable in the quality assurance framework as it is believed that POC tests enhance clinical care. This quality framework largely involves patients and healthcare providers, in the need to achieve quality at the POC. The quality framework is important in the field of POC because, in the long run, it largely affects so many aspects of the healthcare system (includes, but is not limited to cost, social determinants of health, health policy).

The HBM is the second half of the conceptual framework. Patients managing chronic conditions are believed to be more compliant with treatment regimens when they take a more proactive approach to their own healthcare (Charuruks et al., 2006). The HBM plays a crucial role in healthcare autonomy and in guiding decisions to carry out POC tests (Appendix B). The HBM theory originally was developed in the 1950's as a way to help understand how personal beliefs motivate individuals to engage in health promoting behaviours, including physician prescribed preventative actions and healthcare interventions (Graham & Pace, 2008). Hayden (2009) explains that the HBM functions to explain health behaviours independently or in combination, from four different angles. The first angle is perceived seriousness – the belief about the severity of a disease. The second angle is perceived susceptibility – the perception that prompts individuals to adopt healthier behaviours. The third angle is perceived benefits – the opinions on the value of adopting a behaviour that would reduce the risk of disease. The final angle is perceived barriers – the challenges that individuals may face in adopting new behaviours. More recently, the model has further developed to understand what prompts health behaviours (cues to action), how individuals face tasks and challenges (self-efficacy) and finally what factors motivate them to execute certain behaviours (Hayden, 2009). By examining what motivates individuals to engage in ST, how such behaviours come to exist, and what challenges may exist in ST, this model will help to create an understanding of why POCT

may be considered of value in a world where autonomy in healthcare decision-making is considered to be of the utmost significance.

No literature has been published which combines the HBM and clinical governance framework. Since the HBM and clinical governance models are interconnected, the conceptual framework was ideal in creating an understanding of the role of patient autonomy in POC, whilst identifying themes that pertain to elements of quality assurance, patient safety and a greater understanding of the physician's role in POCT within the community. Fusing these two models created an opportunity for an overlapping and intersectional approach to examining the use of POC devices within the community, and in doing so, the quality of this research study was strengthened, as both models are relevant in complementary ways.

3.3. Participants and Recruitment Strategy

Since the research sought to gather the perspectives of both patients and physicians, two groups of participants were involved in this study. The researcher was able to form a liaison with a primary care physician in a medical clinic. With the help of this physician, the researcher was able to get permission to allow hanging a recruitment poster in two medical clinics (see Appendix D) to recruit patients for the study. In addition, with the help of the researcher's medical liaison, the researcher identified primary care physicians who served as key informants in this research study. Once potential participants were identified, the researcher extended a formal letter of invitation to each participant, which included greater detail about the study. Finally, a signed letter of consent was collected from all participants prior to the initiation of data collection (see appendix G).

3.3.1. Patient Inclusion and Exclusion Criteria.

Patients were recruited at random from the medical clinics. Participants who saw the recruitment poster in the medical office voluntarily contacted the researcher, and the researcher provided additional details about the study. This strategy did not yield many participants, thus to increase patient participant recruitment, a change request was filed and approved by the UOIT Research Ethics Board (REB). The change request detailed the involvement of physicians at approved clinics, who would help to identify patients

who would be eligible to participate in the study. As physician offices are often busy, two scenarios to recruit patient participants were possible. If there was time during the appointment, the physician would use the approved recruitment script to explain the research endeavour. If patients were interested in participating, they could take the recruitment script home with them, and contact the researcher to discuss further. If there was no time during the appointment to use the recruitment script, the physician would notify the patient that the researcher is interested in talking to patients who would like to share their views of self-testing. The physician would ask consent to share the patient's contact information, or alternatively, the patient could leave their contact info at a sign up sheet with the reception desk, which the researcher would later collect. The researcher could then contact these patients, and use the approved recruitment script to further explain the details of the study. In both scenarios, the physician and/or the researcher would make it clear to the patient, that if the patient chooses to participate, or not participate, that it would not affect the patient's healthcare services, nor would it affect the physician-patient relationship, and it would not impact their level of care in any way. All patient participation remained completely voluntary.

Participants who met the inclusion criteria were enrolled in the study. Inclusion criteria for the patient pool included recruitment of participants who were 18 years of age and older, of any gender. In order to participate in the study, it was also required that participants be using a glucometer for a minimum of at least three months as part of their diabetes illness monitoring and treatment regime. These criteria were listed as inclusion criteria in order to homogenize (as best possible) the population of patient participants. In this manner, patients who were interviewed shared common experiences of self-testing. Patient participants who acknowledged that they had a background in clinical sciences were excluded from the study, as their knowledge of POC services may have produced indistinct/dichotomous themes (when compared to/against participants with no clinical sciences background) after the analysis stage of research was completed. Additional exclusion criteria included participants who were under the age of 18, participants who did not have diabetes, participants who did not participate in self-testing with a glucometer, participants who did not regularly seek healthcare from a physician, and participants who did not seek care from a physician at the medical clinics.

3.3.2. Physician Inclusion and Exclusion Criteria

Physicians as key informants, were recruited using convenience sampling, a purposeful sampling strategy in which participants are recruited because they may be convenient to study; this technique is also thought to save time, money and effort (Creswell, 2013).

The physician inclusion and exclusion criteria were quite simple. Licensed primary care physicians who were currently practicing were eligible to participate in the study, as they often treat patients with diabetes who self-monitor blood glucose. Physicians who were not licensed or practicing in an area of primary care were excluded from the study. It was essential to get the views of only practicing physicians, as they are actively engaged in patient care, as it pertains to their profession.

3.4. Sampling

A total of six patient participants and six physician participants volunteered their time to share their views and perspectives of ST with the researcher. All twelve of these participants met the inclusion and exclusion criteria to participate in the research.

An additional four patients were invited to participate; however, they did not partake in the research study. Two of these potential participants cited ‘unavailability of time’ to participate in the research study. The other two potential participants did not respond to researcher enquiries about scheduling interview dates, despite multiple efforts to contact the patients.

An additional 15 physicians were invited to participate in the study; two physicians declined to participate, citing ‘lack of time’ as the reason for their unavailability. Despite multiple efforts by the researcher to contact the other 13 physicians, no responses were received.

To ensure confidentiality of participants, each patient and physician was assigned a generic code. Patients were coded as “PT1, PT2, PT3, etc.”, and physicians were coded as “PY1, PY2, PY3, etc.”.

3.5. Ethics Approval

Prior to conducting the research protocol, ethics approval was sought from the UOIT REB. The application was submitted to the REB on Sept 15, 2016 and approval

was granted December 19, 2016. Recruitment of patients and physicians officially began February 03, 2017. Participant data collection spanned a period of two months from March 08, 2017 to May 19, 2017.

All participants were given the opportunity to read the consent form and were given the opportunity to ask questions about the research prior to the commencement of the semi-structured interviews. Participants were also notified of their right to pause or end the interview, if they felt it was too difficult to speak about their experiences, and were notified of their right to voluntarily withdraw from the study at any time, with no consequences.

3.6. Data Collection

The primary method of data collection was semi-structured interviews. In addition, the researcher also collected demographic information from the participants through a self-administered paper/electronic questionnaire. The section below describes the details of the data collection process.

The research sought to obtain these experiences from a homogenous population of end-users (i.e.: glucometer users), in order to identify common themes that influence ST among patients. Additionally, physicians acted as key informers, sharing their views about the effect of ST on patient care.

The use of semi-structured and general open-ended questions were instrumental in creating dialogue to uncover and reconstruct various aspects of the lived experiences of the diabetic patients using glucometers to manage their disease. Individuals suffering from a chronic disease are often subject to other comorbid conditions that can alter their health negatively (CDC, 2016). This represents a vulnerable population of individuals who may seek comfort in knowing that they can rely on a clinical test to obtain results reasonably quickly and monitor their disease state themselves. Conversely, it may provoke greater fear in that patients may perceive testing to be lacking in accuracy and precision, therefore making disease treatment in their home somewhat unreliable.

As the study was designed to collect data from two groups of participants (patients and physicians), a separate interview guide for both groups was generated and structured such that the pool of questions for both physicians and patients were as similar to each other as possible, in order to answer the research questions. By mirroring these

questions, the intention was to capture key perspectives from both groups and understand how ST impacts both the patient and the physician, and furthermore understand the role of autonomy in ST. Additionally, this allowed the researcher to look for similarities and themes in responses between the two groups of participants during the data analysis phase.

3.6.1. Semi-Structured Interviews

In the research process, interviews are considered to be a practical and effective method to collect data as they can provide valuable insight into a given topic from the participants' perspectives. In particular, the interviews can be focused directly on the phenomenon of interest, and may lead the researcher to explore other sources of evidence (Yin, 2009). However, there are also some disadvantages associated with conducting interviews. Yin (2009) suggests that reflexivity may be inherent in interviews, as the research participant may only be giving the researcher what it is they think the researcher wants to hear. Furthermore, if the participant misunderstands the questions, the participant may not be able to clearly describe experiences. In order to address potential shortcomings of the interview questions, the researcher included probing questions in the interview guide in order to encourage participants to further elaborate on the interview questions.

Prior to interviewing the participants, the researcher collected the signed informed consent forms, ensured that any questions they had about the study were answered, and also that participants were aware of their right to withdraw from the study. Participants were given the option to conduct a telephone/skype/face-to-face interview at a date/time most suitable to both the researcher and the participant.

Two face-to-face interviews with patient participants were conducted at a local library in a private meeting room. The other four patient participants preferred to engage in telephone interviews. Patient interviews lasted on average 26 minutes in length; the longest interview was 40 minutes in length and the shortest interview was 15 minutes in length.

Three face-to-face interviews with physicians were conducted at the physician's medical clinic in a private meeting room. One physician chose to participate in a Skype interview, and another two physicians participated in telephone interviews. Physician

interviews lasted on average 30 minutes in length; the longest interview was 43 minutes in length and the shortest interview was 24 minutes in length.

The interviews were conducted using an interview guide developed by the researcher, in order to facilitate answering the primary research questions. Please refer to Appendix L for a copy of the patient interview guide, and Appendix J for a copy of the physician interview guide.

All transcription of the recorded interviews was completed by the researcher, and is further described in section 3.8.1.1.

3.6.1.1 Advantages and Disadvantages of Face-to-Face, Telephone and Skype Interviews

Face-to-face discussions are considered to be the gold standard in qualitative research interviews (Novick, 2008). To begin, there are no literacy conditions required of research participants and it is thought that participants may feel a greater sense of openness during the interview process and that a face-to-face interview increases the ability to collect contextual data (Bowling, 2014; Novick, 2008). Face-to-face interviews allows the researcher the opportunity to ask detailed questions and probe for more information when required, however, it also enables researchers to display visual and feedback cues, which may affect data collection (Novick, 2008). Additionally, face-to-face interviews can be both costly and time consuming (Novick 2008).

The use of telephone interviews in quantitative research methods has been widely studied, is generally well accepted, and is noted to be the most commonly used method of survey data collection within industrialized nations; they produce high quality data that is rich, descriptive and detailed (Novick, 2008). Telephone interviews are thought to save the researcher time and costs associated with travel, while simultaneously allowing them to reach a more geographically extensive pool of research participants, and are proclaimed to ameliorate the safety of the interviewer (Novick, 2008). Within the qualitative realm, the aforementioned advantages apply, as well as allowing research participants the opportunity to remain within a comfortable environment of their own, providing them the opportunity to speak more freely, increasing the perceptions of anonymity, and allowing participants to share sensitive information which they may not

have felt comfortable sharing in person (Sturges & Hanrahan, 2004). Furthermore, they are thought to reduce face-to-face feedback cues (Novick, 2008). Although not encountered in this particular research study, the lack of telephone coverage availability for some research participants is thought to be a disadvantage (Novick, 2008). Novick (2008) also reports that multiple qualitative researchers suggest that telephone interviews need to be brief, reducing the depth and richness of the interview, and that the absence of visual cues in telephone interviews can impair the quality of the data produced, however, there is little evidence to support these claims in qualitative research.

Skype is a telecommunications computer software, designed to allow end-users to participate in video or voice calls for free (Skype, 2017). The use of Skype in qualitative research interviews combines the advantages and disadvantages of both face-to-face interviews and telephone interviews.

As suggested by Burke and Miller (2001), researchers are encouraged to establish a rapport with research participants prior to engaging research participants in discussion about the phenomenon of interest. This act was facilitated by extending a formal letter of invitation to all research participants, which included details about the purpose of the study (see Appendix E and Appendix F). In addition, the interview guide was communicated ahead of time so that all participants had a chance to further reflect on their responses prior to the interview; it is thought that this enhances the quality of the data shared by the participants (Burke & Miller, 2001). Furthermore, research participants in this study were not forced to complete the interview protocol within a pre-defined time limit, regardless of interview modality. All data produced from the study provided generous rich, thick descriptions which contributed to theme generation.

3.6.2. Self-Administered Questionnaire

In order to gather demographic data about the research participants, a self-administered questionnaire was provided (see Appendix I and Appendix K). Research participants were given a choice to answer the questionnaire either electronically or on a hard copy, depending on their preference.

Patients were asked to specify an age range, gender, a range for the number of years performing self-testing, a range for their total income level for the previous year, their highest education level, their current employment status and finally the employment

industry that best fit their current employment status. Physicians were asked to specify an age range, gender and the number of years worked as a practicing physician. These questions were designed to allow for a better understanding of the population involved in self-testing, as well as understanding the views of the individuals who provide medical care to patients.

3.7. Data Saturation

The data collection phase concluded when data saturation was reached. The number of participants required to reach data saturation is influenced by a number of factors, discussed by Morse (2000). First and foremost, by focusing the scope of the study and creating a clear and concise topic to be studied, participants are able to provide in-depth rich, qualitative descriptions of their experiences. This narrows the focus of the experiences shared by participants and helps to create unified themes. Next, the researcher must consider the quality of the data produced in an interview, as some research participants lack focus and may not communicate their experiences well; on the other hand, some research participants may be quite articulate and expressive about the topic being studied (Morse, 2000). Furthermore, Morse (2000) indicates that the researcher may be able to reach data saturation by also considering the study's design and the quality of the data produced. Guest, Bunce, & Johnson (2006) argue that interview structure, content and participant homogeneity are essential in reaching data saturation. Therefore, when participants share similarities in experiences with respect to the phenomena being studied, data saturation can be achieved sooner rather than later. In the analysis phase of the research study, the goal was to look for high-level, dominant and overlapping themes; once these dominant and overlapping themes became recurrent, data saturation was reached. Guest et al. (2006) explain that basic elements for metathemes may be present as early as one to six interviews.

3.8. Data Analysis

3.8.1. Data analysis of semi-structured interviews

Analyzing the data produced from the semi-structured interviews occurred in two steps. The first step involved transcription of the interview data. The second step involved thematic analysis of the data.

3.8.1.1. Transcription of Semi-Structured Interview Data

The researcher transcribed all of the recorded interviews. If any identifying information was released during the interview process, it was removed from the transcribed report. In order to ensure the accuracy of the transcribed interviews, the researcher listened to the audio tapings a second time alongside the transcribed report, and also attempted to have all transcriptions completed within a period of 48 hours. The transcribed data was made available to the research participants in order to reaffirm their statements; this is referred to as member checking. All research participants were given the opportunity to review their interview transcripts in order to confirm that an accurate interpretation of the interview data was made. Participants were given seven days to review the transcribed interviews. No research participants indicated that they would like to modify their transcripts. Once the seven-day period was up, all audio recordings were deleted and transcripts were finalized.

Once all of the interview data had been transcribed, the researcher organized the responses by interview questions to simplify the data analysis process. The researcher began the data analysis phase by reading and re-reading interview transcripts multiple times, while making memos as the transcripts were read. These memos helped to capture ideas, short phrases or key concepts (Creswell, 2010) that appeared during this process. Creswell (2010) suggests that this process allows the researcher to be well immersed into the details of the data and to get a strong grasp of the overall sense of the interview, before the researcher breaks it down into categories or parts.

Analyzing the data produced by a case study informed approach can utilize a variety of techniques. The technique chosen to analyze the data depends on the type of case study; techniques can include pattern matching, explanation building, time series analysis, logic models and cross case synthesis (Yin, 2009). In this explanatory case study research, explanation building was the technique used to analyze the data. Research questions are posed to help understand events that occur, but are not understood. Explanations presented in case study research provide answers to specific research questions. Explanation building is a suitable technique for this research study as this technique is designed to find a compelling explanation as to why a particular phenomenon exists as it does. As a result, an inductive and inferential mode of reasoning,

as opposed to deductive reasoning, is used in explanatory case study research (Belk, 2010).

3.8.1.2. Coding and Thematic Analysis with NVivo 11™

Successful data analysis is influenced by the researcher's familiarity with the tools available at their disposal to process and interpret research data. Lee & Fielding (2004) discuss a battery of tools that may be available - they include literal tools (physically concrete tools), conceptual tools (theoretical or methodological approaches) or operative tools (specific procedures such as segmenting, coding, abstracting, etc.).

Over the past decade, one of the tools that has emerged are computer software packages; they have been created to aid in helping the researcher to decipher, code and categorize large amounts of qualitative data that may be the result of interviews, narrative texts or written materials. Prior to the analysis process, the researcher needs to define an initial set of codes and connect them to the research design. It is suggested that the researcher build codes to help in the data interpretation phase, as well as examine the data for emerging themes. Creswell (2010) explains that themes are considered to be 'broad units' of information that consist of multiple codes which are grouped together to form a single idea. The software packages then aid the researcher to identify codes/outputs to see if any patterns emerge (Yin, 2009).

In this qualitative research study, the computer software package, NVivo 11™ was selected to complete the data analysis and interpretation process. NVivo is designed to provide a powerful analysis of textual data by organizing, analyzing, and finding connections in unstructured qualitative data such as interviews (QSR International, 2000). The first step in the data analysis procedure was to upload the semi-structured interviews into the NVivo software. Next, data analysis was guided by the conceptual framework devised for the study by the researcher. The researcher built an initial set of codes to look for emerging themes. The data was further subjected to several levels of coding using the NVivo software program to categorize similar characteristics and identify groups and subgroups of themes.

3.9. Storage and Retention of Research Data

Confidentiality of data was ensured through the use of Google Docs via Google Apps for Education (UOITnet server). All of the data collected was transcribed and stored on the UOITnet server, and was only accessible by the researcher. An interview transcript was provided to each participant in an electronic or hardcopy format. Member checking thus also served to further reaffirm the statements made by the participants, in order to increase the validity of their statements. All audio recordings were deleted once they were transcribed by the researcher. All data was anonymized to remove the risk of future re-identification of participants. All data produced from the study was destroyed upon the study's completion. All data housed on the UOITnet server was deleted and no electronic or hard copies of the data were kept. These steps ensured confidentiality throughout the research study process.

3.10 Ensuring Trustworthiness in Qualitative Research Methods

A number of frameworks exist which help to assess the rigour and trustworthiness of qualitative research findings (Baxter & Jack, 2008). The basic foundation for a well-written research study is guided by a well articulated case study research question, and evidence which supports the need to perform the research (Baxter & Jack, 2008). The researcher in this study executed a thorough literature review, highlighting the gaps in the literature which further demonstrate the need to conduct this study. Baxter & Jack (2008) further stipulate that an appropriate research design and sampling strategies are necessary, and that the data are collected and analyzed in a systematic way. In this research study, the researcher provides thorough detail (in the above sections of chapter 3) regarding the elements pertaining to research design, methodology, conceptual framework, participant recruitment strategy and data analysis, which demonstrate high levels of organization within the study.

Yin (2009) also proposed four criteria to be used in case study research to ensure the validity of the research and findings: internal and external validity, construct validity and reliability. In the following paragraphs, the researcher establishes how validity was demonstrated.

Internal validity refers to the establishment of a causal relationship between variables of interest (Yin, 2009). In this qualitative study, the researcher achieved internal validity using explanation building as a technique (as described in section 3.8.1.1.) to construct meaning and explain why the phenomenon exists as it does.

The concept of analytic generalizations is used to generalize research findings to a broader theory, and the research design phase is considered to be a key component of ensuring external validity (Yin, 2009). Using analytic generalizations, the researcher was able to link the research findings to broader theories described in the conceptual framework, such as the HBM and clinical governance framework. Furthermore, the discussion portion of the research paper illuminates additional theories, which further connects patient autonomy and self management, especially in the context of chronic diseases.

Yin (2009) explains that the purpose of construct validity is to identify whether the correct operational measures were selected for the concepts to be studied. This was accomplished using converging lines of inquiry in a connecting manor to further establish a chain of evidence. The triangulation of both patient and physician perspectives on the same phenomenon of interest helped to achieve construct validity. Additionally, experienced researchers were enlisted to challenge drafts of the completed thesis for a peer review, to help identify gaps or where additional clarification was necessary.

Finally, reliability is considered to be a dimension of trustworthiness, which serves to reduce errors and biases which may be present in a research study by developing a case study protocol and database as if each stage in the protocol was being audited (Yin, 2009). In order to ensure reliability, the researcher systematically documented each and every research step taken. Dependability of the research findings was enhanced using a code-recode procedure (Krefting, 1991). In this tactic, the researcher coded all of the data, and later returned to recode the same data after a number of weeks to ensure that the same findings were generated.

Chapter 4 – Results

4.0. Introduction

This chapter presents a description of the participants obtained by demographic questionnaires for patient and physician participants. Also presented in this chapter are the results of the data analysis from the open-ended semi-structured interviews with patient and physician participants. Results from both the contextual and conceptual phases of the research are presented and major themes are identified. Minor edits to participant quotes have been made in order to omit unnecessary repetitions and to increase readability of direct quotes, whilst maintaining the integrity of the data.

4.1. Description of Patient Participants

A total of six patients participated in this qualitative inquiry. A table summarizing the patient demographics is found in Appendix S.

Sixty-seven percent (4) of the patient participants were male and thirty-three percent (2) of the patient participants were female. The patient participants varied in age from 56 to 90 years old and patients indicated that they had been self-testing (not limited to glucometer usage) from a range of 0 to 25 years. All patient participants indicated that they are retired from the workforce.

Only five of the six patient participants specified their highest level of education completed. Two patients indicated that they did not obtain a certificate, diploma or degree; one participant indicated that they had completed a high school diploma or equivalent; the final two participants indicated that they completed a college diploma.

Three patient participants indicated that their total income level for the year 2016 was greater than \$35K and all three of these participants identified ‘manufacturing’ as their employment industry. The other three participants declined to specify their total income level for the year 2016; however, they described ‘business, building and other support services’, ‘information, culture and recreation’ and ‘educational services’ as those that best matched their employment industries.

4.2. Description of Physician Participants

There were also six physician participants in this qualitative inquiry. A table summarizing the physician demographics appears in Appendix T.

Physicians varied in age from 26 to 55 years of age. Half of the physician participants were male and the other half of the physician participants were female. Two physicians indicated that they had only been practicing medicine for 0 to 5 years; another two indicated that they had been practicing for 16 to 20 years. The other two physician participants specified that they had been practicing medicine for 26 to 30 years.

4.3. Data Analysis – Contextual Phase

The contextual phase of the data collection was an important aspect of the research, as it helped to build a greater understanding of the stories and perspectives brought forth by both patient and physician participants. The data collection questions helped to provide some background on the research participants, and in this manner, the researcher was able to contextualize the responses received from the research participants.

4.3.1 Data Analysis - Contextual Phase for Patient Participants

The contextual phase of the data collection for patient participants was created to gain an understanding of the participants' awareness of their illness and how it affects their everyday lives. This background information provides a brief contextual understanding of how the participants viewed their world.

All patients who had participated in the research endeavour had been diagnosed with 'diabetes' for a minimum of five years. Patient participants generally had a varying range of knowledge of diabetes. PT3 indicated that she was aware that the diabetes diagnosis would become imminent, as she was first classed as pre-diabetic for a number of years. PT1 who had been diagnosed for over 25 years, shared a multitude of emotions that he had faced over the years with a diagnosis of diabetes, the struggles faced with the illness, as well as how living through the diagnosis had challenged and changed his life for the better. His experience with the illness has led him to become a peer-educator within the community for other patients diagnosed with diabetes. He describes his experience of living with diabetes:

“Other people; getting them to understand what you are going through. What you are dealing with - because diabetes is not visible. It's an invisible disease that attacks from within. And that's the scary part, cause whether you have low sugars or high sugars, both ways are gonna get you. And you have to stay in the middle.

And that's the main thing which I'm bad at – it's so hard. Because I always say too, every diabetic cheats. Doesn't matter who it is; what you're doing. It's just a statement that I use. You could go out for supper and not even realize - your starch, there's sugar in there, which becomes sugar. And your sugar goes up. So, I've learned that, yeah, certain things like Chinese food, I can no longer have. You know like those things. My son comes over, and him and his wife they go and get Chinese food [patient quotes:] *“Well, I'm sorry I have to make my own...”* Otherwise my sugar, it'll go through the roof. And those are just little things that you learn as you go along...It seems like everybody's against you, but they're not, they just don't know what's going on. I wish more people, the classes that I teach, that more people who don't have diabetes would come, because you can learn a whole lot there... on what your partner, or your mother or father is dealing with when they have diabetes. And that's the biggest thing, how to cope with them.”

While PT1 described his experience of living with diabetes on a more personal level, PT3, shed light on the prevalence of diabetes within our society and made reference to the immense cost that diabetes has on our healthcare system, and the impact it has on her family as well.

“Well I know it's very prevalent in our society. I know that it leads to many health problems. I mean I can list the health problems, but you are probably aware of those too. It seems to be more and more people developing it. And people develop it; young children develop it now, more. And then, it seems to be the age. Cause I'm 74. There seems to be – like my brother had it and he had it when he was about 70. And it seems to go and families. My brother-in-law, he had it. And my husband's uncle had passed away with it way back years and years ago, before there was anything like insulin. So I think it's very much family. I'm sure it costing the healthcare system mega bucks too.”

PT4, PT5, PT6 and PT8 spoke of their knowledge of diabetes on a broader scale, and shared what they knew about the disease itself.

“I know that your pancreas doesn't produce the insulin.” – PT4

PT5 recognized the importance of making healthy food choices, a sentiment which was shared by all of the participants:

“I know you have to stay away from the sweet stuff. You have to eat right. Like when we went to... [the dietitian], they told us all, and we stuck to it. My wife got so that she cooked right. You know. And I know diabetes isn't too good if you get it.”

Furthermore, patients reported that the monitoring of their diabetes with routine bloodwork drawn at their local laboratories, sometimes created feelings of anxiety and

unease. Patients explained that phlebotomists who have drawn their blood with poor technique oftentimes leave them with a hematoma¹⁷ or create pain and soreness at the site of the venipuncture¹⁸. They share their experiences of poor blood draws below:

“If somebody is poking at you, and they leave you like black and blue... I know this one girl, I refuse to let her, cause she goes in and then she goes like this [motions to phlebotomist moving needle around in arm]. No thank you. I come out, and I can't use my arm for the rest of the day.” – PT1

“I go up there to this place where they take your blood, and there's women in there that I don't think they should be taking your blood test. They put [the needle] in, and put it in about that far [shows approximately 3 cm of distance into vein]. And the other thing is, they put a bunch of alcohol on it, and don't wipe it off, and that stings. It hurts. One day, I said ‘*ouch that hurts*’. She says ‘*do you want me to take it out?*’ I said ‘*well you got to do it - so finish it.*’ It didn't hurt that bad, but it stung. There's some women, you don't even know they put the needle in! See this here [shows site of blood draw]. That's the size of a quarter and there's a bump... I don't like to complain, but, I know there's two women over there, [and] I'm gonna say ‘*can you get me anyone else?*’ Cause it hurts. And it causes that kind of stuff [points to hematoma].” – PT5

This routine procedure was portrayed to be a negative experience by the patient participants.

4.3.2. Data Analysis – Contextual Phase for Physician Participants

Data collection for physician participants in the contextual phase was designed to gain an understanding of the physicians' awareness on the usefulness and availability of POCT within the community. Physicians spoke of overall awareness of self-tests that are used in monitoring chronic conditions, as well as various screening tests. Physician participants were generally well aware of the availability of self-testing on the market and widely viewed these tests in a favourable manner. They describe their experiences below:

“There are a lot of different tests available that are used and can be helpful. Pregnancy tests. Fertility tests. Glucose testing. I'm sure there's more.” – PY2

“I agree that self-testing is definitely more widely available to patients now, and I think that's a good thing” – PY6

¹⁷ Hematoma: “A circumscribed collection of blood, usually clotted, in a tissue or organ, caused by a break in a blood vessel” (Dictionary.com, 2017).

¹⁸ Venipuncture: “The puncture of a vein for surgical or therapeutic purposes or for collecting blood specimens for analysis” (Dictionary.com, 2017).

“I guess in my opinion, it [POCT] kind of depends on what it's used for, and who it's used by. I think self-testing and point-of-care testing, I think that its great that that's available because it just kind of removes some of the obstacles to patients accessing their own health information, and also gives them some agency in managing their own health conditions. So I think that's a big benefit. It also allows in chronic conditions that require frequent monitoring, it just allows you to get more data points, much more easily versus if they have to travel to the clinic, or of they have to wait and see their health care provider until they get their feedback. It just lets things be a bit more immediate to them. So, I think it's very valuable and I'm sure it's something we will use more and more.” – PY3

Additionally, PY4 and PY1 remarked that the availability of ST for diabetic patients checking their blood glucose at home has been supported by the removal of obstacles associated with this form of ST, as well as various interdisciplinary teams working together to help promote the utility of self-monitoring in the diabetic population. They share their experiences below:

“[Testing] has become more available. Part of it is the interdisciplinary teams. So, physicians are giving the same message as pharmacists, as the diabetic clinics, and I feel everyone is working together to help support the availability. One thing that's very helpful is that the glucometers are generally provided free of charge to the patient. So that gets rid of a lot of barriers. And as long as the test strips are covered by a private insurance plan or the Ontario Drug Benefit Plan, then that also removes a barrier to testing.” – PY4

“Glucose monitors, by and large, have been made free to patients, through different pharma companies, facilitated by diabetes education centers and by local pharmacists, which has been a big plus.” – PY1

4.4. Data Analysis – Conceptual Framework Phase

In order to identify important themes presented in the data, the researcher returned to the conceptual framework to guide the data analysis process. In keeping with the goals of the research objectives, the data collection questions were designed to answer the following questions:

- 1) What is the role of patient autonomy in healthcare? How does patient autonomy or ability to self-manage a health condition with a self-test affect healthcare decision-making for both the patient and healthcare provider?
- 2) What influences patients to participate or not participate in self-testing?
- 3) Who is responsible for following up with self-test results?

For patient and physician participants, the conceptual framework phase was devised to seek an understanding of each participant's views of the value of self-testing, the role of autonomy in healthcare decision-making, various aspects of safety related to ST, and finally how ST would or could change the patient/physician dynamic, both short-term and in the long-term.

All data that is presented was further triangulated by comparing themes that emerged from both the patient and participant groups. During the data analysis process, numerous themes common to both patient and physicians were identified and are listed below.

4.4.1. Impact of Self-Testing to Chronic Disease Management

ST has proven to be a useful tool in chronic disease management, as is described by both patient and physician participants. In this section, the researcher presents the data as two sub-themes of the impact of ST to chronic disease management: increased self-satisfaction and lifestyle adjustments. The data collected suggests that overall, the act of ST creates positive, happier and healthier outcomes for patients in the long run.

4.4.1.1. Increased Self-Satisfaction

In the setting of a diabetes diagnosis, patients explained that monitoring their blood glucose at home was an important aspect of decision making related to their healthcare. In the section below, they explain that the immediate feedback of a blood glucose value led to greater self-satisfaction of their current health status, allowed patients to consider making changes to their diet, exercise plan and lifestyle, as well as being able to confirm or re-affirm their clinical status when they were feeling symptomatic of the disease.

“If I’ve overindulged in something, then I can then I can check right away, and then I know that I better watch it the rest of the day too. So, I think it's great. I think it's the way to keep a tab on your food intake.” – PT3

“If my self-testing is normal, I feel good about it. If it’s high, I want to know why it was so high; or if I know the reason why it’s so high, I cut it out.” – PT4

“When I take my NovoRapid, I test before and then two hours after. So there's six times right there. Before each meal, and after each meal. And then you have morning and night. So it adds up. And when you see the overall picture...when I

do it in the morning - if it's between 6 and 8, or 4 and 8 - it's perfect. If it's over, then I think *'what did I do wrong?'* It gives you a good idea, *'Okay, I had too much cheese or too many crackers, or my snack with my insulin was too much'*. So then you have to reduce it. It does help you. And then when you get up the next morning you see your sugar is between 4 and 8... *'Okay I did something right'*. Then that way, it does show you.” – PT1

“Well I think it [self-testing] can confirm, at times, why you are feeling like you're feeling. You know, I think *'oh I have a feeling my sugars are low'* and you can act on that if in fact you actually do get a low reading.” – PT6

“You know, it's a freedom thing. Like every time you do that, it frees you. And if I don't do it for three or four days, and I do it, and it's still good, I'm still free.” – PT5

4.4.1.2. Lifestyle Adjustments

Lifestyle choices are an important element of disease management in diabetes. Patients shared that a diagnosis of diabetes meant challenging the way one thinks and behaves, as well as adjusting their daily routines in order to improve their own outcomes. PT1 explains: *“If you want to be around, you better [take charge]! That's the main thing. I'm not perfect. I still have high sugars. But you try to watch it; you try to keep an eye; you try to do your best.”* He further goes on to state that a diabetes diagnosis forces the patient to re-evaluate their whole way of thinking and that essentially, a patient has to completely readapt to a new daily way of life in order to achieve positive healthcare outcomes.

“You know if you're a new diabetic, at 75, you have to change your way of thinking. You can't do what you did for 74 years - just eat what you want when you want. How?! You can't do that anymore! You have to change your whole way of life, and it took me a while to clue into that too.” – PT1

Patients acknowledged that food choices played a role in their disease management. The immediate feedback of a test result forced patients to reconsider their food consumption habits. Patients reported improved eating habits; however, it sometimes meant that they needed to give up some of their favourite foods, or such foods needed to be consumed in much smaller quantities. PT4 indicated *“I try to think of - like if [my sugar] is fine, I don't think about it again until next time. But if it's up, I try to figure out what it was that made it go up.”* To add to that, PT3 stated that being

diagnosed with diabetes made her realize that she needed to be more conscious about the amount of sweets she was consuming; something which she did not routinely consider previously. *“Well [self-testing] just makes you more conscious of what you eat. And I mean you pay. I’m going to say you pay for it if you overindulge. I mean, I think I never cared for sweets, until I got diabetes.”* PT5 shared a similar sentiment with regard to his predilection for his favourite foods:

“Breaded tenderloin is a really greasy thing. I love that. So I got it probably twice a month, but I should have it every other week [or] every once a week! But um no. We held to what we shouldn’t eat. And let go of drinking pop. I don’t drink much pop. I drink water. I don’t drink beer. I cut myself way back.” – PT5

Patients also reported that exercise was an important aspect of managing their diabetes.

“You’re better off to get going, because, to me, exercise is the number one enemy of diabetes. The more you do, the better you will feel.” - PT1

“Exercise has a lot to do with it, but because I have a bad back, I go - maybe go over to Walmart or something. Someplace like that. I get a cart and I can walk around and push that, and that’s my exercise. So, I think that’s – you know - one of the good things about [self-testing]. That you can monitor sort of yourself.” – PT3

The quotes shared by patients in the above section clearly demonstrated the reported significance of lifestyle choices in diabetes management.

4.4.1.3. Physician Perspective on Self-Testing in Chronic Disease Management

In chronic disease management, the physicians supported the concept of self-monitoring blood glucose (SMBG) as it enables patients to be more proactive about their healthcare and decision-making related to their disease management, as well as providing an opportunity to enhance the patient/physician relationship by offering education. Additionally, ST provided the physicians with valuable information regarding the patient’s motivations as a participant in their own healthcare; they share their perceptions below:

“I think it’s [self-testing] important initially, because it gives people a manner of empowerment of control. They can see what their numbers are. Some of them, if they’re able to cognitively make the connections between meals and lack of

exercise and sugar readings, sometimes, there may be some behavioral change that comes as a result of that, in regards to their conservative treatment. As their disease progresses and goes on, I think testing becomes important because it becomes a sign of motivation for patients, because it's not fun to prick yourself once a day or three times a week for example or twice a day, to try and help manage your sugar levels together with diet and your meds and exercise” – PY1

“I like the idea of blood glucose testing. I think people can get information from it. For instance, our local diabetes education center is telling everybody they should get a blood glucometer to test their sugars all the time. And many of these people aren't on any meds, or are just on Metformin. And there is actually zero evidence of any benefits in testing in those situations. Now, in my mind, it makes sense that somebody might learn something. You know, they learn how their blood sugars react individually to certain amount of exercise or certain amount of food, and then they could micromanage things.” – PY2

“I believe [self-testing] is very important and the reason for that is, it actually allows patients to participate you know and take ownership; so take ownership of the management of their condition, for example diabetes. You know hopefully by self-testing, it would cause some change in behaviours if they know what those numbers actually are. If it's gonna cause the patient to be more compliant with medication, or to watch what they eat, then you know, that would probably lead to better outcomes. So I'm thinking yeah, so more compliance and also taking ownership and just being involved, a participant in care. –PY6

The above quotes establish why physicians believe that ST in chronic disease management encourages patients to become active participants in their own healthcare.

4.4.2. Decisions that Influence Self-Testing Behaviours in Patients

The use of a glucometer to monitor blood sugar at home undoubtedly plays a role in chronic disease management. Patients reported that ST assisted their daily way of life, and cited convenience, increased control in their sugar management, improved meter technology and being active participants in their own care to seek healthier outcomes, as reasons why ST was so important to them. These behaviours are seen as positive influences that promote the act of ST. Subthemes that garnished negative attention were cost as a barrier to ST in the setting of diabetes and adverse experiences of ST.

4.4.2.1. Convenience

The act of ST in the privacy of one's own home was noted to be quite beneficial for patient participants. PT3 and PT5 explain below that age, mobility and accessibility to

local laboratories can be difficult for some members of the community, as not everyone is able to drive:

“What would we do if we had to go to a center to be tested. Like as I said I am 74. I do drive, but I mean I'm thinking if there's lots of people who are unable to get to a center you know. If you live in the country, how would you manage? And you didn't drive? I mean, I live in town. It wouldn't be such a problem. But I'm still thinking that the healthcare system would be skyrocketing in expenses if we had to go to a center to be tested. It just doesn't make sense to me.” – PT3

“Yeah. there's no problem with taking the test at all. It's easy. It's good. And well anybody can do it. You know what I mean. It's not hard to do...It gives me the freedom of doing it when I want, and I don't have to make an appointment.” – PT5

These quotes essentially demonstrate reasons why ST is considered to be so convenient.

4.4.2.2. Increased Participation in Care

Active participation in one's healthcare treatment regime was reported to be a central aspect of maintaining positive healthcare outcomes. Patient participants shared why ST was seen as a valuable tool to their healthcare when it came to managing their diabetes:

“I can tell you why it was important to me. I knew exactly where I was when I tested. If it [glucose] was too much or not enough. The odd time it was over; but it put me on the straight road.” – PT5

“If I'm thinking oh my sugar could be low I better check, and I check. I'm thinking - because that's in my control. Do you know what I mean? If it's a low it confirms, *'okay, now I can do something about it'*. So, it's almost a bit of a relief.... It puts you more in control. It lets you act if you need to.” – PT6

These quotes suggest that ST can provide meaningful information to patients to further execute decisions as it relates to their health.

4.4.2.3. Improved Blood Glucose Management

Using ST as a tool to improve blood glucose management was seen also as a benefit to patient participants. Patients explained that it helped them to improve and

stabilize their blood sugar readings, as well as provided them with more information about their current health status, which can be comforting.

“Well it certainly helps me feel better knowing why I am feeling the way I am, if in fact it is my sugar level. It happened actually just yesterday, where I took a sugar pill. I couldn't understand why I was feeling the way I was. I took blood pressure and then my sugar level which was low. So, end result was take a sugar pill.” – PT6

“Your benefit is that you can adjust yourself in what you're consuming.” – PT3

“[Self-testing] ...the odd time I would forget. Just like I forgot Monday. But it made my health better...It makes management perfect. I know when my testing is high; if I ate something I shouldn't have. And then, well, if I don't eat nothing wrong, I'm good. I feel good. And for my age I feel damn good. [laughs]” – PT5

“Well, hopefully [self-testing] keeps you in line a bit. And this way, you check your sugar levels on a regular basis.” – PT8

This research data demonstrates that patients correlate their clinical symptoms with their blood sugar values, and that SMBG can further improve a patients' own glucose management practices.

4.4.2.4. Facilitators of Self-Testing

Innovations in technology have ameliorated the ST process for diabetics. Patients describe their experiences with the automation as well as in using glucometers with enhanced features below:

“It's all automation now. It tells you: *Put the strip in*. So you add the strip. And then you punch your finger, and then it says *put blood on strip*. And you know, you just do what it says. You get to know the routine...And then you punch the side of it [glucometer]. It comes up 5.6 or something. That's it. It turns off by itself. Then you put it back in the box, and you say I'll do that again tomorrow night.” – PT5

“I just got a new meter, which I can hook up to my tablet, for Dr.ABC2. Cause I'm bad at writing down my numbers in a book, so she suggested this new meter. And it's an app. You put it on this [tablet]; when you [self-test], it'll [the results] go right to it. [laughs] And then I can just go and see her, and I can bring it up. There it is. And it's so much better.” – PT1

“This new machine I have tells me if I’m above target or, it doesn't say anything if you're below target, or at target. But it does say if you’re above target. So, you sort of think about that...And what I do like about this “*On Target/Above Target*” that comes up if you’re above what you should be, it’ll tell you! It's not just left for you to say, ‘*okay well it was you know, 10.2*’, or whatever it was. It tells you that you’re above the target level for that particular time. And you have the three settings. You’ve got fasting, before a meal and after. So you have the three settings that you use appropriately. I like that. And they have a lot of other bells and whistles.” – PT3

The improvements in meter design and automation have reportedly made performing, interpreting and storing self-test results, much more practical for patients.

4.4.2.5. Cost as a Barrier to Self-Testing

Cost was prominently disclosed to be a barrier to self-testing, by both patients and physicians. Most notably for the diabetic population, the cost of purchasing strips to perform the testing plays a role in influencing the number of times a patient is able to test their blood sugar. PY1 describes how the pharmaceutical industry and the government play a big role in affordability of strips:

“The strips remain the drawing card for the pharmaceutical companies, because you have to pay for those. The government and then several other private insurers have recently put some boundaries on how many strips patients are allowed to use in a given time, which was quite controversial [as it] was received by diabetic folks harshly at first, but I think they’ve come to accept that that's probably a necessary evil in terms of funding and in terms of the reality of how many times a day patients really do need to test their sugars.”

However, he further explains that the affordability of glucometer strips may create barriers to testing blood sugars at home. When strips are subsidized by a drug benefit plan, access to glucometer testing is still possible by patients, however, testing may not occur as frequently, as patients would run out of test strips. PY1 expressed that the affordability of strips is especially difficult for disadvantaged members of the community, further increasing the barriers to testing that those individuals may already face.

“I think for people that are on ODSP (Ontario Disability Support Program) – which is an Ontario government funding mechanism if they are unemployed or don't have any other financial resources, or they’re on Trillium which is another

benefit plan for folks who are working but don't have benefits, or they're on the Ontario Drug Benefit Plan for seniors – then getting strips is not a big deal. Because they are, I think, appropriately paid for or funded. If you are the 'working poor', it becomes a lot more difficult to be able to afford to buy strips. And those are often disadvantaged populations that maybe do not have accessibility to things like ODSB and Trillium for whatever reasons...many, many, many barriers. Like everything, that's the portion of folks of the population that testing is probably not ideally setup for yet. I'm sure there's a big gap, and I see it in my own office."

In the patient participant group, the cost of performing glucose testing at home was also highlighted as a major barrier associated with self-testing. PT1 noted:

"Because I have Green Shield coverage through [workplace] - because I'm retired, I still have all of my benefits. I have heard from some of the elderly, that the government limits them to a certain number of strips. So they have to be careful. But like for myself, I can just go - I get two boxes at a time. 200 strips. About once every two months, maybe less. So it does help."

When the researcher inquired how the cost to own, maintain and perform the self-test, would affect their decision to perform the test, PT1 argued that it would limit the amount of times a diabetic would check their blood glucose levels:

"You would limit your testing because, strips aren't cheap. They're about a hundred bucks, if not more, for say 90 or 100. It adds up. And when you're a senior – like I worked with guys, they retired years ago and their pension is quite a bit less than mine, and they worked at the same place. But because the rate of pay went up when I retired, it makes a difference on your monthly income. I don't want to talk figures but say they were getting \$400 a month, well mine might be \$1200 a month, because he retired 20 years before me, and then he doesn't have the money to go and to be buying all of these strips, if he had no coverage. [So you kind of have to ration your supplies]. And the government has to start to realize too, that these elderly people, if they're diabetic, they need those strips. They need to know what's going on. Like one lady said, '*I can't do it as many times as you, I'll run out of strips.*' And then the government won't do it. Then she's paying out of her pocket. She says '*I don't have the money*'." – PT1

PT3 echoed the same sentiment, and stated:

"Maybe the government will listen after they hear that there are people who can't afford to do it; that maybe more people need to be free to get these things. Because, in the long run, what does it lead to? It leads to more expense." – PT3

Although the overall cost to perform the test was perceived to be a barrier to glucose ST, patients indicated that they would continue to test; however, some individuals would consider testing less frequently if the end-user had to assume a greater portion of the cost to ST.

“It's not so much the meter, it's the strips. They get a little on the pricey side. [If I wasn't covered] I wouldn't do it four times a day. I would probably do two to three times a day.” – PT8

“I don't think it would matter. I mean, you have to do what you have to do. It's [diabetes] not something to take lightly, and it leads to so many health problems. Who wants to have their leg amputated? Or become blind? Who would? I mean...there's no choice there. It is scary.” – PT3

“I'm paying for the strips. I get coverage, but I still pay a fair bit for the strips...It would not really affect my decision to do the testing.” – PT4

“I don't think the cost would affect my decision at all. I mean if it's health-related, that to me is more important.” – PT6

It is clear that patients believe that ST is an important behaviour which provides valuable information about the status of their health and that the perceived fear of negative healthcare outcomes is a contributing factor to one's desire to participate in ST.

4.4.2.6. Adverse Patient Experiences of Monitoring Diabetes with Self-Testing

Although patients were generally quite content testing their blood sugar at home, an element of monitoring the disease which was reported to be a nuisance was the numerous times that patients had to prick their fingers. PT4 explained that for him, he only seems to self-test when he is feeling unwell, because it's not fun to prick yourself every time you eat. Additionally, both PT5 and PT8 suggested that repeatedly performing capillary punctures was both inconvenient and uncomfortable.

4.4.2.7. Physician Perspective on Factors that Influence Self-Testing Behaviours

Although the patient participants cited convenience, increased control in their sugar management, improved meter technology and being active participants in their own

care as positive reasons why ST was important to them, physicians have noted that ST is not always a positive experience. They share their experiences below:

“What I've seen is, there seems to be three groups of people that I see. All three of them have a certain percentage of them that will test. But Group 1, they just have very good sugar control, they have mild disease, somewhat slowly progressive, but they take significant steps to control it on their own or with medicines. The Group 2 are the people that are always uncontrolled. Again, where a small percentage of those folks, maybe 20%, will continue to test, but they seem to stay out of complications and they do reasonably well over the long-ish term. Now we're talking twenty years now of my experience with diabetes so far in practice. And then I see the patients who are just horribly, horribly controlled. HBA1C is always over 90, often over 100. Compliance with medicine is poor; eventually have a vascular outcome or something similar, with very little motivation to test. Some of those people do test, and are just resigned to the fact that their lifestyles are not going to change; they're on a certain amount of medicine – they don't want more, or their disease for whatever reason, is just very, very difficult to control.” – PY1

“I think it's kinda person-by-person basis, right? Cause we definitely see the opposite a lot, where people are not engaged, they don't do their self-testing. Um, but some people just are motivated because they want to be better, or they have a worry about missing something that could be wrong”. – PY3

“So, in some cases yes [self-testing can improve patient care]. So, again, the glucometer, certain selected patients will [test], some patients it will not. And interestingly, again the large population data suggests that twice-daily glucometer testing in type-2 diabetes doesn't improve control or change outcomes. So, I would like to say that it does, but I think there are all those other forces that are preventing people from being compliant...and really [working] on their lifestyle; so their diet and their exercise. You know, I think it's up to the patient. If the patient really internalizes, if they are really serious... they will say *'you know what, I'm going to take control of this, and I do not want to be on 6 different medications everyday.'* Then yes, self-testing is an important tool and a helpful tool for them.... But on the other hand, there are people who go through the motions, and they maybe check a few times before they come to see me, because they know I'll be asking. But they are still 120 kg in weight and they might lose 1 kg. Like oh my goodness, I know you can do better.” – PY4

Physicians essentially reported that a given percentage of the diabetic patient population is motivated enough to participate in their own care, while another section of the population is not, and that each case of active healthcare participation was unique to the patient.

4.4.3. Impact of Self-Testing on Patient Safety

In this section, patients share their thoughts regarding the training received to perform ST on their glucometers, as well as the perceived accuracy of the devices they are using to perform the testing. This is an important section, as it highlights how capable and experienced patients feel about the training and testing process. Furthermore, patients explained how their meters provided self-assurance that accurate readings were being displayed.

4.4.3.1. Training

All patient participants indicated that they were generally quite comfortable with the training procedure, as well as handling and performing testing with their personal glucometer. In the majority of cases, patients were trained by an allied healthcare professional.

“The nurse showed me. It's just a matter of pricking your finger, and putting the tab in. Once you push the tab in, the machine comes on. You get the blood to come, and then you just touch [the glucose strip]. And you wait 5 seconds, and it's there. The training was very simple” – PT1

“The first one I had was called a ‘Breeze’. I don't even know who made it, but it isn't out there anymore. The gal - well she was a pharmacist - she showed me how to use it. It was a very simple one.” – PT3

“The pharmacist took it out, made me do it 2 or 3 times, and I could do it ever since...They just showed me how to do it.” – PT5

“Oh, my wife. I just used to watch her, and sometimes she'd check me too. Give me a stab of the finger and read it, and it was always good.”- PT8

The aforementioned data indicates that a variety of individuals were involved in acquainting patients to their ST devices.

4.4.3.2. Perceived Accuracy of Self-Testing Devices

The accuracy of ST devices is an important element of ensuring good patient care and optimal patient safety, as these results are used by both patients and physicians in clinical decision-making. Both groups reported that finger-prick glucose results correlated well with laboratory glucose values.

“I trust the little meter. It’s pretty accurate with the blood lab when I go for my blood testing.” – PT4

“I went to my doctor, a week ago Friday...and I thought that my testing was higher than the results of my clinic test. He said mine was 6.4, and he said that was good. And that was about an hour after lunch. And I thought that was pretty accurate...I do think that [the glucometer result] gives you some sort of confidence that you're around it [glucose measured by lab]...confident enough to go on. It's not major. It isn't like its 15-point something, or out by that much. I think it's pretty accurate.” – PT3

“It's perfect. Perfect. Easy to use. It's dead on. Like you know, it don't waver.” – PT5

“The one I have is considerably old, but I have confidence in it.” – PT6

“Well hopefully it's accurate. It's just a brand new one.” – PT8

PT4 did remark that he had a couple of glucometers, and had noticed that one meter was providing readings that were not consistent with the other meters. His follow up action was to phone the company, who told him not to worry as the results were within acceptable limits pertaining to the accuracy of the device.

“I got a couple of them there, and one's off a little bit from the other one, so I called the company, and they said there's an allowance for so much of a difference, and they all seem to be okay with it.” - PT4

Of note however, patients lacked the skills necessary to further troubleshoot their machines when necessary. PT5 explains that if he was having an issue with his machine that could not be rectified, then he would consult his physician for advice.

“If I was having a problem with it, and I couldn't rectify it, I'd have a date with the doctor, and he would give me a blood test, or tell me to get a blood test... He'd look after me; tell me what to do. I wouldn't hesitate.” – PT5

Generally, however, the glucometers were perceived to be quite accurate in measuring finger-prick blood glucose by both patients and physicians.

4.4.3.3. Physician Perspective: Reliability of Patient Reported Self-Monitoring Blood Glucose Values

As illustrated above, patients reported feeling quite comfortable with the training process that they received to use their glucometers, and indicated that they were confident

in the results being provided by their meters. Patients and physicians routinely use the self-reported glucose values in their clinical decision-making; therefore, the results must be reliable. Although the majority of patients do not have an educational background in clinical sciences, which would involve an all-encompassing training and understanding of clinical diagnostic devices, physicians indicated that they were generally satisfied with the glucometer results being reported by their patients, and explain why below:

“So, if the patient arrives with a glucometer and with a logbook, I am fairly confident that they are doing it correctly and I can rely on those results, because if a patient is non compliant, then, they aren't testing; they aren't keeping a log book; they aren't showing up. And so, you know, if someone shows up with information, I, in good faith will take that, that they are doing the testing.” – PY4

“Generally, I'm quite confident. I mean, there can be some problems with some of the testers that require you to enter a code and if you put in the wrong code then it can throw things off a bit. But, you know we're also correlating this with symptoms or correlating it with their hemoglobin A1C values. So, if their A1C and their values are completely contradictory, then I might look into what is wrong with the testers. But, otherwise I would assume that they are correct. They [the meters] are quite accurate.” – PY2

“I think you have a better idea, like case-by-case. Knowing whether the patient has been taught. Knowing whether they were the kinda person who would follow instructions to a tee. Maybe if you did like follow-up on your education, having the patient demonstrate the skill of doing the test. Cause I think that's really what we're talking about – about whether the results are reliable, and then also knowing how they recorded their result; like whether they're writing down the numbers at the time, or whether once a week they're like *'oh what were my results this week'*, and they tried to recall them. Like, that makes a difference on the reliability of their result.” – PY3

Physicians acknowledged compliance, patient education and relative ease of meter use as reasons why they believed that the results reported by patients were dependable.

4.4.3.4. Physician Perspective: Interpretation of Patient Reported Self-Monitoring Blood Glucose Values

An element of ST blood glucose that keeps the patient safe is for the patients to understand what the self-test numbers represent. Diabetic education is essential for

ensuring that patients can correctly interpret their ST blood glucose values, and then furthermore, take action when required.

“I think one of the challenges is just, making sure the patient knows what to do with the information and making sure they have the necessary knowledge and skills to be able to kinda interpret the results they're getting, and understand how they relate to them like as an individual patient and how those results relate to the management of whatever their health condition is.” – PY3

“So, a part of diabetic education is for patients to be familiar with what the numbers represent. What's normal versus not normal. So if I say to a patient, *‘for you particularly, I want your fasting sugars to be under 7’*, and they are doing self testing, I am completely fine with them interpreting those kind of things, based on what I've educated them on. So they can know that yep, if it's between 5 and 7, I'm good; I keep doing what I'm doing. If it's under let's say 3 or 2, then I'm very low, I now need to act on this, you know eat and etc.; or if I'm very high, these are the things that I need to be doing. That part I'm comfortable with...I think for self-testing to be an effective tool, patients need to have proper education. So that needs to be available to patients, to know how to interpret the results; know when to seek help; they understand the implications of a normal; they understand the implications of an abnormal reading, and again, when to show up to the doctor.” – PY6

Physicians discussed that educating patients about their health condition was an important aspect of correctly interpreting self-reported blood glucose values.

4.4.4. Impact of Glucose Self-Testing to Healthcare Decision-Making

Healthcare decision-making involves both the patient and the physician reaching a consensus on a treatment plan which is the most appropriate for the patient's condition. For patients who complied with a ST regimen and routinely logged their blood sugar values, the data points provided physicians with a better overall picture of the patient's glucose management. Blood glucose values measured over a series of weeks at various times during the day were thought to be more helpful in understanding the patient's condition, than a single fasting blood glucose value drawn by the laboratory for routine three-month bloodwork checkups.

“Definitely, it plays a role in decision making, because it gives me an idea... I can check an A1C which gives me a three-month average, but you know if it's high or low, I don't know where those numbers are coming from. Is that they're waking up and their fasting sugars are very high? Or are they getting low at night? I won't

know that from my blood test, because it's just for that one time when they go to the lab. But if a patient is tracking over the course of a week, two weeks, a month, and I'm seeing different readings, of course that's valuable information. So from the diabetic standpoint, it's very useful.” –PY6

“I think of self-testing for sugar the same way I do about having a blood pressure monitor at home. If it's accurate, and it works, it helps me. It helps them. Empowers them. Motivates them. Bring them into treatment ideas. Helps them accept their diagnosis, which is often difficult even after years. And it's a huge plus to me if they remember to bring all those numbers in. Because many patients, particularly when we talk about hypertension, which has a subjective feel to it in terms of how the patient is that day, or how worried or anxious they are - it can go up and down with your epinephrine levels of course. Sugar doesn't do that; not as dramatically as blood pressure does. So home blood pressure measurements that are 130 on 80 at home consistently, versus my 160 on 90 because the patient just ran up the stairs, or they're freaking out about their blood pressure - those numbers at home make my life a lot easier. It also keeps the patient safe because I'm not piling medicines up on them, to the extent where they stand up and get dizzy and fall down and break a hip. So - very helpful! Sugar is much the same” – PY1

Furthermore, PY1 goes on to explain that single blood glucose values can also be important indicators of a patient's health, when interpreted in the bigger clinical context of the patient's medical history. This is why routine logging of glucometer readings can be important.

“I don't let individuals sugar measurements change my management. Like most GPs, I actually don't even test patients' fasting sugars anymore in their bloodwork. I've run their sugar diabetes management now with an HBA1C with their every 3-month test. It has been shown to be more accurate for microvascular complication. It is done non-fasting. Its very easy. I don't send patients for fasting bloodwork for anything anymore, because new guidelines have come around to say that lipids don't have to be checked by fasting anymore. So, rather than create another barrier where you have to be fasting to get your bloodwork, I let them go any time during the day. It's been profoundly more easy, and I have noticed much better ongoing results with my HBA1C management that way. So, sugars that are taking don't cause me a lot of stress as a GP. An HBA1C that's rising in keeping with patients' sugars - So if someone came to me and said they had sugar of 20 the other day, or 22, and they've had it for three or four days, and they were reasonably well controlled, I know they have an infection somewhere. Something bad is happening. So there's something. I look at it that way. But that doesn't

make me jump to double the doses of their medicine or increase their insulin or anything like that necessarily. I investigate as to why their sugars have suddenly become out of control and then look at that. But I do pay attention. I don't just blow off reported sugars from patients because I find that most of them are experienced, and I believe the numbers. I just have to make sure that I have the right data and the right proof to change medicine based on, just regular finger-prick sugars.” – PY1

ST also is seen to help facilitate the doctor’s role in providing clinical counsel. PY4 shares how the experience of ST can act as a safeguard for elderly patients who drive vehicles. She explains:

“So, for something straightforward like glucometer testing, you know blood sugar testing, it's a helpful tool for education, for helping me guide what medications I prescribe. And um, I think about diet modification. So it can be an important tool. Maybe I should mention another thing for self-testing; in patients that are on insulin and are driving, the Ministry of Transportation is really watching, especially as people get older, just really watching closely to see if these patients are at risk of hypoglycemia, or getting in car accidents because their sugars are low. So, recently, knowing what the ministry is looking at as people get older, I will actually tell my patients, I say *“Okay, you’re on insulin, you are driving, I want you to start checking - taking your sugar every time before you get in the car. If your sugar is below five, I don't want you to get in the car; you need to have a snack. If your sugar is acceptable, then it's in your meter and its time-stamped. And if you get in your car and anything happens, then you actually have evidence to protect you.”* Because if there is an accident involving a person on insulin, then they are at risk. You know the other lawyers are going to say *‘you shouldn't have been driving this could have been due to a low blood sugar’* and then they actually will charge the patient and they will go after the doctor as well for letting someone who has uncontrolled diabetes drive. So that's where having a glucometer with a date and time, and educating the patients about *‘every time you get in the car I want you to check sugar. You're protecting yourself. You're protecting me. You're protecting others on the road.’* That's a real concrete benefit of it. So that's a positive I see.” – PY4

For patients, an integral part of understanding and interpreting self-test results is readily having access to information and/or resources that help the end-user to interpret the test results. With home blood sugar testing, patients reported that the information and resources received to interpret their test results was limited. Patients reported being ‘self-taught’ how to interpret their self-test results.

“I don't really [access resources]. Other than the documents that come with your machine, and what I have read through the years.” – PT3

[My resources are] – I had a lot of history of diabetes in my family. If I'm really high and there's something wrong, I have to go and get it checked out.” – PT4

“I was given pamphlets with my machine. And I been told the numbers for the normal range - the normal range of numbers to expect, or what's acceptable. So, my only concern is, what if it's too high? I'm not sure what to do in an instance when it's too high at this point. But I've never had that problem. And I do regular follow up visits with the doctor.” – PT6

“Well the resource, like I say, is my wife, my family doctor, and the pharmacist. I ask him questions too.” – PT8

Although patients indicated that they may lack additional resources to interpret their self-test results, it remains clear that in context of diabetes, or chronic illness management, ST provides important information to both the healthcare provider and to the patient, in order to make decisions to help ameliorate the patient's care.

4.5. Significant Themes in Key Informant Interviews

Interviews with physicians as key informants on the topic of ST was an important aspect of this study, as it helped to draw further attention to the ongoing discussion of ST in patient care. In this section, eight metathemes of conducting ST are identified and presented below.

4.5.1. Motives to Seek Out Other Self-Tests

Patients shared mixed thoughts on the reasons why they would seek out and initiate other forms of ST.

PT8 explains that since he already routinely requires medical follow-up for his other comorbidities, participating in other self-tests did not interest him. He explained that visiting his family physician, who routinely orders and interprets his laboratory test results, made him feel more comfortable.

“Well this is what I usually do; I go through him [family physician]. Plus, I got other health issues too and that. So this way he keeps a tab on everything... [I] don't know if I would do [self-testing] or not on my own. Just like I say, I go through my family doctor. Not too keen on it – drawing your own blood and that. I just feel more confident with the doctor.” – PT8

However, PT1 suggests that more testing is better, and that if one tests more, then one is more likely to discover asymptomatic or hidden healthcare conditions that require medical follow-up. PT1 states that access to more self-tests “it can only be a positive – the more you test, the better you're going to know what's going on in your body, and that’s the most important”.

Echoing the above sentiment shared by PT1, physicians also described why they believe ST is an important act for their patients, as a systematic means to be more involved in one’s own healthcare.

“A patient who goes out and seeks their own testing is probably going to be a patient who’s like you know, wanting to be like more motivated. So motivated to know about their treatment options; motivated to perhaps follow the treatment plan that you come to an agreement on.” – PY3

“They're looking for hope. In my cynical days I say, in general, our society has a very low tolerance for any discomfort, any pain, any sense that they are not well, but there are a lot of worried-well. So people that have normal bodily symptoms that they interpret as being something wrong, and they want to find an explanation; like they become convinced that something is wrong, and that we're missing something. So, we just have a lot of anxiety and worry, and again, pressure that everyone is going to be happy, and healthy and pain-free. Free of physical pain. Free of emotional pain. All the time. That's not our reality. People are not good with living with uncertainty and living with any sort of discomfort. So when they’re uncertain and they have some discomfort, they’re going to look for some ways to alleviate that. And so they will spend hundreds of dollars on vitamins and supplements, and look for self testing” – PY4

“I think it's important to patients because I think patients very strongly want to know what's going on in their body and they want to make their own decisions and so on. Um, and I think they also want the convenience of having their own testing. So I think that's an important thing.” – PY5

These quotes suggest that physicians believe that ST can become a patient driven process, as a means to identify healthcare concerns.

4.5.2. Impact of Self-Testing on Education and Counseling

Physicians discussed the importance of education and counseling involved in ST within their patient population, as patients lack the medical background, training and clinical judgement of physicians. PY4 states that ST “provides an opportunity for some

shared responsibility and increasing communication and a chance to educate.” Of note however, PY3 points out that ST “definitely affects how you counsel the patients regarding their concerns.”

If medical advice is sought by patients either prior to or after the ST process, PY2, PY3 and PY5 suggests that physician involvement at either stage could help provide patients with much needed clinical guidance to make educated choices, ultimately supporting patients as autonomous individuals. In addition, the process of seeking out medical advice in this setting also ensures that patients become more aware about other potential healthcare concerns that could be related to their self-tests.

“If a patient came to me and said I’m thinking of getting this test, or checking it or doing this, I would say to them that, you know they can certainly do whatever they wish to do. However, I would explain to them that to a major extent, there’s the pros and cons. There’s the convenience factor of doing their own thing. If they were able to follow the instructions and do the test, they’re usually pretty easy to do... That being said, all my patients who do self-monitoring of their blood sugars, I ask them to bring in all the results so we can go over them together and I can help with interpretation of what the results are, and also, interpretation on how best to alter their medications to get them to be as healthy as possible; and the same thing would go with these other self-tests. If it was a matter of an HIV test, then I would say to them *‘lookit, we’re better off doing it through the lab’* and *‘why would you waste your money on this kit’* and so on. *‘We can do it and discuss it’*. To me, it’s a matter of them having the knowledge to make an informed decision.” – PY5

“There should be some education on like why they pursued self-testing and whether the test is something that can be reasonably thought to be helpful for them, or whether it’s questionable or whether the test is truly indicated. I’m not sure if really educating the patient is sufficient, cause you shouldn’t really expect the general public to have the same knowledge of what kind of medical tests are indicated as you would of their doctor. So I mean, I don’t know if just educating the public is sufficient.” – PY3

“The problem is we take away those teachable moments though. So that person who comes to me for their strep swab, I can explain to them that strep is actually bacterial and treating will make one day of difference, where if it’s viral [its] going away on its own. And you can often treat and cure strep on your own. I can explain if they are coming to me with their HIV test. We can talk about the risky behaviour, and talk about, instead of just testing yourself for every three months for reassurance, how about changing your behaviour to make a difference. If they’re just doing this on their own, then they’re reassuring themselves, without actually making any efforts to change their behaviour. So it’s their choice, but it

means that we're missing out on teachable moments. I think that its going to be sort of a buyer beware thing, that you know, the buyer will have more autonomy, but they're going to miss out on the ability to make some changes.” – PY2

In this section, physicians contextualized and emphasized the importance of educating patients in the setting of ST to make sensible and well-informed choices.

4.5.3. Impact of Clinical Test Results to Healthcare Decision Making

4.5.3.1 Interpretation of Self-Test Results

Interpretation of self-test results is an important aspect of clinical decision making for both patients and physicians. When patients voluntarily exercise their will to participate in ST, they must also be ready to handle the outcome and significance of the self-test result. Furthermore, if patients present their doctors with ST results, physicians are tasked with evaluating the self-test result in the context of the patient’s history. Physicians explained that self-tests which have been on the market for many years such as glucometers, pregnancy tests, and ovulation testers were generally more reliable, and again, given the patient’s clinical context, it would affect whether or not the self-test would be repeated with standardized labs.

“If there's things that I can't say are validated, I may need to repeat some of those things” – PY2

“People as an example people who do pregnancy test and come to me and say they're pregnant, I know those tests are reliable I don't recheck them. They're pregnant! If somebody used a fertility test, an ovulation tester to help get them pregnant, we just go with it. I mean that’s fine. That doesn’t bother me at all. We just run with the pregnancy at that point...As the technology evolves, as the quality of testing evolves, and as my knowledge of the testing quality evolves, it will impact whether I am repeating things or not, um, and sort of what we do from there.” – PY2

“I think the urine tests are pretty accurate and pretty good, although there are different ones out there and they have different ranges, although most of them are more standardized now. In the olden days, not all pregnancy urine tests were the same, with the same sensitivity and accuracy. So it depends on the test and what they're doing, and to a major extent, I often will repeat whatever test they did. So if it's a urine test, we will repeat the urine test. If it's a blood sugar test – sometimes they'll come in and they’ll say it's high or it's 20 or whatever – when we do a proper venipuncture and check the blood sugar, we often find that the

number is different than what the finger prick blood sugar shows. So, they're not the most accurate. So, depending on whether it would affect the change of my treatment plan, I would repeat things and/or order other auxiliary tests to help me with the proper diagnosis and proper plan – PY5

Patients also shared their thoughts on how access to other self-tests could affect their healthcare. Although PT1 was quite comfortable performing ST on his glucometer, he indicated that when it came to performing other self-tests that are available on the market, he would prefer that a qualified healthcare professional complete the testing for him. PT1 explained that because he has routine bloodwork drawn every three months, any interpretation of lab test results and follow-up would be completed at the physician's office, which was seen to be more beneficial for him. Patients indicated that interpretation of results without having more knowledge about the test or the meaning of the test results made them uneasy.

“I would not want to do a laboratory test on my own. I would let somebody else do it; somebody that's qualified. I don't feel I'm qualified to do that. My own little meter that's fine. But like I said, I go once every three months [for routine bloodwork]. All the doctors get a copy... And it's so important, you know, that every doctor gets your result. And I can get it too. I can go online and get it no problem. But sometimes, just going in and going over things with the doctor, makes a difference. So that way, I feel it's more benefit to have a lab. You go in to the lab, and let them do it, rather than you do it at home. Because most people, will not send that result to the doctor. They'll just keep it. I've been around long enough to know. Myself? I probably wouldn't hide it from the doctor, cause I'm only hurting myself.” – PT1

A similar sentiment was shared by PT6, explaining that self-test results could be misunderstood by patients/consumers if they are not trained to comprehend the meaning of the result in their given clinical context. However, if individuals are fully informed about the test and what the results mean, then it allows the end-user to take action when necessary. Additionally, PT1 and PT6 went on to stress the importance follow-up visits with physicians after ST, as described below:

“If you want to help yourself, yes you will go and see him, and show him the results, and let him know, or her - what is going through your body, and what your body is doing. It is only of benefit to you.” – PT1

“I think it's important. I think follow-up is good in any circumstance, especially self-testing, in case you're misinterpreting the results or you're looking for clarification of the results. I think it is important. Yes.” – PT6

From the patient's perspective, ST and the ensuing follow-up with a qualified healthcare provider is considered to be an integral part of understanding one's own health.

4.5.3.2. Personal Electronic Access to Laboratory Test Results

During the interview, the researcher also inquired how physicians felt about patients interpreting lab tests results, given the fact that they do not have a background in medical knowledge or clinical training. In many of these circumstances, the patients are conducting self-tests and interpreting the results themselves. One theme that emerged from this discussion was online access to patient lab test results, with physician ordered laboratory tests. In the following section, physicians present their thoughts about patient access to personal laboratory test results.

“I do a lot of work in Urgent Care, and I see people coming into urgent care. Now – these people undoubtedly suffer from an anxiety condition anyways, but when they see a little red mark beside one of their tests, even though they don't know what it means at all, they freak! They run to the doctors. That is in general, not helpful, because if you don't tell them exactly what it is they expect to hear at that time – if you tell them it's okay and they don't believe you, and you can see it by looking in their eyes, they'll go to the next walk-in clinic. It has been a disaster. Now, having said that, that's one side of it. For the right patient, empowering! Empowering them again to look up their bloodwork and to be in charge of their numbers and have access to them without having to see the doctor, is awesome! The issue is – is there a greater benefit for empowering that group of patients than the increased cost to the system, when we drive a very anxiety-ridden patient into a walk-in clinic. Not even their own family doctor. Right? Because they typically don't phone their family doc; they just run to the walk-in clinic when they see something red. That I think, the balance of the good and bad of that will be borne out after people look at those metrics I think over a few years. But from my own experience in my office where we're not talking about patients running to the walk-in clinic running from anxiety, it's been actually, for me it's been routinely positive. My patients will come in and say “*yeah, yeah, yeah, I know my potassium was high last time...I cut off all my potatoes.*” Right? Because they go on the internet, and it says potatoes and oranges and bananas.” – PY1

“People come to me and they apologize. ‘*Oh, you know, I know I really shouldn't look things up on Google.*’ But I say ‘*no, no it's okay if you look things up... it's just - I do appreciate - let's chat about it. Let's make sure we can review.*’ Cause you can look things up, but to actually understand the true big picture clinical – and even many doctors have troubles up keeping up with the evidence to figure out what to do about something. So it shouldn't be – you know like my diabetics who buy their insulin over the counter or get a prescription and just don't come to see me for a year or two years. I mean, that's really not going to be good care in the end. You know, trying to be their own doctors?! We need to work together. They need to come. Let's talk about what's the evidence; what should we be doing? Should they be on this medication? That medication? How high is their A1C? How do we need to adjust things? Is there evidence for a statin or not? They have the right and I think all the power to them in looking at their own results, but I do appreciate you know reviewing it with them to talk about what it means.” – PY2

“So I mean that's a huge challenge, and that's one that we already see quite often because patients already do look up their own lab results, like at some of our local laboratories. So we have encountered that, and patients will like call the office and they'll say like ‘*oh my number was this*’... or you know, it'll be like outside the normal range, but they have no understanding of like if it's way outside the normal range, if it's dangerous, or if it's just possibly a normal variation or a variation related to their health condition, or it's something they've always had. So there's all those variables. Where if you have the whole context and you have the medical knowledge, you might be reassured by a normal lab result, or you might be worried by a normal lab result, depending on what the history is. So most patients certainly don't have that kind of background knowledge about their health condition. They might not know what the test is; they might not know what the test is looking for; and they very well might not know how to interpret a result. And then that can cause them either a lot of worry where they shouldn't have it, or potentially they might be reassured where they shouldn't be reassured, depending on the individual situation. So I think it's important, maybe for both doctors and patients to know if patients will have, like access to information like that, and just knowing if that's something that's going to affect your follow-up; kind of like anticipating those situations. – PY3

Essentially, physicians explained that patient access to laboratory test results has its benefits and its drawbacks. From one perspective, patients have the right to access their own medical information. In the right patient, access to one's own medical information can be motivating. However, depending on the patient, this can become worrisome. Some patients become highly anxious when they see results that are not perfectly within the normal reference range for laboratory test results. With the

abundance of literature and information available through the Internet, patients can freely inquire why their lab test results may be out of range. This can introduce even greater anxiety and fear where there perhaps should not be any. Conversely, patients may be reassured when they should not be, by negative or normal lab test results, if they are not interpreting them in the correct clinical context.

4.5.4. Impact of Self-Testing on the Patient/Physician Relationship

The act of ST in the patient population has its strengths and weaknesses. As a result, the effects of ST in the general population are noted to impact the patient/physician relationship in various ways. Physicians expressed various thoughts on how ST can impact their relationship with their patients:

“I would say by and large, self-testing has improved relationships and improved patient care. It gives me added information and helps me think about things that I have not thought about before actually... So, yes, self-testing for me facilitates my role as a family doc, virtually all the time” – PY1

“On a personal level, I don't hold it against somebody, it doesn't affect my relationship in that sense. It only would affect my relationship if they then choose not to see me about stuff. So then I'm just out of the loop. And so it just impedes that long-term relationship. I don't hold it against them. It's just, the reality is, I'm not a part of the process, and therefore, we're not building the relationship in the same way, and I can't be as strong or as helpful a role potentially. But I think if somebody is testing stuff, and when they get results, looking for next steps come to me, and we sort of create the plan together, then it's going to be positive...But I think that the piece that's lost here is, you know, me seeing them...and helping them out through [self-testing and self-management]; helps to build a relationship. So we may lose that a bit. But maybe that's just me being selfish; I like building those relationships.” – PY2.”

“Definitely the monitoring that I ask patients to do - when they do it definitely helps our relationship. When they don't do it, obviously I feel frustrated. But when they do do it, it helps.”- PY3

“I try not to be judgemental or dismissive. I'll take that information and review it with the patient. And I may say, *‘What's your understanding of this? What has been explained to you? What do you expect me to do with this information?’* And, so then depending on that, depending on what the patient's expectations are, then I will sit back and say, *‘Okay so, if you're asking my opinion, in my professional opinion, from the evidence I know and my past experience, this is what I would*

recommend. And if you agree with the patient, if you are on the same line, that's okay. But, if I don't agree with what they have been told and what they expect, I will say that...So sometimes you do have to draw a line in the sand and say "*you know what, I respect that you did this but, you know I will have to respectfully disagree with what your expectation are, and what your interpretation is*". So you have to try and find a way to continue to maintain that patient-doctor relationship and work through that. But certainly I don't – you can't discharge a patient from your practice. You can't be unprofessional. You just have to find a way to work with that." – PY4

"It's one aspect of my work which is working with the patient to let them reach an understanding of all aspects of their health and allow them to make informed decisions on how to be as healthy as they can...I think [self-testing] is helpful and good because I have a very good rapport and relationship with my patients, and I feel they can discuss anything at all and everything with me. I encourage them to be very active participants in their health. So I don't have a problem with it. I would say that it probably slows me down a little bit and so on. It's this kind of education that I find is most valuable, and that's how I look at myself as a physician/educator, so that they're educated on the body and they're educated about what's going on in their life, and I'm a partner in their care for themselves." – PY5

Based on their personal experiences of ST, all patient participants indicated that they had only really participated in the ST process with glucometers. This group of patients did not have very much experience performing other self-tests. However, when asked to describe how ST affected their relationship with their physician, all patient participants shared the common opinion that ST did not really affect their relationship with their physicians, and if it did, it was beneficial. Patients also cited that having a doctor that actually 'listened' to their concerns, instead of being rushed out the door with a handful of prescriptions, was an important part of relationship building.

"[Self-testing] should strengthen the relationship. Cause he's going to tell you, or she, what's going on. And you should be ready to listen. Makes a difference. Cause it's only going to help you; in the end, that's the bottom line - helping yourself." – PT1

"He's a good doctor. A lot of people said he was a younger doctor. He's not that old. I don't know, he's 55. Maybe? But he has your interests at heart. And there's some guys that take you in there; this, that and the other...and they just want to give you pills. *Did they talk to you? No, they didn't have time! Well get another doctor, and*

talk to him. He always makes sure he gets in touch with you. He knows what you're doing.” – PT5

“I’ve been with him. Well, he took over the practice; I was with the doctor before... So he's been 20 some odd years my physician. So, there's a relationship built up there.” – PT8

Patients indicated that they were generally satisfied with their doctor/patient relationship. Additionally, the data presented in this section makes it clear that in many ways, the act of ST can facilitate the role of the physician in diagnosis and treatment; however, ST can also negatively impact the patient/physician relationship when patients disagree with the course of treatment or clinical advice being given by their physician based on self-test results.

4.5.5. Impact of Self-Testing on the Cost to the Canadian Healthcare System

Considering the overarching role that physicians play not only in the community, but in each and every patient’s healthcare plan, physicians shared their thoughts on whether or not ST as a healthcare intervention for health promotion and illness prevention behaviours could act as a tool to save the healthcare system money; their thoughts are provided below:

“A lot of the times you’re going to find that a lot of the [self-testing] is repeated by the physician with a standardized lab. So, I'm not a hundred percent certain how much this is going to save money for the government. And I think if you add up all healthcare expenditures, be it public and private, I would think that probably it will quite possibly increase it. So I'm not sure if it's going to be a major savings.” – PY5

“I think that unregulated testing... you walk down to the shopping plaza, and someone pricks your finger, and tells you your cholesterol is 6.8 – totally, completely out of context for a patient, that information, out of context, out of environment for patients, I would say in the large majority of times is not going to be helpful. And when it is successful at bringing the patient to the family doc, for a review of their cholesterol, let’s say, or blood pressure.... that stuff that does bring people back to the office, it is continually frustrating and amazing, that even after 20 minutes, 30 minutes, sitting down in the office and discussing all that – with appropriate full cholesterol panel testing, and follow-up with the patient – no change is made to their lifestyle or to their interests. So we have spent a finger-prick cholesterol, a full cholesterol panel and usually a kidney and a blood liver enzyme to go with it, half an hour of physician’s time, or an NP’s time, which results in billing to the healthcare system for very little measurable impact. This

becomes very problematic! ... Our current system is moving to a model of service rather than knowledge. Like, I'm no longer a doctor – I'm now a monkey with a signature... *“sign this... someone said I need that... sign it” - “you actually don't need that” - “they said I need that - sign it”* ... And I think in a society like ours, where a large number of people still work and pay tax to support this system, I think that is a disaster.” – PY1

“Self-testing can often lead to more pressure for more testing within our healthcare system. Some more use of resources, more lab tests, more x-rays, ultrasounds, more referrals to specialists. So, it becomes patient-driven as opposed to physician driven.” – PY4

One quite noteworthy comment made by PY2 makes it clear that decentralization of laboratory tests may shift the burden of the ST cost onto the consumer; however, the centralization of standardized laboratory tests to an electronic platform, called OLIS (Ontario Laboratories Information System) will help to decrease healthcare spending. Access to the electronic OLIS database allows physicians to download a patient's medical records that provides them with laboratory results which were conducted elsewhere within the province; this one step could help save money, as physicians would not be duplicating laboratory tests.

“The decentralization I think will actually increase costs. It might shift the burden to the individual, but will actually increase the cost, because I think some things will be repeated. Way more tests are going to be done. Physicians – we're being trained to be careful and judicious with our use of tests, and use the ones that have evidence. But when the public is doing this, it won't be based on that. It will just be based on what they can be convinced by the commercials; which commercials can convince them to test. So I think overall, it will actually increase the cost, take the burden off the taxpayer and give it to the individuals who are prey to these anxieties. So I don't actually think it's going to save, and then there's going to be some repetition. Centralization like the lab results all going into a central database, where now if I find out somebody's had a blood test, I can go to this OLIS, I can click on my EMR, and it downloads into my EMR. So I have less chance of duplication that way. I can see what's been done at this hospital, but I did not previously have results, and I can make sure I don't have to repeat it. So I think decentralization is not going to save costs, I think centralization will.” – PY2

Undoubtedly, physicians generally share the opinion that ST (not in the context of chronic disease management) will not save the healthcare system money; rather it may increase healthcare expenditures due to additional usage of healthcare resources.

Physicians also indicate that when patients participate in ST, the process becomes more patient driven as opposed to physician driven, which impacts patient care and patient outcomes (to be discussed in the next section).

4.5.6. Impact of Self-Testing to Patient Care and Patient Outcomes

4.5.6.1. Impact of Self-Testing on Patient Outcomes

Physical and emotional wellbeing are important aspects of consideration when allowing patients to perform ST at their own discretion. Patient safety and patient care must never be compromised. ST is often initiated by patients, as described above, with the intent and long term goals of being happier and healthier by taking a more proactive approach to one's own healthcare. However, physicians indicate that an increased amount of ST does not always translate into improved patient outcomes:

“I mean it would be nice to say that by empowering patients and giving them monitors and decentralizing [testing], that that will lead to healthier outcomes and save the system money. I think in reality, there's some benefit and it's probably lower what the models would show. Just because humans being human, it is hard... It's hard to stay compliant. So, despite health promotion, education, availability of self testing, there are so many pressures in our society that go against that, such as availability of junk food, people who are sedentary, so they're in desk jobs, they spend all their spare time on the computer, they don't know how to cook, so they are eating restaurant food and fast food. Those are huge societal forces that go against health promotion.” – PY4

“I know a lot of self-testing does not change patients' outcome, unfortunately; behaviors and their actual hard outcomes like heart attacks or hospitalizations or pneumonia frequencies or exacerbations of COPD or strokes from their blood pressure, or blindness from their eyes from their diabetes. It doesn't – my perspective from my own little world is that I have not seen a large impact on hard outcomes for patients. In a socially supported system, testing is great, and I like testing, but I think we need to be very aware in our system that testing does not translate necessarily into outcome improvement.” – PY1

“You know, we can provide all the education. We can provide the health promotion. We have community centers around here with a low-cost or no-cost. We have a walking indoor walking track in Clarrington, with a soccer field where people can go and walk everyday, inside free of charge. So, there are opportunities available with low-cost, low-barriers, but people have to take

advantage of it. Like they really have to make that decision to get out of their cars or get off their couch.” – PY4

Physicians expressed that ST did not necessarily change a patient’s ‘hard’ outcomes, that ST may actually increase angst in an already anxious individual, and that societal forces and social determinants of health play a role in influencing patient outcomes.

4.5.6.2. Impact of Self-Testing on Patient Care

The process of patient initiated ST can be beneficial in some cases, as it could improve patient care. However, PY1 explains that these tests would have to be indicated as useful in the patient’s treatment and care plan.

“I definitely think there’s potential for self-testing to improve patient care. Um. Like I say, patients who know their condition needs monitoring, or patients who are in an at-risk population who like certain test would be recommended, I mean the ability for the patients to initiate that test is important. And like potentially there's great benefit to the patients and to like public health in general for having that available.” – PY3

Physicians also expressed that ST may also impact patient care if there is a fragmentation in the continuity of the patient’s care:

“[ST] takes me out of the loop somewhat, which doesn't bother me per se, but I think can potentially hurt the patient, because it just means I don't know what's going on. I'm not part of that process. Same way that if they go to the walk in clinic exclusively as opposed to seeing a primary care physician, you know, for continuity of care. You're losing out on that continuity of care if you're doing this sort of exclusively... I just think that the one thing that's really, really beneficial about the Canadian Medical System is continuity of care, and I hope that people wouldn't lose on that continuity of care with a private care provider because they're doing less testing.” – PY2

“So I think they need to have access to a family doctor. That’s the reality. Because lots of people offer testing and have no idea about what the context is or even what the next steps are, cause it's a money-maker. Its money. All kinds of people paying money to have stuff done, and the person doing it really certainly is not going to be there 10 years later to help support the patient, and probably doesn't understand the pathophysiology of the disease that they're looking at in the context of the patient either, and unfortunately the only one realistically suited to that task is the patient's primary care provider. Whether that happens to be a GP or an NP or an intern. Whatever. Whoever that happens to be. But somebody who

understands pathophysiology of disease and can assimilate all their other medical problems and medicines into some kind of diagnosis and feasible plan for them – PY1

Education and counseling is also an important element of good patient care.

Patients who conduct ST need to be fully aware of the implications of ST prior to the test occurring and need to be ready to understand what the results mean for themselves in their clinical contexts.

“The downside, how [self-testing] could affect my role as a physician, if patients are just interpreting those results on their own, not coming in to get further assessments, so they're just using whatever information they have, then that could probably lead to not the best care for that patient, because they have kind of taken the matter in their own hands.” – PY6

PY5 shares an example of the use of home pregnancy tests to consumers within the general population when the test is performed without thinking of its consequences.

“So you know, as long as patients have the ability to go and get proper education, proper counseling; so if you came to the Emerge or Urgent Care, and said *“I think I might be pregnant - can I have a pregnancy test?”* Before we do the test, we would council you: *“Okay before we do the test what would you do? What's your thoughts? What supports do you have? Is this a good thing or a bad thing?”* It's much easier to talk about that when it's still a hypothetical situation, than *‘oh you are pregnant and now what are you going to do?’* It can make people even more uncomfortable. So, I can see a lot of my colleagues saying it would be better if they didn't have these tests out there, because people come into the walk-in clinic *‘I'm pregnant, what am I going to do? I think I might want to kill myself’* and so on, because they do the test without thinking what it means and what are they going to do about it.” –PY5

Physicians believe that access to a family physician to complete medical follow-up, is an important part of the ST process. If patients exercise their right to self-test, then they should also be ready to consult a primary care provider who can help manage their concerns and support them in healthcare decision-making. Furthermore, patients may be harmed by the ST process if they do not have the proper support structures in place to guide them through the eventuality of the result's meaning.

4.5.7. Physician Perspective: Benefits and Challenges Faced with Self-Testing

4.5.7.1. Benefits

Clearly, the benefits of performing self-testing have been shown to be numerous. Physicians reported that patient self-tests do sometimes present useful information to clinic visits. In addition, POCT has proven to be of extraordinary value with great clinical utility, in countries where access to healthcare resources are scarce.

“If you're talking about like resource allocation and the time physicians spend, I think there's many cases where the patient being able to test themselves can bring you a lot more information to the encounter and like in some ways optimize your efficiency there.” – PY3

“I've done remote medicine work and volunteer work in third world countries, and the use of point-of-care testing is a very useful and a pivotal part of doing that kind of medicine in a safe fashion...doing point-of-care testing when you don't have the availability of a lab nearby and so on, it's a huge savings, and it's an important comfort and it allows you to do much better medicine and so on. So it's a positive thing.” – PY5

PY3 also shared her knowledge of a recently created ST program in British Columbia (BC) that can be initiated by patients. The clinical utility and effectiveness of performing self-initiated ST in this manner can potentially be of great value to the general public. PY3 explains:

“I recently learned about a self-testing program in BC that's for sexually transmitted infections, where patients who are asymptomatic but just wanna be screened, can download a lab req online by entering their demographics. And I think it has some questionnaires, so it can like tell you what kind of test you might be eligible for just based on the questionnaire. And then they just drop off their requisition, drop off their urine sample to a lab. So there's no seeing a doctor involved. And like that's a kind of self-testing that I would totally support because, you know, sexually transmitted infection screening is one of those things that there's a lot of barriers to, or perceived barriers for patients. So I think, that's a great way to support public health and to support patients who maybe don't have a doctor, or don't wanna go or can't go, or those kinds of things to be able to be tested for something that is, like, you know important for population health, and where I think there's probably a lower risk...”

Unmistakably, the use of ST can contribute immensely to improved resource allocation and may facilitate improved community health and health promotion.

4.5.7.2. Challenges

ST is not without its challenges however. Physicians shared their thoughts on dealing with ST in the general patient population, and explained how availability of such tests can impact negatively on patient care. First off, physicians explained that one of the challenges associated with ST is ensuring that the results are interpreted within the clinical context of the patient.

“I think that – like replacing Primary Care with a computer, or people doing anonymous test at home – I think that’ll be a mistake, because I think our ability to interpret with context, like a big picture context, is important.” – PY2

“I think there's definitely a risk of harm in over testing, and definitely I think the public believes that more testing is better, and the more testing you are, like the healthier you are and the more likely you are to catch something that could be dangerous. And I think there's less appreciation in the public of like the potential harms of testing, and the risk of like abnormal tests and a cascade of further tests, which might have potential harms.” – PY3

PY6 also notes that ST may provide the patient with false reassurance, as their gap in clinical knowledge may make them vulnerable to other health conditions. A patient’s visit to the office would allow the physician to examine other aspects of the patient’s health. She illustrates this thought using sexually transmitted disease (STD) contraction as an example:

“If a patient is worried about say STDs, and just do an HIV self test, that's probably a patient I want to see in the office just to address any concerns. There might be additional tests that needs to be done, that the point-of-care testing wouldn't do. If a patient had an unprotected sexual encounter, and they're worried about it, I mean HIV is just one of many. So, that's a patient I would prefer to see versus encourage to self test. Is there a reason why they want to go anonymous? Is there something with the physician-patient relationship? Other things that I'd probably want to explore.” – PY6

Additionally, PY3 noted that an increased amount of ST would likely lead to a greater chance of encountering abnormal test results.

“I guess it depends what they're testing. Cause, I guess one concern I have, if testing is freely available to patients rather than ordered by physicians, is like the

risk of over testing. And then the risk of kind of like spurious results being received by the patient, or you know, results that don't fit the clinical picture being received by the patient. Or just kind of doing too many tests, cause obviously the more tests you do, the higher the chance that one of them will be outside the normal range just by chance.” – PY3

These are noted to be prominent themes which continue to challenge physicians when patients present to them with their self-test results.

4.5.8. Ethical Considerations in Self-Testing

4.5.8.1. Vendor & Merchant Accountability

As self-tests become more widely available to consumers, physicians explain that the merchants selling the testing need to be more widely accountable for the distribution of the self-test devices. Such a process should or would include access to resources that aid in the interpretation of self-test results, as well as fair marketing practices.

“It’s hard to just get down to what the stuff that's worth looking at, and figure out which stuff that is, versus all the testimonials that anybody can put, that may or may not be valid; ...the commercialized testimonials, that we don’t know are commercialized, that people are basically paid to write a testimonial in favor or against something. So I think there is a lot of potential for abuse.” – PY2

“If we're going to generalize it for all tests, I mean, I guess there would have to be some onus on the companies making these products. So, you know have this information available with some of these devices so that patients know what to do.” – PY6

“I think my bottom line is, I think there is a lot of potential for benefit. There is a lot of potential for commercial abuse to the uninformed consumer, who, the people selling these tests, they’re expensive usually and you are preying on people's anxiety about things – that may or may not be a real anxiety, that should not have been a real concern to them. Um. Like commercial genetic testing and stuff like that. Sometimes you’re just going to find things that are positive, but aren’t really relevant, and raise people's anxieties. So we have to be careful about that. And unfortunately, I can’t trust the marketers to be necessarily very ethical about that.” – PY2

Furthermore, physicians argued that there needs to be limitations set out on the availability of self-tests, as well as increased merchant responsibility for the ramifications of making such tests available.

“If the patient is self-paying, then I mean, you can make all kinds of arguments for-or against; although like that does have some repercussions on what I say about follow-up. Cause I do think it's not like responsible to offer patients self-testing, if they're not going to have the follow-up, and that's because they'll have all kinds of results that they don't know how to interpret. So I do think if self-testing is going to be offered, whoever is offering it has a responsibility to be able to follow-up with the results and to be able to monitor all the results. Cause you also can't trust a patient to look at the results and know if it's something that is fine or to know if it's something that requires follow-up – unless say they've had the condition for a long time and they are extremely knowledgeable about that individual test. But in general it's not responsible to give that responsibility to the patient, to know if something needs follow-up or not. And then like I say, if patients are self-testing and self-paying, then that does raise a huge question of like, are like they also paying for the interpretation of the result? Are they also paying for the follow-up of abnormal results? You know, and that's all something that would have to be sorted out, otherwise we could be talking about large increases to the cost of healthcare, and questionable benefits to the patients, right? So, ideally you want something that's going to benefit the patients and not have excessive costs associated with it, rather than something that's going to harm the patient and have excessive costs, right?” – PY3

“I would prefer if we had some kind of reasonably strict regulations, that it wasn't marketed to people the same way that you market pills on American commercials, or um, or toilet paper. I would prefer it if the marketing was actually more responsible...So if they actually marketed it appropriately, and not inappropriately, and not buying into people's anxieties...If they encourage people to follow up with their primary care physicians, then I think absolutely; it gives people more control, which I think is a plus. We know that people have to take control of their health care, you know...So I think that appropriate marketing with proper rules, and you know, proper sort of follow-up, it can be – it can certainly be a positive.” – PY2

“I guess my concern is where they're self-testing, so say something that is marketed online, where the person who's offering it is going to benefit financially from it. So has a hidden interest - whether or not - whether the interest is open or hidden; that they are going to profit from the patient being told that *'you know you have a deficiency in some sort of zinc or vitamin, and I mean I can sell you something to change that'*. Even though in my mind, it's not actually clinically valid or clinically significant.” – PY4

The above section demonstrates why physicians expressed strong concerns related to the availability of ST to patients as consumers, as well as discussing why they believe that it is highly inappropriate to expect patients to be able to interpret their results and expect them to know if the result requires follow-up.

4.5.8.2. Consumerism

One theme that presented itself among multiple physicians was the concept of self-solicited testing which was funded by the consumer, but not necessarily prescribed by the patient's primary care physician. To begin, PY2 suggests that consumerism does not equate to medicine:

"I mean it happens, and it's fine, but, its just – I look at it as very similar to people who go to their naturopath or go to their chiropractor and get a bunch of tests done. The only thing I can say is that it's their power to do that, and it's fine to do that, and that that's sort of consumer's choice, but I don't think of that as medicine. I think that that is more consumerism." – PY2

"I think a lot of the tests that they are going to buy kind of over the counter or do on their own are just – again – its somebody selling them a test. Whereas, at least when you come to a physician, I am actually not getting any advantage from you, sort of doing a test or not doing a test. Its based on the evidence. I am not selling you a product. I am not getting any advantage from it. And, so you know, I do think that that's better. But people have the right to do that. Like I said, they can go to the naturopath, and get all these tests done, that may raise anxiety, maybe false reassurance, may lead to you know, sort of inappropriate or unnecessary treatments..." - PY2

"Its people with more vague, undefined – *"I'm tired, I'm anxious, I'm not sleeping, I hurt all over"* – those are the ones that are going to naturopaths and coming back with blood tests; in some cases that I would never have ordered, but they have had ordered by another practitioner. I have to be careful. I have to respect the fact that the patient has gone there. I have to continue an open communication. I think if you were too judgmental, and just say that's a bunch of crap, then you're not actually helping improve your relationship with your patient, and its going to be harder to work with them. But I think there are times you have to say, like *"lookit, I think..."* - because again they perhaps have had to pay for those blood results or lab tests. I say *'I think you are buying false hope. I think you are spending money and it's not going to improve your health, and its not going to change your outcome'*. I will say, *'From where I sit, and what the*

research I have done and what the evidence that I understand it to be, is that spending \$300 on a blood test that looks at a hundred things that you're allergic to is not evidence - you know is not helpful and is not going to really change anything'. You're walking a fine line.” – PY4

“I feel bad saying it, but one of my experiences with that kinda situation is when patients go to like a naturopathic doctor, and they get like a very complete blood panel done, or some kind of testing which I don't really have much knowledge about, and I'm not really sure of the validity about. Like I had a patient who came with, a very very long list of potential allergens; that's happened to me a couple times. ... A lot of times I feel frustrated in those situations.” – PY3

PY1 also shares the story of an encounter with one of his patient's:

“I have ladies have scrapes of their buccal mucosa to get their hormones done through the chiropractors and the naturopaths, who are having regular periods, which means that their hormonal access is all normal, but their buccal mucosal progesterone is not normal necessarily... When she had her blood hormones done by the OBGYN, of course they were all normal. So she comes back furious mad, that none of us are listening because her hormones – the naturopath told her – her hormones are all screwed up, that's why she's not feeling well. Then we're in a pickle. What we do? So I said '*You have to go back to the naturopath to get managed for that, because I don't think I can – that's not my area*'. And that's okay. I'm not sure that that's professional or appropriate – but again it's the patient's choice to spend their money in that regard and to believe one over the other, which is okay.” – PY1

In this section, the data suggests that physicians face a number of ongoing challenges in their offices when patients engage in self-testing themselves or through other allied-health professionals and then return to their primary care provider for follow-up medical advice.

4.6. Summary of Data Analysis

This chapter provided a detailed analysis of themes which emerged from both patient and physician interviews. Patients described their awareness of their disease as well as discussing the impact of ST on chronic disease management. Participants indicated that ST increased patient healthcare self-satisfaction and that ST generally helped guide food choices in a diabetes diagnosis. Additionally, patients indicated that factors such as increased participation in one's own healthcare, convenience of ST and

improved blood glucose management positively affected their decision to participate in ST. However, the cost of ST and adverse effects encountered during the ST process were seen as barriers to ST. The impact of ST on patient safety was also presented. Findings indicated that device training and the perceived accuracy of self-test devices play a role in participating in ST.

Interviews with physician participants presented thoughts as to why patients seek out ST, how ST impacts clinical decision making, education and counseling, how it affects the patient/physician relationship, the impact ST has on the cost to the Canadian healthcare system, and how ST affects patient care and patient outcomes. Physicians also discussed how the reliability and interpretation of patient reported self-test values plays a role in a patient's healthcare decision-making process. Additionally, the findings highlight physician perspectives regarding the benefits and challenges faced with ST as well as identifying ethical considerations in ST. This study generated new data, to be discussed in the following section, as well as corroborating findings suggested by other researchers.

Chapter 5 – Discussion of Key Findings

5.0. Introduction

The focus of the research study was designed to address the research questions specified below.

- 1) What is the role of patient autonomy in healthcare? How does patient autonomy or ability to self-manage a health condition with a self-test affect healthcare decision-making for both the patient and healthcare provider?
- 2) What influences patients to participate or not participate in self-testing?
- 3) Who is responsible for following up with self-test results?

A mirrored interview guide was devised to address these research questions in order to capture both the patient and physician perspectives for key elements in the ongoing discussion of autonomy in POCT. By carrying out the research protocol, the researcher was able to collect and analyze data from six patient participants and six physician participants, to shed light on the significance of autonomy in healthcare as it relates to POCT. The conceptual framework devised for the research study guides the ensuing discussions carried out in this chapter, reflects the goals of the research study and describes the role of autonomy in healthcare and how it relates to the decisions that impact one's motivations to participate in ST and the impact of ST on patient care and patient outcomes.

5.1. Role of Patient Autonomy in Healthcare

As previously described, respect is considered to be the underlying principle in patient autonomy, in which patients are supported in decision-making as it relates to the healthcare interventions they choose to receive or refuse (Entwistle, Carter, Cribb & McCaffery, 2010). In this section, we explore the role of autonomy in ST, especially in the context of chronic disease management.

In diabetes, self-care behaviours and knowledge of the illness comprises multiple elements which includes, but is not limited to SMBG. Other significant elements include maintaining an active lifestyle with regular exercise, regulating food choices, being vigilant of illness related complications and adhering to medications as required (Toobert

et al., 2000; Fitzgerald et al., 1998). Sedentary lifestyles, poor diet and weight gain are considered to be strong predictors of a diabetes diagnosis (Hu et al., 2001). Patients who are diagnosed with diabetes have difficulties with regulating their sugar metabolism. When food is consumed, it is broken down into “proteins, fats, and carbohydrates into amino acids, fatty acids, and simple sugars”, with glucose being the simplest form of the body’s fuel (Mccoy, 2009). When consuming foods high in sugar over an extended period of time, problematic health issues¹⁹ can arise, hence the importance of making healthy food choices in diabetes (HFAH, 2017). Research studies indicate that increased physical activity reduces the chances of developing non-insulin dependent diabetes mellitus (Helmrich, Ragland, Leung & Paffenbarger, 1991; Hjerkind, Stenehjem, & Nilsen, 2017). In addition, Pan et al. (1997) reported that diet modification in combination with an exercise regimen could significantly decrease the incidence of diabetes in individuals with impaired glucose tolerance.

Data collected in this research study supported the ideology that SMBG motivated patients to want to involve themselves more in their own healthcare and in all aspects of decision making as it related to their healthcare. Patients who were effective in functioning autonomously acknowledged that their behaviour was successful when it occurred voluntarily and not a result of a controlled external influence. In this study, ST in chronic disease management reportedly improved the eating habits of the patients and caused them to initiate adjustments to their lifestyles, eating habits and exercise regimes. The immediate feedback of the ST result played a substantial role in this scenario, as patients were able to assess how their food choices and exercise routines affected their finger-prick glucose readings. Furthermore, the immediate feedback of a ST result provided patients with greater peace of mind with regard to their clinical status. The act of ST in this context supported patients to autonomously make decisions that impacted various aspects of their health and well-being as it related to diabetes. Williams, Freedman and Deci (1998) explored a theory of human motivation, known as the self-determination theory. In this theory, it is postulated that healthcare behaviour is autonomously initiated versus controlled. In autonomously motivated behaviour,

¹⁹ Problematic health issues: includes but is not limited to kidney disease, heart disease, stroke, as well as vision or nerve problems (TeensHealth, n.d.).

individuals feel appreciative of their health outcomes when actively participating in their healthcare, whereas a controlled behaviour would only take place if the individual was pressured to participate in such a behaviour by some external force. The positive effects of the act of ST as an autonomously initiated behaviour in chronic disease management is evident in this research study as patients and physicians described their views on the utility of ST in the management of the disease. In this research study, patients shared the sentiment that the act of ST was self-initiated, with no external influences, to monitor blood glucose results in order to obtain valuable clinical information. Additionally, physicians explained that, in their experience, patients who were able to make the connection between food choices, exercise, and blood glucose values were generally more successful in keeping their illness and related comorbidities more in control. Research conducted by Williams, Freedman and Deci (1998) provided strong support for the self-determination theory. The researchers established that when individuals participated willingly in their own healthcare interventions, in the context of diabetes chronic disease management, they experienced a greater sense of ownership of their healthcare. As a result, patients were able to maintain their glucose levels within a healthier range for the long-term. The concept, understanding and utility of ST in chronic disease management shared by the patient and physician participants in this research study agree with the self-determination theory posited by Williams, Freedman and Deci (1998).

Additionally, although some self-initiated self-tests can provide valuable clinical information to physicians, physicians continue to be judicious about the tests that they order as healthcare expenditures in Canada continue to grow. The Canadian Institute for Health Information reported that in 2016, total health expenditures were estimated to reach \$228 billion dollars, a figure which represents approximately 11% of Canada's gross domestic product in 2016 (CIHI, 2016). Entwistle et al. (2010) explain that supporting patients in making autonomous decisions can be a sensitive matter. If physicians are more prone to offering and allowing choice rather than facilitating a dialogue that allows patients to make informed decisions, the principle of autonomy can fail in protecting individuals who are considered to be otherwise competent but find it difficult to choose between healthcare interventions. These patients may lack a strong

sense of confidence, or may be unsure about what treatment options are more preferable, or may perhaps blame themselves if their outcomes are poor. In these situations, Entwistle et al., (2010) suggest that patients may not feel autonomous at all, and rather they end up feeling abandoned as they must choose a healthcare intervention offered to them by their physician. This is why the patient/physician relationship is so important. Patients need to trust that their physicians are providing the most appropriate advice for the patient's optimal health. Patients who experience positive relationship building with their physicians are more likely to trust in their judgement and their clinical advice. Pearson and Raeke (2000) explain that, theoretically, patient trust enhances the patient/physician relationship and, as a result, patients are more likely to be satisfied and have greater compliance with treatment regimens.

5.2. Decisions Which Influence Participation in Self-Testing

As previously described, the HBM functions to explain health behaviours independently or in combination from four different angles: perceived seriousness, perceived susceptibility, perceived benefits and perceived barriers. These health behaviours are influenced by measured variables in the clinical governance framework: risk management, clinical and cost-effectiveness, and patient outcomes.

Risk management is an important aspect of the ST process. In this research study, patients reported that they were generally quite content with their glucometers and perceived the meters to be quite accurate. Although SMBG is known to be a relatively safe process, patients did not know how to initiate troubleshooting procedures, nor did they share if they were aware of the potential for pre-analytical, analytical or post-analytical errors in the testing process. Additionally, only two of the six patients reported that an allied health professional made sure that they were competent to perform the testing on their own, and one patient reported that he solely relied on his spouse for the instrument training. Research in healthcare environments has indicated that deficiencies in training practices, lack of internal quality control and inconsistencies in calibration procedures were all points within the total testing process where the risk of introducing errors was more pronounced (du Plessis, Ubbink & Vermaak, 2000). Healthcare environments are subjected to standardized procedures and regular competency audits; such a process in risk management makes it easier to account for additional training and

follow-up procedures as necessary. ST in homecare environments are not currently subjected to standardized procedures or competency audits to monitor risk management, and patients may experience harm as a result.

The clinical and cost-effectiveness portion of the clinical governance framework and the HBM guide the next portion of this discussion. In the context of chronic disease management, the results of this study make evident that healthcare autonomy plays a significant role in guiding patient decisions to participate in ST. Patient participants in the research study reported that ST motivated them to actively participate in their own care, as it was feared that lack of participation may ultimately lead to worst-case scenarios in their disease progression. Here, the HBM supports the ideology that explains that participating in ST stems from the perceived seriousness and perceived susceptibility of the disease. The HBM also supports the construct of perceived benefits, as diabetic patients listed numerous examples in which ST was beneficial to the management of their disease. Finally, patients discussed the ways in which ST might be seen as a health behaviour that sheds light on the perceived barriers or challenges that they face in adopting such a healthcare intervention. When this same group of patient participants were asked if they would consider participating in other self-tests that were available on the market, a mixed response from patient participants was received. Diabetic patients are constantly in contact with members of their healthcare team in order to receive care as it relates to their illness. They are subjected to routine laboratory tests and follow-up visits with the appropriate physician/specialist. Thus, patients reported that any healthcare concerns that they have would be brought up at their routine clinic visits, and that any laboratory testing that would be required could be ordered by the physician at that time. This, in turn, meant that patients did not have to pay out of pocket to perform ST as there was a higher likelihood that the blood tests would be covered by the Ontario Health Insurance Plan (OHIP). Patients also explained that they felt more comfortable leaving the interpretation of test results to their healthcare provider. One patient however did express that the more one tests, the more knowledgeable one becomes of one's own health. Physician participants were also of the opinion that when patients are interested in participating in various self-tests, they are often more willingly involved as participants in their own healthcare.

This study's use of the clinical governance framework and the HBM help to explain the healthcare behaviours exhibited by the patients. In order to contextualize these health behaviours, we must understand the role of health promotion, community health and the social determinants of health in affecting such behaviours, which ultimately influence decision-making as it relates to ST.

5.2.1. Health Promotion and Community Health

O'Donnell (2009) explains that health promotion is a science in which individuals are encouraged to achieve a state of optimal health by maintaining a balance of physical, emotional, social, spiritual, and intellectual health (Appendix N). In general, health promotion is an important aspect of health maintenance, and in chronic diseases such as diabetes, the significance of health promotion becomes quite apparent as patients require increasingly greater amounts of interactions with a team of healthcare providers in order to manage their illness. MacQueen et al. (2001) explain that an important determinant of health outcomes is the context of a community. The authors suggest that public health programs defined at the regional and national levels are set to have prevention and interventions take place at the community level. Thus, community collaboration is considered to be an important approach for effective community health programs. In the context of chronic disease management, as well as the need to provide enriched accessibility of community health interventions to the general population, there needs to be greater emphasis and education placed on the importance of available community based healthcare programs which have been created to assist in health promotion. One physician participant in this study clearly indicated that although opportunities for health promotion with low-cost and minimal barriers may be available, patients still need to make a conscious effort to be active participants in managing their health. Therefore, it is important to understand how the social determinants of health (SDH) play a role in influencing decision-making in the patient population, when considering ways in which achieving optimal health can be attained.

5.2.1.2. Social Determinants of Health

Chronic illnesses such as diabetes are largely affected by personal lifestyle choices such as diet selection and inclination to participate in exercise. Cloninger (2013)

argues that these variables are seen “as expressions of personality traits that are partly unconscious and hence resistant to change”. Additionally, Cloninger (2013) suggests that the SDH, elements that are not within an individual’s control, can also play a role in influencing poor lifestyle choices. Annandale & Field (2007) explain that the interaction and intersectionality of social structures, material factors, and biology affect the individual behaviours that guide the lifestyle choices that ultimately produce health inequalities as a consequence of one’s social context. Therefore, in order to address these challenges, community health and health promotion has become progressively more important, more patient-centered and more focused on generating interventions “that promote change in complex biopsychosocial systems, rather than attributing effects to causes that are highly interdependent on contextual influences. Effective health promotion for chronic disease needs to consider a person’s individual, familial, social, political, cultural, and spiritual context” (Cloninger, 2013).

Furthermore, it is clear that the diabetic population, especially those who are aging, need access to ST in order to monitor their condition. According to the PHAC (2011), a diagnosis of diabetes proportionally increases with advanced age. In the year 2008-2009, Canada-wide statistics demonstrated that the greatest increase in the prevalence of diabetes occurs after the age of 40, with the highest proportion of individuals diagnosed with diabetes being aged 75 to 79 (PHAC, 2011; Appendix O). Population data indicates that Ontario has the largest population, accommodating roughly 40% of the Canadian population, with the majority of the population residing in urban areas; the province of Ontario is thus proportionately home to the largest bracket of individuals in the 65+ age range (Mercado, Páez & Newbold, 2007). One must consider how the SDH such as employment, income, social environments and social support structures play a role in health promotion, community health and supporting diabetics as autonomous individuals. Research indicates that the elderly population is highly dependent on private automobiles for their transport, but also the elderly tend to make less trips outside the home (Mercado, Páez & Newbold, 2007). Thus, there is a clear need to ameliorate the accessibility of ST, so that as individuals with diabetes continue to age, they do not need to leave their home and travel to a clinic to be tested. This highlights the importance of having a glucometer and a plan for the affordability of glucose test strips.

Additionally, both physician and patient participants in the study shed light on immense costs related to ST, as clinical and cost-effectiveness is an important aspect of ST. In 2009, the Canadian Agency for Drugs and Technologies in Health (CADTH, 2010) reported that there was limited utility in SMBG for patients who were not dependent on insulin to manage their diabetes. By 2013, the Ontario Ministry of Health and Long-Term Care introduced a limit on the number of strips allowed (on a weekly basis) to perform ST, in order to help control costs incurred to the healthcare system. One physician explained that members of the community who are the ‘working poor’ face increased challenges in obtaining test strips and often they are members of an already disadvantaged population for whom testing may not be ideally set up for yet. One patient also made reference to the fact that although workplace pension plans do help with the cost to purchase test strips, not everyone can afford to purchase the strips. Public funding mechanisms such as the Ontario Drug Benefit, Ontario Disability Support Program and Trillium Benefit can help to subsidize the cost to purchase glucose test strips to some extent, however, individuals who are denied these benefits or those individuals who do not have access to a suitable pension plan or a retirement savings fund will undoubtedly suffer by not being able to perform their ST. Mancuso (2010) explains that for uninsured individuals, socioeconomic and other demographic factors may be thought to be barriers in diabetes management. Additionally, the availability of resources alone may not always be the ultimate deciding factor in managing a chronic condition such as diabetes; social and psychological factors may play a role in impeding a successful SMBG regime (Mancuso, 2010). Therefore, there is great importance on stabilizing patient blood glucose readings, as patients who successfully manage their sugars are more likely to achieve a better quality of life, and are less likely to become an added burden of costs to the healthcare system.

In summary, results of this research study indicated that one’s decision to self-test was influenced by several factors that were viewed in a positive manner, namely the convenience of ST, active participation in one’s own healthcare, improved glucose management, and other elements that facilitated the act of ST. Patients in this study indicated that ST provided the convenience of performing the testing in the comfort of their own homes, not having to travel to a clinic to be tested and having the freedom to do

the testing whenever they wanted. The testing was considered to be a valued tool to aid in the stabilization of their blood glucose values and the management of their condition because it motivated them to make better decisions so that their health would not be compromised. Factors that discouraged the act of ST included cost to perform ST and adverse effects of ST. Although the cost to perform the testing sometimes acted as a barrier to ST, patients indicated that they wanted to continue to test as they believed it was important to their health management. The examination of the HBM and the clinical governance framework shed immense light on healthcare behaviours exhibited by the patients and their decisions to participate in ST. Moreover, it is evident that choices to participate in ST are shaped by greater societal forces and contextual variables, which are elements that are not personally within an patient's control.

5.3. Accountability in Self-Testing

The data presented in this research study suggests that when patients participate in ST in the context of chronic disease management, accountability in following up with self-test results is somewhat more regimented and the responsibility is shared between both the patient and their healthcare provider. Patients who were compliant with their ST and strived to attain and maintain positive health outcomes, provided their physicians with valuable clinical data to monitor and treat their patients. Conversely, when patients did not participate regularly in ST and lacked the motivation to improve their health, physicians were tasked with providing additional ongoing education to their patients on the importance of stabilizing blood glucose values in order to improve health outcomes.

When patients in this study were asked about initiating and engaging in other forms of ST, patients were generally less knowledgeable about the testing process and the interpretation of test results. Additionally, physicians suggested that patients do not have the appropriate medical knowledge required to make clinical decisions that could affect their health status both immediately and in the long term. Therefore, patients may not receive the appropriate follow-up or treatment.

Accountability in ST needs to be further understood and should be considered to be a long-term goal in improving healthcare delivery and patient safety. Therefore, the researcher of this thesis suggests that a chain of accountability be created whereby each link in the chain is responsible to some extent for ensuring that ST does not harm the

patient. The chain of accountability is discussed in more detail as a recommendation in section 5.4.2.

5.4. Recommendations

5.4.1. Looking Ahead: Is a Chain of Accountability Appropriate?

According to Deber (2014), accountability is multidimensional; it consists of financial, performance, and political/democratic indicators. Deber (2014), explains that a more distinct understanding of what is meant by accountability means identifying what is one accountable for, by whom, to whom and how is one considered to be accountable, and finally how measures of accountability are linked to a set of concepts in which rewards are identified and punishments are enforced when outcomes are not met. Accountability for ST in the community should involve a community-based approach. This requires the involvement of key stakeholders within the community including with physicians, nurse practitioners and various allied health professionals to form a partnership with patients and organizations which advocate for patient safety in healthcare, in order to strengthen accountability in ST. By considering the variables which affect accountability in ST, short term and long term goals need to be identified and policymakers need to consider how to effect such goals.

Additionally, accountability and patient care for self-initiated tests needs to be further defined and the makers of self-tests need to take a greater responsibility for ensuring that self-test results are met with an appropriate follow-up. There needs to be increased education and a greater overall awareness that patient-initiated ST is a form of consumerism. In order to meet such expectations, the researcher of this thesis has suggested the creation of a chain of accountability, in which four links in the chain of accountability are identified: vendors, merchants, consumers and physicians ([Appendix P](#)). When clinical diagnostic tests are made available to consumers, the vendors of the diagnostic tests need to be at the forefront of the chain of accountability. They have a significant ethical responsibility to ensure that if they are making these items available to consumers, that the tests are to be used in a safe and responsible fashion. Next in the chain of accountability are the merchants who distribute clinical diagnostic tests. Merchants need to ensure that self-tests are only available to the portion of the population

for whom the testing may be truly warranted, as there is a greater chance of causing harm to the patient if testing is not conducted for the appropriate indications. The next link in the chain of accountability is consumers. Patient autonomy plays a significant role in one's choice to participate in ST, and a variety of reasons may exist for why patients choose to participate in ST. One such reason is wanting to understand more fully what is going on in their body, and how they can help themselves to achieve healthier and happier health outcomes. Consumers are accountable to the merchants and vendors, by making a well-informed choice to participate in a self-test. Consumers are also accountable to themselves and to their healthcare providers to fully acknowledge the ensuing test result, and initiate medical follow-up as required. ST is of no benefit to the patient if the results are not interpreted within the correct context or followed-up with, in a timely manner. The final link in the chain of accountability is primary care providers. Physicians are accountable to both their patients and to the vendors of self-tests. It is the responsibility of these medical professionals to ensure that self-test results reported by patients receive a fair evaluation and follow-up. Physicians can be considered advocates for patient safety, as they play a role in education and counseling in medical practice. If physicians find that self-tests are being marketed unfairly or with deceptive practices, then they too have a responsibility to advocate against the availability of such tests. However, because self-tests are also a valuable and useful tool in healthcare, vendors need to work with physicians to ensure that clinical tests are used appropriately in the right context. Vendors also need to make sure that the merchants who sell the tests, participate in fair marketing practices and that the self-tests do not fall prey to consumer anxieties. The chain of accountability becomes a cyclical process, in which each link in the chain is responsible to some form of accountability, both forward and backward.

Accountability in POCT does not solely rest on the vendors of POC devices. Pharmacies are another key player in the discussion of accountability in POCT. In chronic disease management, pharmacists have the chance to be at the forefront in the prevention and management of diabetes. In a pilot study conducted by Papastergiou, Folkins & Li (2016), testing for hemoglobin A1c at the POC by pharmacists revealed that pharmacists have an increased opportunity to identify patients who required further clinical intervention based on their hemoglobin A1c result; such interventions included “a

discussion of the patient's A1c, communication with the physician, device (blood glucose monitor) training, lifestyle counselling, dietitian and physician referrals, and booking a follow-up appointment with the pharmacist". This exemplifies how accountability to patients at a community-based level, is an approach which is useful in POCT.

5.4.2. Long-Term Goals: Models for Safe and Effective Delivery of Self-Initiated Testing

As we look ahead to the recommended models for the safe and effective delivery of self-initiated ST, it is imperative that we understand the role of pharmacists within the community, especially as the scope of practice for pharmacists continues to expand. Pharmacists are allied health professionals who play a key role in providing health promotion to patients, collaborate with other healthcare professionals and key stakeholders in the pharmacy industry, and refer patients for appropriate medical advice where necessary (WHO, 1998). Pharmacists are frontline healthcare providers who have the ability to guide self-testing options in POC. One suggested element to regulate the availability of ST could be as simple as moving the clinical tests to an 'over-the-counter' model, where patients who were interested in purchasing selected self-tests could purchase them at a pharmacy if they met the criteria to perform the test. In this scenario, pharmacists become the first point of contact for patients, to ensure that conducting the self-test is truly indicated for the patient. A pharmacist's comprehensive training in medical life sciences makes them an invaluable partner in this model for delivery of POCT.

Another long-term goal that could prove to be beneficial for the safe and effective delivery of self-initiated testing could be modeled after a pilot program that offers online testing services for sexually transmitted infections (STI) in British Columbia, Canada. In this pilot program, residents living within selected areas of British Columbia have access to safe, confidential and reliable tests to screen for STI's. According to the Vancouver Island Health Authority (2016), patients interested in being screened for STI's such as chlamydia, gonorrhoea, syphilis, HIV and hepatitis C, simply need to download an electronic requisition and answer a few questions on the requisition. Next, they provide a clinical specimen to one of the participating laboratories; participants are then notified when test results are available. If all results are negative, the results are released to the

patient and may be viewed online with access via a personal password. If test results are either inconclusive or positive, the patient would be contacted by a nurse so that follow-up and appropriate treatment can be initiated. This is an excellent example of a community health program that supports population health by removing selected barriers to clinical testing and treatment. Although this particular scenario does not involve the use of self-test devices, it mirrors the concept of upholding patient autonomy by supporting a patient's desire to conduct a clinical laboratory test to obtain more information about one's own health status. Elements of confidentiality or even the patient/physician relationship, may be factors which steer some individuals towards self-testing in the first place. Using the existing model in British Columbia, a privately funded or publicly overseen program could be created which would provide laboratory-quality testing and could act as the link to initiate follow-up medical advice where it is necessary. In order to determine which lab tests patients are eligible for, a screening procedure with a questionnaire could be developed. To avoid increased costs being absorbed by the current healthcare system, consumers would bear the cost of the service, as they would be performing the testing for their own satisfaction. If such a program were ever to become privatized, there would also be a greater likelihood of improved turnaround times, as consumers would be paying for a service directly. This type of model would ensure that laboratory test results are interpreted with the correct clinical context, that patients are encouraged to follow-up with a primary care physician where necessary and that extra clinical investigations are not ordered as a result of improperly interpreting self-test results reported by patients.

5.4.3. Short-Term Goals

Patient care and patient outcomes in ST are important. One recommended short-term goal is to place a much greater emphasis on thorough training of self-tests and self-test devices. This would ideally include a comprehensive seminar on how to troubleshoot faulty POC testing platforms, as well as providing end-users with greater access to material to help them assess the validity of results being reported. Patients need to be educated further about the importance of calibrations, quality control material and factors that can affect self-test results. A mechanism or process by which end-users can participate in some form of external quality assurance and competency checks, ideally

once or twice per year, could also be of benefit to patient care, although this would undoubtedly increase costs to an already burdened healthcare system. Additionally, it is suggested that policymakers develop a quality framework to address the safe usage of self-tests outside of regulated healthcare environments, to ensure that clinical diagnostic tests are used safely in clinical decision-making.

5.5. Directions for Future Research

This study provided an opportunity to examine the current state of knowledge of the role of autonomy in ST and the clinical decision-making processes that arise as a result of ST. Safety guidelines can always be improved to provide greater protection to patients/consumers. In order to strengthen best practices and improve an optimal experience for healthcare delivery, further research is required to establish and enforce a minimum set of safety standards, which are both stringent and rigorous, in patient-driven ST. It is imperative that quality goals be defined, as this is an important concept in establishing and improving safety in ST. The establishment of a set of quality goals will certainly help to increase the reliability of self-test results, and will hopefully decrease costs placed on the healthcare system, as a result of unsafe or unstandardized ST practices. Additionally, it is recommended that the economic impact of the availability of decentralized laboratory tests in Canada, also be studied, in order to ascertain whether ST reduces or in fact increases, costs related to healthcare delivery. A smaller scale community level pilot study could be launched to evaluate this area of research, with a larger provincial or Canada-wide study following afterwards.

Additionally, two long-term recommendations suggested by the researcher include the creation of a chain of accountability and alternate models for safe and effective delivery of self-initiated ST. In order for either of these models to be successful, several political and financial obstacles will need to be overcome in order to bring these recommendations to fruition. Research, planning, development and inter-professional collaboration will all be required. It is suggested that future research look at how models of healthcare delivery have changed over the past century, and how public policy and healthcare policy guide measures for successful community health interventions.

5.6. Study Strengths

In the past, many scientists considered case study research unfavourably, as researchers who used the case study methodology were not organized, their work lacked focus, did not follow a systematic procedure, and allowed biases to contaminate their research findings (Yin, 2009). In this research endeavour, the researcher stayed focused and organized and ensured that a methodical case study informed approach was used, following the teachings from Robert Yin's case study methodology as a guide. The researcher in this qualitative research study succinctly presented the research evidence obtained and all evidence was systematically reported. This ensures that the reader can confirm on their own, that the research findings emerged from the data and experiences of the research participants, rather than from any bias or subjectivity of the investigator (Ponelis, 2015). Multiple iterations and revisions of the thesis have ensured that the paper is well written paper and findings are presented with focus and clarity. Additionally, the researcher had several other readers challenge the document with alternative views and opinions in order to achieve a well-balanced and well-written paper. The insight brought forth from multiple readers helped to improve portions of the research paper which may have lacked focus or were inarticulate. In order to enhance the trustworthiness of the findings, the researcher created an audit trail to document each research step taken from the start of the research procedure to the end of the completed research thesis.

Hodkinson and Hodkinson (2001) also explain that a researcher's expertise may raise doubts about their objectivity in the research. The primary researcher's knowledge of the medical laboratory services sector is a key element of this research endeavour. This knowledge facilitated the creation of the goals of the research study. Furthermore, the researcher's experience in health sciences research helped to generate interview questions that ultimately facilitated answering the goals of the research endeavour. As a qualitative researcher, the researcher ensured that the data being presented was continuously scrutinized to understand its significance as it relates to the phenomenon of interest. The researcher controlled for bias by adhering to data collection protocols; all data was collected on an audio recording device, which was then transcribed by the researcher, and furthermore, research participants had a chance to read a copy of their transcript to ensure that an accurate interpretation of their interview data was made. In qualitative research,

this is known as ‘member checking’; a procedure which serves to ensure that interpretations and conclusions are made accurately and furthermore serves as a technique to establish validity, by giving participants a chance to read their own interviews (Cohen & Crabtree, 2006; Tobin, 2010). Additionally, the triangulation of perspectives (patient and physician) on the same issue further validated the meanings brought forth from the data. These measures all verify that data collection and analysis was impartial and unbiased.

5.7. Study Limitations

A limitation of this qualitative research study is that the findings are not generalizable, as is seen in traditional quantitative research (Hodkinson & Hodkinson, 2001). No attempts were made by the researcher to generalize the findings to other populations within the province of Canada, or even around the world. The researcher fully acknowledged that the data was collected from a small pool of research participants. As the data is non-numerical in nature, there is no way to ascertain that the sample was a typical representative sample of the larger population.

In order to homogenize data collection questions, two distinct groups of research participants were sought. Data collection from patient participants was targeted to only glucometer users. This however, completely excluded individuals who may have had experience with other POC tests. Each end-user of self-tests may bring with them very different and distinct experiences of conducting tests at the POC. It would be preferable to capture the ST experience of patients who have used devices/self-tests other than glucometers.

Likewise, physicians may also encounter a variety of experiences in their profession, and consequently may have different views of patient initiated ST. Ideally, physicians across Ontario, or even within a cross-section of Canadian provinces would have been suitable for the study, however, this was not a feasible option for the scope of the Masters thesis. Capturing the views of ST from other allied healthcare providers who are familiar with ST could also prove to be beneficial. This would include, but is not limited to registered nurses, respiratory therapists, pharmacists and paramedics. Nurse practitioners are another group of healthcare providers who have prominent roles, especially within community-based settings. It would be ideal to capture their perspective

as well, as they function autonomously to “diagnose, order and interpret diagnostic tests, prescribe pharmaceuticals and perform specific procedures within their legislated scope of practice” (Donald et al., 2010).

The views of all of these participants would be extremely useful to expand on the debate of autonomy in healthcare, and furthermore, would add value to the discussion of patient safety and healthcare decision making when ST is self-driven. This would be considered a large scale study, well beyond the scope of a master’s thesis.

5.8. Concluding Summary

This qualitative research study provided a unique opportunity to reflect on the utility of patient-driven ST, from both a patient and physician perspective. The study shed light on the role of autonomous behaviours in ST, accountability in self-initiated ST, and further explained how healthcare behaviours are affected by the need for ongoing health promotion and community health. The study acknowledged that within pre-established healthcare settings, measures of accountability were well developed for the use of diagnostic POCT, however, the lack of a defined set of standards outside of such settings drew significant attention. Patient autonomy in healthcare continues to face ongoing ethical challenges, especially as the landscape in healthcare, technology and newly emerging bacteria/viruses and illnesses put pressures on our healthcare system. Additionally, the researcher suggested both short-term and long-term goals that could prove to be beneficial in supporting patient safety. Firstly, increased end-user training, along with more education and a purposeful focus on the development of a quality assurance framework, would undoubtedly be of benefit to patients and to the healthcare system as a whole. One long-term goal that is suggested is the creation of a chain of accountability as a basepoint for engaging in the discussion of autonomy as it relates to measures of accountability in patient-driven ST. Furthermore, regulation of ST outside of accredited healthcare facilities is crucial to ensure the promotion of a culture of sustained community engagement and patient safety. Another long-term goal involves a revision in the practice of accessibility of self-testing to consumers. This long term goal involves either moving self-tests to an ‘over-the-counter’ model, where clinical tests are only available where indicated, or conversely, the creation of a public or privatized online testing service. The execution of any such goals requires ongoing funding, infinite

amounts of research and an interdisciplinary approach that connects multiple key players in the healthcare sector in the quest to promote patient safety. The findings of this study suggest that the dialogue on the role of patient autonomy in healthcare needs continued analysis, and perspectives need to be re-framed in order to understand how the evolution of change affects patients, physicians and society as a whole.

References

- Accreditation Canada. (2013). *Point-of-Care Testing*. Retrieved from <https://accreditation.ca/point-care-testing>
- Annandale, E., & Field, D. (2007). Socio-economic inequalities in health. In Taylor, S., & Field, D. (Eds). *Sociology of health and health care (4th ed.)*. (pp.45-68). Oxford, England: Wiley-Blackwell.
- Badrick, T. (2013). Evidence-Based Laboratory Medicine. *The Clinical Biochemist Reviews*, 34(2), 43–46.
- Bashshur, R. L., Shannon, G. W., Smith, B. R., Alverson, D. C., Antoniotti, N., Barsan, W. G., ... Yellowlees, P. (2014). The empirical foundations of telemedicine interventions for chronic disease management. *Telemedicine and E-Health*, 20(9), 769-800. doi: 10.1089/tmj.2014.9981
- Baxter, P., & Jack, S. (2008). Qualitative Case Study Methodology: Study Design and Implementation for Novice Researchers. *The Qualitative Report*, 13(4), 544-559.
- Belk, A. (2010). Explanation building. In A. J. MillsG. Durepos & E. Wiebe (Eds.), *Encyclopedia of case study research* (pp. 368-370). Thousand Oaks, CA: SAGE Publications Ltd. doi: 10.4135/9781412957397.n137
- Bowling, A. (2014). *Research Methods In Health: Investigating Health And Health Services* (4th ed.). England: McGraw-Hill Education/Open University Press.
- Burke, L. A., & Miller, M. K. (2001). Phone Interviewing as a Means of Data Collection: Lessons Learned and Practical Recommendations. *Forum Qualitative Sozialforschung / Forum: Qualitative Social Research*, 2(2). doi:<http://dx.doi.org/10.17169/fqs-2.2.959>
- Canadian Agency for Drugs and Technologies in Health (CADTH). (2014). Point-of-Care Testing of International Normalized Ratio for Patients on Oral Anticoagulant Therapy: Systematic Review and Economic Analysis. *CADTH Optimal Use Report*, 13(1b). Ottawa: The Agency. Retrieved from: http://www.cadth.ca/media/pdf/OP0515_POC%20INR_Science_Report.pdf
- Canadian Agency for Drugs and Technologies in Health (CADTH). (2010). *Self-Monitoring Blood Glucose*. Retrieved from <https://www.cadth.ca/self-monitoring-blood-glucose>

- Canadian Diabetes Association. (2009). *An Economic Tsunami: The Cost of Diabetes in Canada*. Retrieved from <http://www.diabetes.ca/CDA/media/documents/publications-and-newsletters/advocacy-reports/economic-tsunami-cost-of-diabetes-in-canada-english.pdf>
- Canadian Institute for Health Information. (2016). *National Health Expenditure Trends, 1975 to 2016*. Ottawa, ON. Retrieved from https://secure.cihi.ca/free_products/NHEX-Trends-Narrative-Report_2016_EN.pdf
- Centre for Connected Health Policy. (2010). *What is Telehealth?* Retrieved from <http://cchpca.org/what-is-telehealth>
- Centres for Disease Control and Prevention. (2015). *Waived Tests*. Retrieved from <http://wwwn.cdc.gov/clia/resources/waivedtests/>
- Centres for Disease Control and Prevention. (2016). *Chronic Disease Overview*. Retrieved from <http://www.cdc.gov/chronicdisease/overview/>
- Charuruks, N., Surasiengsunk, S., Suwanwalaikorn, S., Pothisiri, W., Wongboonsin, K., & Kost, G. J. (2006). Impact of self-monitoring of blood glucose in diabetic patients in Thailand. *Point of Care*, 5(4), 155-159. doi: 10.1097/01.poc.0000243979.85019.cb
- Cloninger, C. R. (2013). Person-centered Health Promotion in Chronic Disease. *International Journal of Person Centered Medicine*, 3(1), 5-12. doi: 10.5750/ijpcm.v3i1.379
- Cohen D., & Crabtree, B. (2006). *Qualitative Research Guidelines Project*. Retrieved from <http://www.qualres.org/HomeMemb-3696.html>
- College of American Pathologists. (2012). *POCT Tool Kit*. Retrieved from http://www.cap.org/apps/docs/committees/pointofcare/poct_tool_kit.pdf
- Creswell, J. W. (2013). *Qualitative inquiry and research design: choosing among five approaches* (3rd ed). Thousand Oaks, CA: Sage Publications.
- Deber, R. B. (2014). Thinking about Accountability. *Healthcare Policy*, 10(SP), 12–24. doi: 10.12927/hcpol.2014.23932

- Denzin, N. K., & Lincoln, Y. S. (1994). *Handbook of qualitative research*. Thousand Oaks, CA: Sage.
- Dictionary.com Unabridged. (2017). *Hematoma*. Retrieved from <http://www.dictionary.com/browse/hematoma>
- Dictionary.com Unabridged. (2017). *Venipuncture*. Retrieved from <http://www.dictionary.com/browse/venipuncture>
- Dilts, T. J. (1998). Point-of-care Testing: A Step to the Future. *BD VACUTAINER Lab Notes*, 8(1), 1-13. Retrieved from <http://www.bd.com/vacutainer/labnotes/>
- Donald, F., Martin-Misener, R., Bryant-Lukosius, D., Kilpatrick, K., Kaasalainen, S., Carter, N., . . . DiCenso, A. (2010). The primary healthcare nurse practitioner role in Canada. *Nursing Leadership*, 23 (Special Issue) Dec 2010, 88-113. doi:10.12927/cjnl.2013.22271.
- du Plessis, M., Ubbink, J. B., & Vermaak, W. J. (2000). Analytical quality of near-patient blood cholesterol and glucose determinations. *Clinical Chemistry*, 46(8 Pt 1), 1085-1090.
- Ehrmeyer, S. S. (2011). Plan for Quality to Improve Patient Safety at the Point of Care. *Annals of Saudi Medicine*, 31(4), 342-346. doi: 10.4103/0256-4947.83203
- Ehrmeyer, S. S., & Laessig, R. H. (2007). Point-of-care testing, medical error, and patient safety: a 2007 assessment. *Clinical Chemical Laboratory Medicine*, 45(6), 766-773. doi: 10.1515/CCLM.2007.164
- Entwistle, V. A., Carter, S. M., Cribb, A., & McCaffery, K. (2010). Supporting Patient Autonomy: The Importance of Clinician-patient Relationships. *Journal of General Internal Medicine*, 25(7), 741-745. <http://doi.org/10.1007/s11606-010-1292-2>
- Farrance, I. (2012). *Review: Policies, procedures and guidelines for point-of-care testing*. Australasian Association of Clinical Biochemists. Retrieved from <https://www.aacb.asn.au/documents/item/635>
- Fitzgerald, J. T., Funnell, M. M., Hess, G. E., Barr, P. A., Anderson, R. M., Hiss, R. G., & Davis, W. K. (1998). The Reliability and Validity of a Brief Diabetes Knowledge Test. *Diabetes Care*, 21(5), 706-710. doi: 10.2337/diacare.21.5.706

- Flyvbjerg, B. (2006). Five Misunderstandings About Case-Study Research. *Qualitative Inquiry*, 12(2), 219-245. doi: 10.1177/1077800405284363
- Free, A. H., & Free, H. M. (1984). Self testing, an emerging component of clinical chemistry. *Clinical Chemistry*, 30(6), 829-838.
- Freedman, D. B. (2002). Clinical governance: implications for point-of-care testing. *Annals of Clinical Biochemistry*, 39(Pt 5), 421-423. doi: 10.1258/000456302320314421
- Friedman, B.A., & Mitchell, W. (1993). Integrating Information from Decentralized Laboratory Testing Sites. *American Journal of Clinical Pathology*. 99(5), 637-642.
- Glanz, K., Rimer, B.K., & Viswanath, K. (2008). *Health Behavior and Health Education: Theory, Research, and Practice* (4th ed.). San Francisco: Jossey-Bass. Retrieved from: <http://www.esourceresearch.org/Default.aspx?TabId=731>
- Graham, G., & Pace, T. (2008). Health belief model. In F. T. Leong (Ed.), *Encyclopedia of counseling* (Vol. 4, pp. 236-237). Thousand Oaks, CA: SAGE Publications Ltd. doi: 10.4135/9781412963978.n77
- Grispen, J. E. J., Ickenroth, M. H. P., de Vries, N. K., Dinant, G.-J., Ronda, G., & van der Weijden, T. (2010). Improving behaviour in self-testing (IBIS): Study on frequency of use, consequences, information needs and use, and quality of currently available consumer information (protocol). *BioMed Central Public Health*, 10(1), 453-461. doi: 10.1186/1471-2458-10-453
- Harder, H. (2010). Explanatory case study. In A. J. Mills, G. Durepos & E. Wiebe (Eds.), *Encyclopedia of case study research* (pp. 371-371). Thousand Oaks, CA: SAGE Publications Ltd. doi: 10.4135/9781412957397.n138
- Harper, C.C. (n.d.). FDA/CHRH Public Meeting: Blood Glucose Meters. Retrieved from <https://www.diabetestechology.org/FDA/Harper-%20PQQ%20and%20other%20interferences.pdf>
- Hayden, J. (2009). *Introduction to Health Behavior Theory*. Burlington, MA: Jones & Bartlett Learning.

- Heisler, M., Piette, J. D., Spencer, M., Kieffer, E., & Vijan, S. (2005). The relationship between knowledge of recent HbA1c values and diabetes care understanding and self-management. *Diabetes Care*, 28(4), 816-822.
- Helmrich, S.P., Ragland, D.R., Leung, R.W., & Paffenbarger R.S. Jr., (1991). Physical activity and reduced occurrence of non-insulin-dependent diabetes mellitus. *New England Journal of Medicine*, 325, 147-152
- Hennink, M.M., Hutter, I., & Bailey, A. (2011). *Qualitative Research Methods*. London, United Kingdom: Sage Publications Ltd.
- Henry Ford Allegiance Health. (2017). *The Importance of Healthy Eating When You Have Diabetes*. Retrieved from <https://www.allegiancehealth.org/wellness/article/889606>
- Hjerkind, K. V., Stenehjem, J. S., & Nilsen, T. I. (2017). Adiposity, physical activity and risk of diabetes mellitus: prospective data from the population-based HUNT study, Norway. *British Medical Journal Open*, 7(1), e013142. doi: 10.1136/bmjopen-2016-013142
- Hodkinson, P., & Hodkinson, H. (2001, December). *The strengths and limitations of case study research* (Vol. 1, No. 1, pp. 5-7). Paper presented at the Learning and Skills Development Agency Conference at Cambridge, UK.
- Holloway, H. (2005). *Qualitative Research in Health Care*. New York, NY: Open University Press.
- Hu, F. B., Manson, J. E., Stampfer, M. J., Colditz, G., Liu, S., Solomon, C. G., & Willett, W. C. (2001). Diet, Lifestyle, and the Risk of Type 2 Diabetes Mellitus in Women. *New England Journal of Medicine*, 345(11), 790-797. doi: 10.1056/NEJMoa010492
- Janesick, V. J. (1999). A Journal About Journal Writing as a Qualitative Research Technique: History, Issues, and Reflections. *Qualitative Inquiry*, 5(4), 505-524. doi: 10.1177/107780049900500404
- Jones, B. A., & Meier, F. A. (2005). Point-of-care testing error: sources and amplifiers, taxonomy, prevention strategies, and detection monitors. *Archives of Pathology & Laboratory Medicine*, 129, 1262-1267.

- Jones, C. H. D., Howick, J., Roberts, N. W., Price, C. P., Heneghan, C., Pluddemann, A., & Thompson, M. (2013). Primary care clinicians' attitudes towards point-of-care blood testing: a systematic review of qualitative studies. *BMC Family Practice*, *14*(117).
- Kearns, A. J., O'Mathuna, D. P., & Scott, P. A. (2010). Diagnostic self-testing: autonomous choices and relational responsibilities. *Bioethics*, *24*(4), 199-207. doi: 10.1111/j.1467-8519.2008.00711.x
- Kendall, J., Reeves, B., & Clancy, M. (1998). Point of care testing: randomised controlled trial of clinical outcome. *BMJ: British Medical Journal*, *316*(7137), 1052–1057.
- Krefting, L. (1991). Rigor in qualitative research: The assessment of trustworthiness. *American Journal of Occupational Therapy*, *45*(3), 214-222. doi: 10.5014/ajot.45.3.214
- Kricka, L. J., & Price, C. P. (2009). Public opinion and experience of point-of-care testing: results of a small pilot survey. *Point of Care*, *8* (4), 160-164.
- Laurence, C. O., Gialamas, A., Bubner, T., Yelland, L., Willson, K., Ryan, P., & Beilby, J. (2010). Patient satisfaction with point-of-care testing in general practice. *British Journal of General Practice*, *60*(572), e98-e104. doi: 10.3399/bjgp10X483508
- Laverack, G., & Labonte, R. (2000). A planning framework for community empowerment goals within health promotion. *Health policy and planning*, *15*(3), 255-262.
- Lee, R. & Fielding, N. (2004). Tools for qualitative data analysis. In M. Hardy & A. Bryman *Handbook of Data Analysis* (pp. 530-546): SAGE Publications Ltd. doi: 10.4135/9781848608184.n23
- Lewandrowski, K. (2009). Point-of-care testing: an overview and a look to the future (circa 2009, United States). *Clinics in Laboratory Medicine*, *29*(3), 421-432. doi: 10.1016/j.cll.2009.06.015
- Lippi, G., Guidi, G. C., Mattiuzzi, C., & Plebani, M. (2006). Preanalytical variability: the dark side of the moon in laboratory testing. *Clinical Chemistry & Laboratory Medicine*, *44*(4), 358-365. doi: 10.1515/CCLM.2006.073

- MacQuarrie, C. (2010). Holistic designs. In A. J. Mills, G. Durepos & E. Wiebe (Eds.), *Encyclopedia of case study research* (pp. 442-443). Thousand Oaks, CA: SAGE Publications Ltd. doi: 10.4135/9781412957397.n164
- MacQueen, K. M., McLellan, E., Metzger, D. S., Kegeles, S., Strauss, R. P., Scotti, R. & Trotter, R. T. (2001). What Is Community? An Evidence-Based Definition for Participatory Public Health. *American Journal of Public Health, 91*(12), 1929–1938
- Mancuso, J. M. (2010). Impact of health literacy and patient trust on glycemic control in an urban USA population. *Nursing and Health Sciences, 12*(1), 94-104. doi: 10.1111/j.1442-2018.2009.00506.x
- Markets and Markets. (2014). *Point-Of-Care Diagnostics / Testing Market by Products (Glucose Monitoring & Infectious Diseases Testing Kits, Cardiac & Tumor Markers), by End Users (Self & Professional Monitoring), Over the Counter & Prescription Based - Global Forecast to 2018*. Retrieved from <http://www.marketsandmarkets.com/Market-Reports/point-of-care-diagnostic-market-106829185.html>
- Markets and Markets. (2016). *Point-Of-Care Diagnostic Market worth \$27.5 Billion by 2018*. Retrieved from <http://www.marketsandmarkets.com/PressReleases/point-of-care-diagnostic.asp>
- Maxwell, J. A. (2005). *Qualitative research design: An interactive approach (2nd Ed.)*. Thousand Oaks, CA: SAGE Publications
- Mccooy, K. (2009). *Diabetes and Sugar Metabolism*. Retrieved from <http://www.everydayhealth.com/diabetes/understanding/how-sugar-is-metabolized.aspx>
- Melo, M. R., & Rosenfeld, L. G. (2007). Meeting the challenges of globalisation and miniaturisation in laboratory services. *Malaysian Journal of Pathology, 29*(2), 57-61.
- Mercado, R., Páez, A., & Newbold, B. (2007). Policy Areas Impinging on Elderly Transportation Mobility: An Explanation with Ontario, Canada as Example. *Social and Economic Dimensions of an Aging Population, 187*. Retrieved from <http://socserv.mcmaster.ca/sedap/p/sedap187.pdf>

- Morse, J. (2000). Determining Sample Size. *Qualitative Health Research*, 10(1), 3-5. doi: 10.1177/104973200129118183
- Morse, J. (2012). *Qualitative Health Research: Creating a New Discipline*. Walnut Creek, CA: Left Coast Press
- Nouwen, A., Ford, T., Balan, A. T., Twisk, J., Ruggiero, L., White, D., . . . White, D. (2011). Longitudinal motivational predictors of dietary self-care and diabetes control in adults with newly diagnosed type 2 diabetes mellitus. *Health Psychology*, 30(6), 771-779. doi:10.1037/a0024500
- Novick, G. (2008). Is There a Bias Against Telephone Interviews In Qualitative Research? *Research in Nursing & Health*, 31(4), 391-398. <http://doi.org/10.1002/nur.20259>
- O'Donnell, M. P. (2009). Definition of Health Promotion 2.0: Embracing Passion, Enhancing Motivation, Recognizing Dynamic Balance, and Creating Opportunities. *American Journal of Health Promotion*, 24(1), iv-iv. doi: 10.4278/ajhp.24.1.iv
- Ontario Health Quality Council. (2008). *Accountability Agreements in Ontario's Health System: How Can They Accelerate Quality Improvement and Enhance Public Reporting?* Retrieved from http://www.hqontario.ca/Portals/0/modals/qi/en/processmap_pdfs/resources_links/accountability_agreements_in_ontario-july_31_2008.pdf
- Opdenakker, R. (2006). Advantages and Disadvantages of Four Interview Techniques in Qualitative Research. *Forum Qualitative Sozialforschung / Forum: Qualitative Social Research* 2006, 7(4). doi: 10.17169/fqs-7.4.175
- Ortlipp, M. (2008). Keeping and Using Reflective Journals in the Qualitative Research Process. *The Qualitative Report*, 13(4), 695-705. Retrieved from <http://nsuworks.nova.edu/tqr/vol13/iss4/8>
- Pan, X.-R., Li, G.-W., Hu, Y.-H., Wang, J.-X., Yang, W.-Y., An, Z.-X., . . . Howard, B. V. (1997). Effects of Diet and Exercise in Preventing NIDDM in People With Impaired Glucose Tolerance: The Da Qing IGT and Diabetes Study. *Diabetes Care*, 20(4), 537-544. doi: 10.2337/diacare.20.4.537

- Papastergiou, J., Folkins, C., & Li, W. (2016). Community pharmacy-based A1c screening: A Canadian model for diabetes care. *International Journal of Pharmacy Practice*, 24(3), 189-195. doi: 10.1111/ijpp.12228
- Park, E.-J. (2006). Telehealth Technology in Case/Disease Management. *Lippincott's Case Management*, 11(3), 175-182.
- Pearson, J. (2006). Point-of-care-testing and Clinical Governance. *Clinical Chemistry and Laboratory Medicine*, 44(6), 765-767. doi: 10.1515/cclm.2006.129
- Pearson, S. D., & Raeke, L. H. (2000). Patients' Trust in Physicians: Many Theories, Few Measures, and Little Data. *Journal of General Internal Medicine*, 15(7), 509-513. <http://doi.org/10.1046/j.1525-1497.2000.11002.x>
- Plebani, M. (2009). Does POCT reduce the risk of error in laboratory testing? *Clinica Chimica Acta*, 404(1), 59-64. <http://dx.doi.org/10.1016/j.cca.2009.03.014>
- Ponelis, S. R. (2015). Using interpretive qualitative case studies for exploratory research in doctoral studies: A case of Information Systems research in small and medium enterprises. *International Journal of Doctoral Studies*, 10, 535-550. Retrieved from <http://ijds.org/Volume10/IJDSv10p535-550Ponelis0624.pdf>
- Public Health Agency of Canada. (2008). *What is Health?* Retrieved from <http://www.phac-aspc.gc.ca/ph-sp/approach-approche/qa-qr5-eng.php>
- Punch, K. F. (2006). *Developing effective research proposals* (2nd ed.). London: Sage Publications.
- QSR International. (2000). *What is NVivo?* Retrieved from <http://www.qsrinternational.com/what-is-nvivo>
- Rajan, A., & Glorikian, H. (2009). Point-of-care diagnostics: market trends and growth drivers. *Expert Opinion on Medical Diagnostics*. 3(1), 1-4. doi: 10.1517/17530050802651579
- Rana, S. V. (2012). No Preanalytical Errors in Laboratory Testing: A Beneficial Aspect for Patients. *Indian Journal of Clinical Biochemistry*, 27(4), 319-321. doi: 10.1007/s12291-012-0271-2
- Robertson, A., & Minkler, M. (1994). New Health Promotion Movement: A Critical Examination. *Health Education & Behavior*, 21(3), 295-312. doi: 10.1177/109019819402100303

- Senécal, C., Nouwen, A., & White, D. (2000). Motivation and dietary self-care in adults with diabetes: Are self-efficacy and autonomous self-regulation complementary or competing constructs? *Health Psychology, 19*(5), 452-457. doi:10.1037/0278-6133.19.5.452
- Service Canada. (2015). *Medical Laboratory Technologists and Pathologists' Assistants*. Retrieved from http://www.servicecanada.gc.ca/eng/qc/job_futures/statistics/3211.shtml.
- Sibbald, B., & Roland, M. (1998). Understanding controlled trials: Why are randomised controlled trials important? *British Medical Journal, 316*(7126), 201.
- Skype. (2017). *About Skype*. Retrieved from <https://www.skype.com/en/about/>
- St John, A., & Price, C. P. (2014). Existing and Emerging Technologies for Point-of-Care Testing. *The Clinical Biochemist Reviews, 35*(3), 155-167.
- Sturges, J. E., & Hanrahan, K. J. (2004). Comparing Telephone and Face-to-Face Qualitative Interviewing: A Research Note. *Qualitative Research, 4*(1), 107-118. doi: 10.1177/1468794104041110
- TeensHealth. (n.d). *When Blood Sugar is Too High*. Retrieved from <http://kidshealth.org/en/teens/high-blood-sugar.html>
- The World Health Organization. (1998). *The Role of the Pharmacist in Self-Care and Self-Medication*. Retrieved from <http://apps.who.int/medicinedocs/en/d/Jwhozip32e/2.html#Jwhozip32e>
- Thompson, A. N., Ragucci, K. R., Fermo, J. D., & Whitley, H. P. (2009). Evaluation of patient perceptions and outcomes related to anticoagulation point-of-care testing in ambulatory care clinics. *Pharmacy Practice, 7*(4), 213-217.
- Tobin, R. (2010). High-Quality Analysis. In A. J. Mills, G. Durepos & E. Wiebe (Eds.), *Encyclopedia of case study research* (pp. 438-439). Thousand Oaks, CA: SAGE Publications Ltd doi: 10.4135/9781412957397
- Toobert, D. J., Hampson, S. E., & Glasgow, R. E. (2000). The summary of diabetes self-care activities measure: results from 7 studies and a revised scale. *Diabetes Care, 23*(7), 943-950. doi: 10.2337/diacare.23.7.943
- Vancouver Island Health Authority. (2016). *Online testing service for sexually-transmitted infections comes to Vancouver Island*. Retrieved from

http://www.viha.ca/about_viha/news/news_releases/nr_onlineSTDtesting_22feb2016.htm

- Walsh, J., Roberts, R., Vigersky, R. A., & Schwartz, F. (2012). New Criteria for Assessing the Accuracy of Blood Glucose Monitors Meeting, October 28, 2011. *Journal of Diabetes Science and Technology*, 6(2), 466–474.
- Wians, F. H. (2009). Clinical Laboratory Tests: Which, Why, and What Do the Results Mean? *Laboratory Medicine*, 40(2), 105-113. doi: 10.1309/LM4O4L0HHUTWWUDD
- Wiersma, W., & Jurs, S. G. (2009). *Research methods in education (9th ed.)*. Boston: Pearson Education.
- Williams, G. C., Freedman, Z. R., & Deci, E. L. (1998). Supporting autonomy to motivate patients with diabetes for glucose control. *Diabetes Care*, 21, 1644-1651.
- Willis, J. W. (2007). *Foundations of Qualitative Research: Interpretive and Critical Approaches*. Thousand Oaks, CA: Sage Publications Inc.
- Xiao, H. (2010). Single-case designs. In A. J. Mills, G. Durepos & E. Wiebe (Eds.), *Encyclopedia of case study research* (pp. 868-870). Thousand Oaks, CA: SAGE Publications Ltd. doi: 10.4135/9781412957397.n320
- Yin, R. K. (2009). *Case study research: Design and methods* (4th ed.). Thousand Oaks, CA: Sage Publications.
- Youngs, J., & Hooper, C. (2015). Ethical implications of HIV self-testing. *Journal of Medical Ethics*, 41(10), 809-813. doi: 10.1136/medethics-2014-102599

A. Appendix A - Research Ethics Board Approval Notice

Sana Iqbal <sana.iqbal@uoit.net>

Research Ethics Board Approval Notice

1 message

researchethics@uoit.ca <researchethics@uoit.ca>

Mon, Dec 19, 2016 at 11:44 AM

To: "Dr. Brenda Gamble (Primary Investigator)" <brenda.gamble@uoit.ca>

Cc: "Sana Iqbal (Student Lead/Post-Doctoral Lead)" <sana.iqbal@uoit.net>, researchethics@uoit.ca

Date: December 19, 2016

To: Brenda Gamble

From: Shirley Van Nuland, REB Chair

Title: Patient and Physician Views of Self-Testing

Decision: APPROVED

Current Expiry: December 01, 2017

Notwithstanding this approval, you are required to obtain/submit, to UOIT's Research Ethics Board, any relevant approvals/permissions required, prior to commencement of this project.

The University of Ontario, Institute of Technology Research Ethics Board (REB) has reviewed and approved the research proposal cited above. This application has been reviewed to ensure compliance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2 (2014)) and the UOIT Research Ethics Policy and Procedures. You are required to adhere to the protocol as last reviewed and approved by the REB.

Continuing Review Requirements (all forms are accessible from the [IRIS research portal](#)):

- **Renewal Request Form:** All approved projects are subject to an annual renewal process. Projects must be renewed or closed by the expiry date indicated above ("Current Expiry"). Projects not renewed within 30 days of the expiry date will be automatically suspended by the REB; projects not renewed within 60 days of the expiry date will be automatically closed by the REB. Once your file has been formally closed, a new submission will be required to open a new file.
- **Change Request Form:** Any changes or modifications (e.g. adding a Co-PI or a change in methodology) must be approved by the REB through the completion of a change request form before implemented.
- **Adverse or Unexpected Events Form:** Events must be reported to the REB within 72 hours after the event occurred with an indication of how these events affect (in the view of the Principal Investigator) the safety of the participants and the continuation of the protocol (i.e. un-anticipated or un-mitigated physical, social or psychological harm to a participant).
- **Research Project Completion Form:** This form must be completed when the research study is concluded.

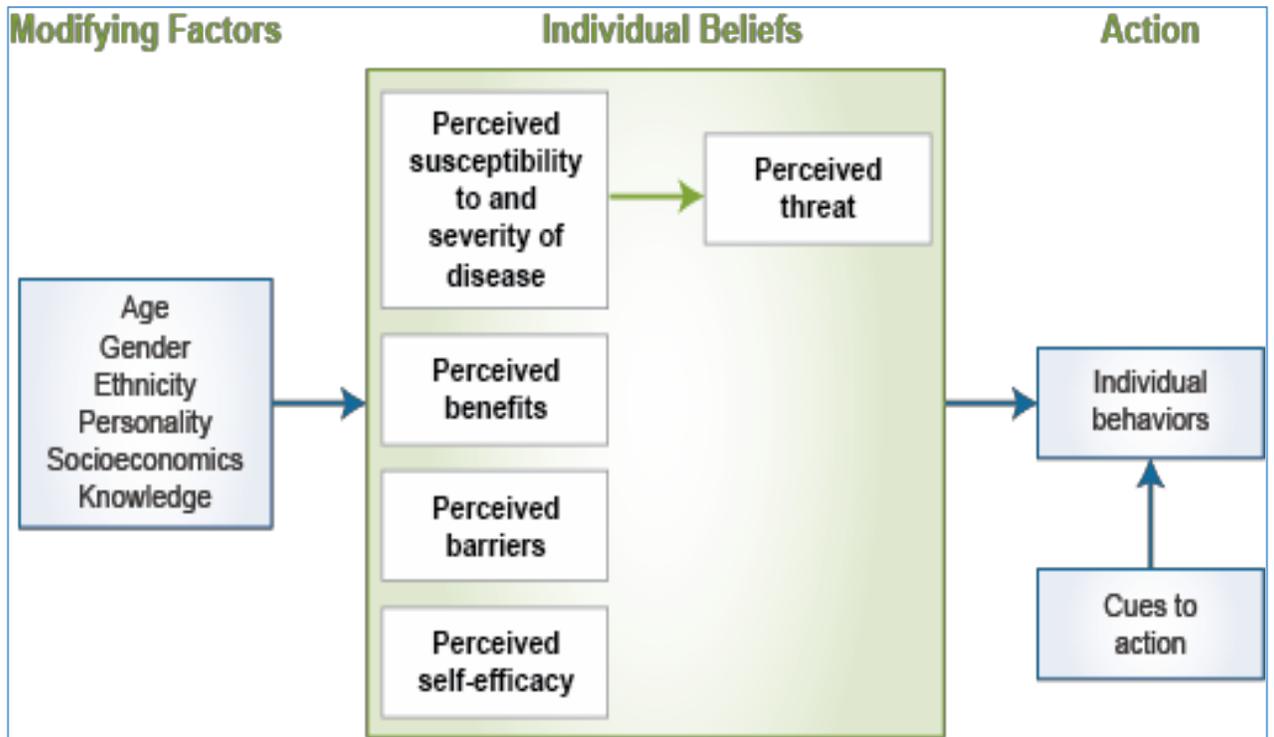
Always quote your REB file number (14116) on future correspondence. We wish you success with your study.

Dr. Shirley Van Nuland
REB Chair
shirley.vannuland@uoit.ca

Janice Moseley
Research Ethics Coordinator
researchethics@uoit.ca

NOTE: If you are a student researcher, your supervisor has been copied on this message.

B. Appendix B - Health Belief Model



Source: Glanz, Rimer & Viswanath, 2008

C. Appendix C - Hierarchy of Concepts

Hierarchy of Concepts		
Deduction ← Induction →	Research area	Point of Care Testing
	Research topic	Managing a chronic disease using a point of care test
	General Research Questions	What factors are considered in the relationship between glucometer usage and chronic disease management?
	Specific Research Questions	What is the role of healthcare autonomy in influencing decisions to use a point of care test to manage chronic illnesses? Who is responsible for following up with self-test results?
	Data Collection Questions	Refer to research questions listed in Appendix J & Appendix L

Adapted from Punch, K. F. (2006, p. 21). *Developing effective research proposals* (2nd ed.). London: Sage Publications

D. Appendix D - Patient Recruitment Poster

RESEARCH ETHICS BOARD
OFFICE OF RESEARCH SERVICES

This study has been approved by the UOIT Research Ethics Board REB [File # 14116] on Dec 19, 2016.

***Are you a person with
diabetes, aged 18 years or
older?***

***Do you use a glucometer to
monitor your blood sugar?***

.... if so, you may be interested in participating in a research study with the University of Ontario Institute of Technology (UOIT), Faculty of Health Sciences.

We're looking for volunteers to talk to about their views and experiences with self-testing, for a study entitled:

“Patient and Physician Views of Self-Testing”

If you are interested in participating or would like more information, please feel free to contact the primary researcher at sana.iqbal@uoit.net

E. Appendix E - Patient Letter of Invitation



RESEARCH ETHICS BOARD
OFFICE OF RESEARCH SERVICES

LETTER OF INVITATION

Dear Participant:

Sana Iqbal is an MHSc candidate at the University of Ontario Institute of Technology (UOIT), Faculty of Health Sciences. Under the supervision of Dr. Brenda Gamble, PhD, Sana will be conducting a health sciences research study entitled "*Patient and Physician Views of Self-Testing*".

The purpose of this study is to examine what motivates or drives individuals to initiate 'self-testing' of laboratory tests within home care environments, a setting which is not formally monitored by any external regulatory agencies. The results of this study represents an opportunity to examine the relationship between patient decision making and available options for self testing, as well as uncovering gaps in safety processes that assure that laboratory testing at home is performed with care. The findings of this study will present valuable information for future decision-making for various stakeholders, policymakers, clinicians and patients alike. This study has been approved by the UOIT Research Ethics Board (File #14116) on December 19, 2016.

The study seeks to gather information from two groups of participants, namely patients and physicians. Individuals who are known to have diabetes, who are adults, aged 18 years or older and have been using a glucometer as part of their blood glucose monitoring regime (for a minimum of at least three months) may be eligible to participate in the study. Licenced practicing primary care physicians will also be interviewed in order to gather information on physician views of self-testing. Participants will be asked to participate in an interview style dialogue with the researcher, which will be approximately 30-60 minutes in length.

Participation in the study is completely voluntary. All data gathered during the study will be held in the strictest of confidence. If you choose to withdraw from the study, there will be no consequences to you for withdrawing, and all data collected from your participation in this study will be destroyed. Of note however, if you choose to withdraw after the data collection and analysis phase of the study has already been completed, your data will already be incorporated into aggregated data form. At this point, your data will have all identifiers removed, but will no longer be able to be destroyed. There is no financial compensation for participating in this study.

If you should choose to participate in this study, you will be provided with an informed consent form to sign. If you have any questions, please do not hesitate to contact the primary researcher at sana.iqbal@uoit.net.

Thank you!

Sana Iqbal, BHSc, MLT
MHSc Candidate
University of Ontario Institute of Technology
2000 Simcoe Street North
Oshawa, ON L1H 7K4
Email: sana.iqbal@uoit.net

F. Appendix F - Physician Letter of Invitation

RESEARCH ETHICS BOARD
OFFICE OF RESEARCH SERVICES

LETTER OF INVITATION

Dear Physician:

My name is Sana Iqbal and I am currently an MHSc candidate at the University of Ontario Institute of Technology (UOIT), Faculty of Health Sciences. I am conducting a qualitative research study entitled "*Patient and Physician Views of Self-Testing*", which has been approved by the UOIT Research Ethics Board [File #14116] on December 19, 2016.

In your role as a Primary Care Physician, you are being invited to participate in this study, to share your views and perceptions of self-testing, as both the patient and physician perspective on self testing is an important one, and needs to be understood.

Purpose and Structure of Research Study:

Physicians often use laboratory test results to guide clinical decision making and therapeutic health interventions, in order to provide care for their patients. As the technology within the sector of Point-of-Care Testing continues to grow, a wide variety of point-of-care (POC) tests will become more accessible for use in a number of settings. This may essentially decentralize central laboratory testing by allowing healthcare practitioners and patients alike, the opportunity to perform an ever-growing number of laboratory tests, anywhere and at any time. This represents an important shift in healthcare culture, which needs to be examined. The findings of this study will present valuable information for future decision-making to various stakeholders, policymakers, clinicians and patients alike.

The study seeks to gather information from two key groups of participants: primary care physicians and patients. Patients with diabetes who use glucometers to monitor their blood glucose levels will be asked to share their views of self-testing, as this represents the largest and most homogenous population of POC test users. Licenced practicing primary care physicians will also be interviewed in order to gather information on the physician views of self-testing. Participants will be asked to take part in a semi-structured interview style dialogue with the researcher, which will be approximately 30-60 minutes in length. There is no financial compensation for participation in this study. Participation in the study is completely voluntary, and all data collected will be held in the strictest of confidence. There will be no consequences to you if you choose to withdraw from the study.

If you would like any additional details, have any questions about the study, or are interested in sharing your views of self-testing, please do not hesitate to contact me at sana.iqbal@uoit.net or at xxx-xxx-xxxx (telephone/text). If you should choose to participate in this study, you will be provided with an informed consent form to sign.

Thank you for your time and consideration.

Kind Regards,

Sana Iqbal, BHSc, MLT, MHSc Candidate
University of Ontario Institute of Technology
2000 Simcoe Street North
Oshawa, ON L1H 7K4
Tel: xxx-xxx-xxxx
Email: sana.iqbal@uoit.net

G. Appendix G - Letter of Consent



RESEARCH ETHICS BOARD
OFFICE OF RESEARCH SERVICES

Letter of Consent

Dear Participant:

You are invited to participate in this research study entitled “*Patient and Physician Views of Self-Testing*” with the University of Ontario Institute of Technology (UOIT), Faculty of Health Sciences. This study has been approved by the UOIT Research Ethics Board [File #14116] on Dec 19, 2016. Before proceeding, I wish to thank you again for your time. Your participation in this research endeavour is greatly appreciated.

If you have any questions concerning the research study or experience any discomfort related to the study, please do not hesitate to contact the primary researcher, Sana Iqbal, at xxx-xxx-xxxx or sana.iqbal@uoit.net.

If you have any questions concerning your participation in the study or regarding your rights as a participant, complaints or adverse events, you may contact the Research Ethics Board through the Ethics and Compliance Officer – researchethics@uoit.ca or 905.721.8668 x. 3693

Please carefully read the information below regarding the study.

Purpose of Research

The purpose of this study is to examine what motivates or drives individuals to initiate at-home ‘self-testing’ of laboratory tests, a setting which is not formally monitored by any external regulatory healthcare agencies. The results of this study represents an opportunity to examine the relationship between patient decision making and available options for self testing, as well as uncovering gaps in safety processes that assure that laboratory testing at home is performed with care. The findings of this study will present valuable information for future decision-making for various stakeholders, policymakers, clinicians and patients alike.

What does the study involve?

The study will involve the use of a semi-structured interview format, which will last approximately 30-60 minutes. You will be provided with a list of the questions ahead of time, so that you may prepare for the interview. The questions are aimed at gathering what you perceive to be the benefits and/or risks associated with ‘self-testing’ and patient care. A short questionnaire with demographic questions will also be asked; answering these questions is also voluntary.

Potential Benefits and/or Risks

There are no personal benefits for participating in the study. Your voluntary participation in the study however, will add value to research in healthcare, particularly pertaining to the field of Point of Care and Community Health. The research may conjure any number of emotions in you, the participant, while you are describing your experiences with Point of Care Testing. If you should feel any feelings of discomfort during the interview process, it is your right to choose not to answer any of the questions, withdraw from the study, or temporarily pause the interview process, with no consequences.

Storage of Data

Data collected from the study will be stored in a secure manner using encrypted files housed on the UOITnet server within the electronic application 'Google Apps for Education'. Data housed within Google Apps for Education is encrypted. This ensures that information which is stored on the server is secure, even while it is in transit. This also prevents unauthorised access, loss, or corruption to the data. Only the principal investigator will have access to such data. Once the study has been completed, all data will be destroyed and removed from the UOITnet server; no electronic or hard copies of the data will be kept.

Confidentiality

All data gathered during the study will be held in the strictest of confidence. You will never be personally identified as being a participant in the study; each participant will be assigned with a pseudonym and their real identity will never be divulged. Interview data will be collected on an audio-recording device. Once all of the verbal and written data collected has been transcribed, the original audio recordings will be destroyed. The data will be considered anonymized after it has been de-identified and stripped of all identifiers. To ensure participant confidentiality, this code will not be shared with anyone. Once the interviews and their meaning have been confirmed by the participant, all information will be irrevocably stripped of direct identifiers, and no code will be kept to allow for future re-linkage. This removes the risk of any future re-identification of participants, essentially anonymizing the data.

Participation & Withdrawal

Participation in the study is completely voluntary. If you choose to withdraw from the study, there will be no consequences to you for withdrawing, and all data collected from your participation in this study will be destroyed. Of note however, if you choose to withdraw after the data collection and analysis phase of the study has already been completed, your data will already be incorporated into aggregated data form. At this point, your data will have all identifiers removed, but will no longer be able to be destroyed.

Compensation

There will be no financial compensation for participation in this study.

Dissemination of Results

An electronic copy of the thesis will be accessible online, once completed. This information will be communicated when available. In addition, findings from this study may be published in academic journals or presented at research conferences.



RESEARCH ETHICS BOARD
OFFICE OF RESEARCH SERVICES

Consent

If you choose to participate in this study, please read and sign the declaration below.

I have fully read the letter of consent and understand the study being described. As a research participant, I have had an opportunity to ask questions pertaining to the study and my questions have been answered. I understand that I may ask more questions at any time. I understand that at any point during the research process, I may withdraw from the study with no consequences. I hereby voluntarily consent to participate in the research study, and a copy of this Consent Form has been given to me for my records.

Name: _____

Date: _____

Signature: _____

H. Appendix H - Thank You Letter

Date

Name

Address/email address

Dear _____:

I would like to say thank you for taking the time to participate in my research study entitled "*Patient and Physician Views on Self-Testing*" with the University of Ontario Institute of Technology (UOIT), Faculty of Health Sciences.

As you are aware, the purpose of this study was to examine what motivates or drives individuals to participate in point of care laboratory testing within home care environments, a setting which is not formally monitored by any external regulatory bodies. The results of this study represents an opportunity to examine the relationship between patient autonomy and options for self testing, as well as uncovering gaps in safety processes that assure quality testing at the point of care. The findings of this study may have implications for various stakeholders, policymakers, clinicians and patients alike. Upon completion, the findings of this study may be accessed electronically from the National Library Archives of Canada.

If you know of someone who may be interested in participating in this study, please do not hesitate to get in touch with me with their contact details. Thank you again for your time and assistance in this research endeavour.

Sincerely,

Sana Iqbal, BHSc, MLT
MHSc Candidate
University of Ontario Institute of Technology
2000 Simcoe Street North
Oshawa, ON L1H 7K4
Email: sana.iqbal@uoit.net

I. Appendix I - Physician Survey of Demographic Information



Survey of Demographic Information for **Physicians**

1) Age:

- 18-25 26-30 31-35 36-40 41-45 46-50 51-55
- 56-60 61-65 66-70 71-75 76-80 81-85 85-90
- 90+ Prefer not to answer

2) Gender:

- Male Female Other-Please specify: _____ Prefer not to answer

3) How many years have you been a practicing physician?

- 0-5 6-10 11-15 16-20 21-25 26-30 31-35
- 36-40 40+ Prefer not to answer

J. Appendix J - Physician Interview Guide

RESEARCH ETHICS BOARD
OFFICE OF RESEARCH SERVICES

Physician Views of Self Testing: Interview Guide**Introductory Question**

- 1) Statement: With an improvement in technology and better appreciation of the diagnostic tools that laboratories can offer, self-testing has become more mainstream and largely accessible to the general public over the past decade.

As a physician, can you talk to me about your thoughts on the availability of self-testing to the general public?

Physician Views of Self-Testing:

- 2) Do you believe that self-testing is important to patients? Why?
- 3) Scenario: A patient has participated in self-testing and reports to you with a test result. How confident are you that the testing was performed properly, and thus they are reporting to you with an accurate result?
- 4) Can you share with me some of your thoughts about patients interpreting lab test results, considering they don't have a background in medicine?
- 5) As a healthcare provider, what are your thoughts on patients performing self-testing (self-initiated) vs physician prescribed laboratory testing?
- 6) A wide variety of diagnostic self-tests are becoming more mainstream and largely accessible to the general public. As a healthcare provider would you ever encourage or discourage a patient to participate in self-testing? Why?
- 7) As a healthcare provider, what are your immediate thoughts after a patient has told you that they engaged in self-testing, and subsequently shares the results of the test with you?

Impact of Self-Testing to Healthcare:

- 8) Can you talk to me about how patient self-testing impacts your role as a physician?
- 9) Discuss Statement: According to the Public Health Agency of Canada (2010), the economic burden of healthcare in Canada continues to grow. What still remains to be examined is the impact that the decentralization of laboratory testing will have on the economic burden of illness and healthcare in Canada.
 - In your role as a physician, what are your thoughts on self-testing as a healthcare intervention for health promotion and illness prevention behaviours, as such behaviours may save the healthcare system millions of dollars in the future...
- 10) Do you believe that self testing can improve patient care? Why or why not? Is access to more self tests a good thing?
- 11) How does patient self-testing affect your relationship with your patient?
- 12) Is there anything else you would like to share with me?

K. Appendix K - Patient Survey of Demographic Information

**RESEARCH ETHICS BOARD
OFFICE OF RESEARCH SERVICES**

Survey of Demographic Information for Patients**1) Age:**

- 18-25 26-30 31-35 36-40 41-45 46-50 51-55
 56-60 61-65 66-70 71-75 76-80 81-85 85-90
 90+ Prefer not to answer

2) Gender:

- Male Female Other-Please specify: _____ Prefer not to answer

3) For how many years have you been performing self-testing? (May include any type of self testing, not inclusive to glucometer usage)

- 0-5 6-10 11-15 16-20 21-25 26-30 31-35
 36-40 40+ Prefer not to answer

4) Please specify your total income level in the year 2016:

- \$5000 and over \$10000 and over \$15000 and over \$20000 and over
 \$25000 and over \$35000 and over \$50000 and over \$75000 and over
 \$100000 and over \$150000 and over Prefer not to answer

5) Please specify your highest level of completed education:

- Prefer not to answer
 No certificate, diploma or degree
 High school diploma or equivalent
 Postsecondary qualification
 → (includes: Trades Certificate, Registered Apprenticeship Certificate or Trades Certificate or Diploma other than Registered Apprenticeship Certificate)
 College Diploma
 University certificate below bachelor level
 Bachelor's Degree
 University certificate above bachelor level
 Medical degree
 Master's degree
 Earned doctorate



**RESEARCH ETHICS BOARD
OFFICE OF RESEARCH SERVICES**

6) Please select the employment status that best fits your current employment (or past employment if you are not currently working):

- Currently not employed Sick Leave Other-Please Specify: _____
- Maternity Leave Retired Prefer not to answer

7) Please select the employment industry that best fits your current employment (or past employment if you are not currently working):

- Prefer not to answer

Goods-producing sector:

- Agriculture Forestry, fishing, mining, quarrying, oil and gas
- Construction Manufacturing Utilities

Services-producing sector:

- Wholesale and retail trade Transportation and warehousing Educational services
- Professional, scientific and technical services Accommodation and food services
- Business, building and other support services Health care and social assistance
- Finance, insurance, real estate, rental and leasing Information, culture and recreation
- Other services (except public administration) Public administration

L. Appendix L - Patient Interview Guide

RESEARCH ETHICS BOARD
OFFICE OF RESEARCH SERVICES

Patient Views of Self Testing: Interview Guide**Introductory Questions**

- 1) When did you first become aware that you had diabetes?
- 2) Can you tell me what you know about diabetes?
- 3) What is your experience of living with diabetes?

Glucometer and diabetes specific questions

- 4) Can you tell me about your experience of self-testing?

Probing questions:

- a. *Can you tell me more about why or why not being able to self-test is important to you?*
 - b. *How frequently do you self-test?*
 - c. *Do you feel there is value in being able to test your glucose level yourself?*
- 5) How does self-testing impact the management of your diabetes? How does it impact your overall health and well being?
 - 6) Can you tell me about the training you received to perform self-testing on your glucose meter?
 - 7) How would you describe your confidence level in performing the test?
 - 8) Tell me about your confidence level in the glucose meter you are using to perform the testing...
 - a. *Probing Questions: How do you react to the result that is produced after you've completed your testing?*
 - i. *Do you try and correlate the number given by the glucose meter with your symptoms? Or conversely, do you decide to self-test only when you feel symptomatic of your diabetes?*

General questions about self-testing

- 9) Can you tell me about some of the challenges or benefits you've experienced with performing self-testing?
- 10) Do you feel there is value in being able to perform laboratory testing on your own, rather than having to go through your physician?
- a. Probing Questions: Why would you want to perform a self test?*
- 11) How frequently would you perform other self tests if they were available to you?
- 12) Can you talk to me about what emotions you might associate with being able to perform a laboratory test on your own? How does participating in self-testing make you feel?
- a. Probing Statement: For example, a home pregnancy test for someone wishing to get pregnant could create emotions of joy upon learning that the test is positive, or conversely, feelings of unhappiness if the test result is negative.*
- 13) Do you follow up with your physician after completing any type of self testing?
- a. Probing Questions: Is it important to follow-up with a physician with your self test results? Why or why not? Does it depend on the nature of the test?*
- 14) Concerning the cost of performing self-tests (glucose meter or any other self test): Are you paying out of pocket to perform your self test?
- 15) How would the cost to own, maintain and perform a self test affect your decision to actually perform the test?
- 16) Can you talk to me about the process you go through when you are trying to interpret your test results? Walk me through your thought process when you obtain your self-test results...
- a. Probing Questions: What information and/or resources do you have available to you to interpret test results? What is your level of confidence in the information provided by that resource?*
- 17) Do you believe that self-testing can improve your own healthcare? Why or why not?
- a. Probing Statement: Could you talk to me about your thoughts on whether access to more self tests could be a positive/negative thing?*



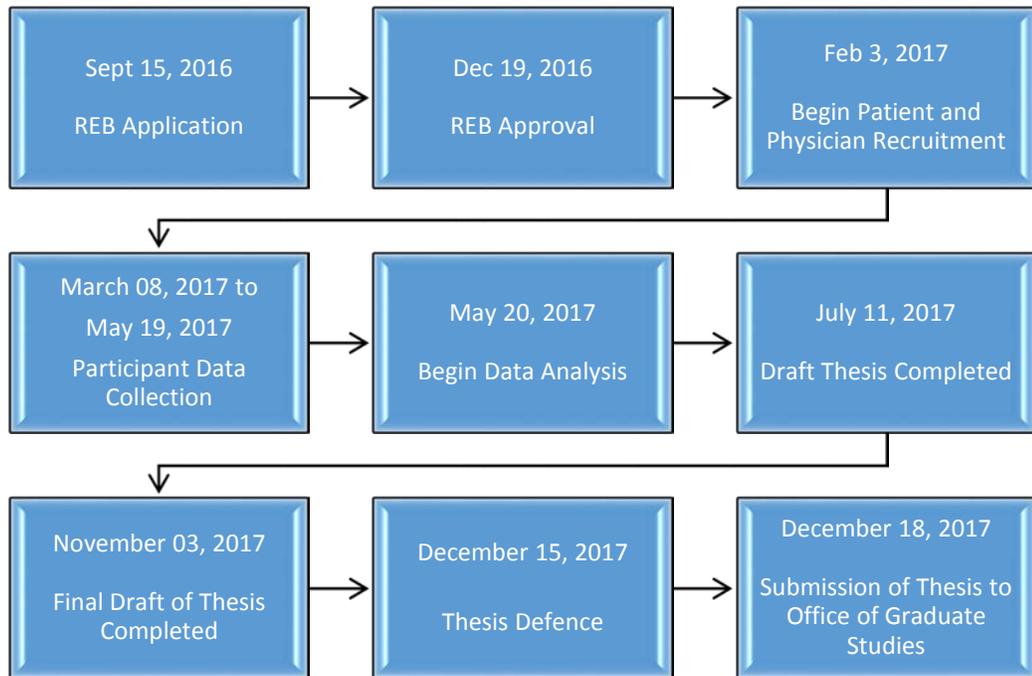
RESEARCH ETHICS BOARD
OFFICE OF RESEARCH SERVICES

18) How does self testing affect your relationship with your physician?

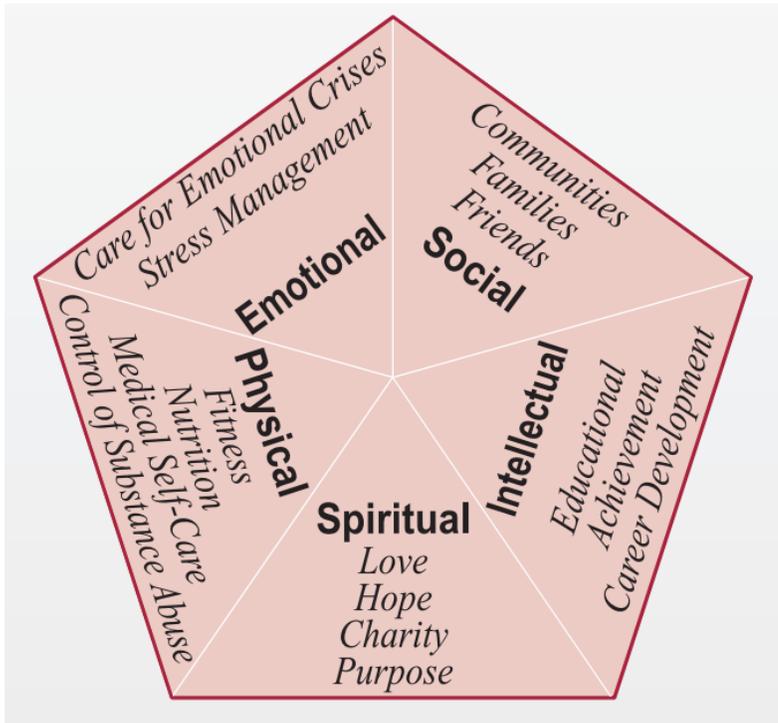
a. *Probing Questions: How does self-testing help or hinder your relationship with your physician? Or is your relationship unchanged?*

19) Is there anything else you would like to share with me?

M. Appendix M - Research Timeline

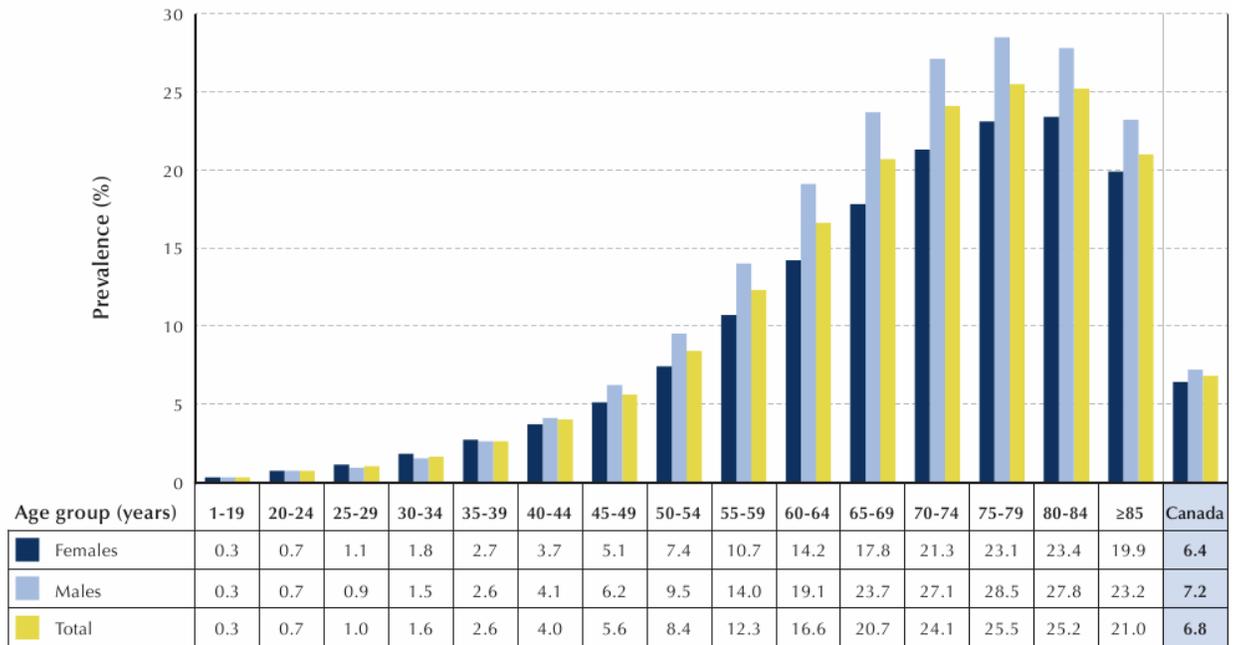


N. Appendix N - Health Promotion Matrix

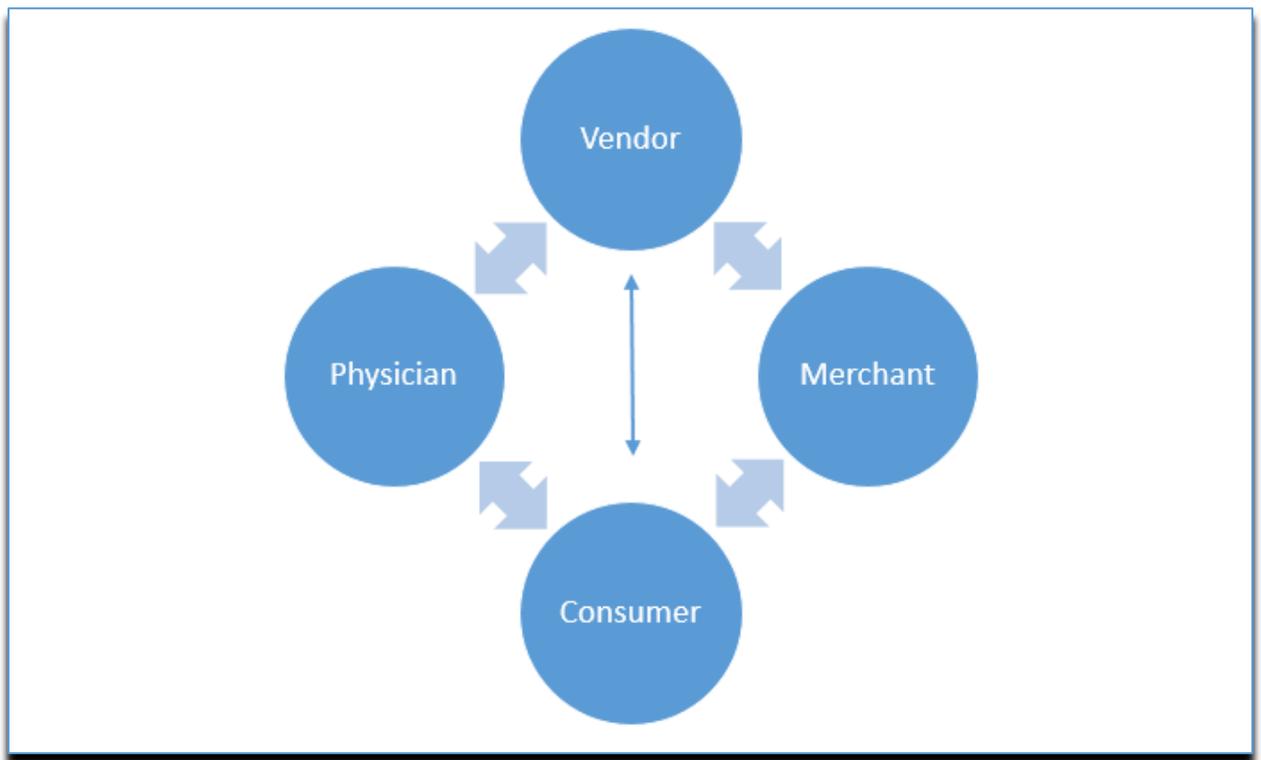


Source: O'Donnell, M. P. (2009). Definition of Health Promotion 2.0: Embracing Passion, Enhancing Motivation, Recognizing Dynamic Balance, and Creating Opportunities. *American Journal of Health Promotion*, 24(1), iv-iv. doi: 10.4278/ajhp.24.1.iv

O. Appendix O - Prevalence of diagnosed diabetes among individuals aged one year and older, by age group and sex, Canada, 2008/09



Source: Diabetes in Canada. *Public Health Agency of Canada*. (2011). Retrieved from <http://www.phac-aspc.gc.ca/cd-mc/publications/diabetes-diabete/facts-figures-faits-chiffres-2011/chap1-eng.php#DIA>

P. Appendix P - Chain of Accountability

Source: Iqbal, S. (2017). Patient and Physician Views of Self-Testing

Q. Appendix Q – ISO and CSA Standards

Organization	Relevant Laboratory Standard	Description (From Source)
<p>International Organization for Standardization (ISO)</p> <p>Full-text standards are available by purchase only</p>	<p>ISO 15189:2012 — <i>Medical laboratories -- Requirements for quality and competence</i></p> <p>www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=56115</p>	<p>ISO 15189:2012 specifies requirements for quality and competence in medical laboratories.</p> <p>ISO 15189:2012 can be used by medical laboratories in developing their quality management systems and assessing their own competence. It can also be used for confirming or recognizing the competence of medical laboratories by laboratory customers, regulating authorities, and accreditation bodies.</p>
	<p>ISO 22870:2006 — <i>Point of care testing (POCT) -- Requirements for quality and competence</i></p> <p>www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=35173</p> <p>This standard is applied in conjunction with ISO 15189:2007 (<i>Medical Laboratories -- Requirements for quality and competence</i>)</p> <p>www.iso.org/iso/home/store/catalogue_ics/catalogue_detail_ics.htm?csnumber=56115</p>	<p>ISO 22870:2006 gives specific requirements applicable to point of care testing and is intended to be used in conjunction with ISO 15189. The requirements of this International Standard apply when POCT is carried out in hospital, clinic and by a health care organization providing ambulatory care. This International Standard can be applied to transcutaneous measurements, the analysis of expired air, and in vivo monitoring of physiological parameters.</p> <p>Patient self-testing in a home or community setting is excluded,</p>

Organization	Relevant Laboratory Standard	Description (From Source)
		<p>but elements of this International Standard can be applicable.</p>
	<p>ISO 15197:2013 — <i>In vitro diagnostic test systems -- Requirements for <u>blood-glucose</u> monitoring systems for self-testing in managing <u>diabetes mellitus</u></i></p> <p>www.iso.org/iso/home/store/catalogue_ics/catalogue_detail_ics.htm?csnumber=54976</p>	<p>ISO 15197:2013 specifies requirements for in vitro <u>glucose</u> monitoring systems that measure <u>glucose</u> concentrations in <u>capillary blood</u> samples, for specific design verification procedures, and for the validation of performance by the intended users. These systems are intended for self-measurement by lay persons for management of <u>diabetes mellitus</u>.</p> <p>ISO 15197:2013 is applicable to manufacturers of such systems and those other organizations (e.g. regulatory authorities and conformity assessment bodies) having the responsibility for assessing the performance of these systems.</p>
	<p>ISO 17593:2007 — <i>Clinical laboratory testing and in vitro medical devices -- Requirements for in vitro monitoring systems for self-testing of <u>oral</u> anticoagulant <u>therapy</u></i></p> <p>www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=36872</p>	<p>ISO 17593:2007 specifies requirements for in vitro measuring systems for self-monitoring of <u>vitamin K antagonist therapy</u>, including performance, quality assurance, and user training and procedures for the verification and validation of performance by the intended users under actual and simulated conditions of use. ISO 17593:2007 pertains solely to prothrombin time-measuring systems used by individuals for monitoring their own <u>vitamin K antagonist therapy</u>, and which report results as international</p>

Organization	Relevant Laboratory Standard	Description (From Source)
		<p>normalized ratios (INR). ISO 17593:2007 is applicable to manufacturers of such systems and those other organizations (e.g., regulatory authorities and conformity assessment bodies) having the responsibility for assessing the performance of these systems.</p>
	<p>ISO/TS 22367:2008 — <i>Medical laboratories -- Reduction of error through risk management and continual improvement</i></p> <p>www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=40918</p>	<p>ISO/TS 22367:2008 characterizes the application of ISO 15189 as a system for reducing laboratory error and improving patient safety by applying the principles of risk management, with reference to examination aspects — especially to pre- and post-examination aspects — of the cycle of laboratory medical care. ISO/TS 22367:2008 proposes a methodology for finding and characterizing medical laboratory errors that would be avoided with the application of ISO 15189.</p>
<p>Canadian Standards Association (CSA)</p> <p>Full-text standards are available by purchase only</p>	<p>CAN/CSA-Z22870-07 (R2013) - <i>Point of Care Testing (POCT) - Requirements for Quality and Competence. (Adopted ISO 22870:2006, first edition, 2006-02-01, with Canadian deviations)</i></p> <p>http://shop.csa.ca/en/canada/medical-laboratory-systems/canca-z22870-07/inv/27027682007</p>	<p>CAN/CSA-Z22870-07 gives specific requirements applicable to point-of-care testing and is intended to be used in conjunction with ISO 15189. The requirements of this International Standard apply when POCT is carried out in hospital, clinic and by a health care organization providing ambulatory care. This International Standard can be applied to transcutaneous measurements, the analysis of expired air, and in vivo</p>

Organization	Relevant Laboratory Standard	Description (From Source)
		<p>monitoring of physiological parameters.</p> <p>Patient self-testing in a home or community setting is excluded, but elements of this International Standard can be applicable.</p>
	<p>CAN/CSA-Z902-10 - <u>Blood and blood components</u> http://shop.csa.ca/en/canada/blood-and-blood-components/canca-z902-10/invt/27020812010</p>	<p>CAN/CSA-Z902-10 is intended to ensure that the critical elements and methods of <u>blood</u> safety, efficacy, and quality are incorporated into facility procedures.</p>

Source: Canadian Agency for Drugs and Technologies in Health (CADTH). (2014). Point-of-Care Testing of International Normalized Ratio for Patients on Oral Anticoagulant Therapy: Systematic Review and Economic Analysis. *CADTH Optimal Use Report, 13(1b)*. Ottawa: The Agency. Retrieved from: http://www.cadth.ca/media/pdf/OP0515_POC%20INR_Science_Report.pdf

R. Appendix R - National and international requirements for quality management of POCT

Jurisdiction	Assessment & selection of appropriate device/s for specified clinical task & setting	Training & competency of operators (& ongoing skill maintenance)	Patient/sample ID & secure recording of results	Quality Control (QC) of the device (including records & corrective actions)	Assessment (EQA) of testing regime (including operator and comparative assessment)
Ontario Ministry of Health (for hospitals & long-term-care homes). Requirements based on ISO 22870.	◆ Mandatory Determine 'fitness for purpose', clinical need, fiscal justification and resource requirements. Performance goals should be the same as a licensed laboratory.	◆ Mandatory Training, certification and recertification of POCT operators. Ensure that only certified operators perform POCT.	◆ Mandatory Definition, documentation and implementation of processes & necessary procedures. Ensure that POCT results are recorded in the patient record in appropriate detail & that the person performing the test is known.	◆ Mandatory Establish procedures which identify non-conformities. QC as recommended by manufacturer with regular review by experienced person. Frequency determined by device used & test performed.	◆ Mandatory Participation in an EQA for comparative assessment & peer review or regular comparison of results with a licensed laboratory. Frequency determined by EQA provider for the particular test.
Ontario, INR POCT (physicians & patients)	◆ Guideline Device must be thoroughly evaluated prior to clinical implementation and provide results comparable to an established laboratory method.	◆ Guideline / Policy Operators must receive adequate training of key competencies with an annual review.	◆ Guideline Unique patient identifiers associated with each result, patient record to include name, result, intended INR range, device & test strip information.	◆ Guideline QC external from POCT manufacturer is preferred. Recommendations regarding when to perform QC given.	◆ Guideline EQA, minimum of twice per year (patients & doctors). Operators with >10 patients per day should participate in a formal EQA program.

Source: Farrance, I. (2012). Review: Policies, procedures and guidelines for point-of-care testing. Australasian Association of Clinical Biochemists. Retrieved from <https://www.aacb.asn.au/documents/item/635>

S. Appendix S - Demographic Description of Patient ParticipantsSurvey of Demographic Information for Patients**1) Age:**

- 18-25 26-30 31-35 36-40 41-45 46-50 51-55
 56-60 61-65 66-70 71-75 76-80 81-85 85-90
 90+ Prefer not to answer

2) Gender:

- Male Female Other-Please specify: _____ Prefer not to answer

3) For how many years have you been performing self-testing? (May include any type of self testing, not inclusive to glucometer usage)

- 0-5 6-10 11-15 16-20 21-25 26-30 31-35
 36-40 40+ Prefer not to answer

4) Please specify your total income level in the year 2016:

- \$5000 and over \$10000 and over \$15000 and over \$20000 and over
 \$25000 and over \$35000 and over \$50000 and over \$75000 and over
 \$100000 and over \$150000 and over Prefer not to answer

5) Please specify your highest level of completed education:

- Prefer not to answer No certificate, diploma or degree High school diploma or equivalent
 Postsecondary qualification (includes: Trades Certificate, Registered Apprenticeship Certificate or Trades Certificate or Diploma other than Registered Apprenticeship Certificate)
 College Diploma University certificate below bachelor level Bachelor's Degree
 University certificate above bachelor level Medical degree Master's degree Earned doctorate

6) Please select the employment status that best fits your current employment (or past employment if you are not currently working):

- Currently not employed Sick Leave Other-Please Specify: _____
 Maternity Leave Retired Prefer not to answer

7) Please select the employment industry that best fits your current employment (or past employment if you are not currently working):

- Prefer not to answer

Goods-producing sector:

- Agriculture Forestry, fishing, mining, quarrying, oil and gas
 Construction Manufacturing Utilities

Services-producing sector:

- Wholesale and retail trade Transportation and warehousing Educational services
 Professional, scientific and technical services Accommodation and food services
 Business, building and other support services Health care and social assistance
 Finance, insurance, real estate, rental and leasing Information, culture and recreation
 Other services (except public administration) Public administration

Demographic Description of Patient Participants							
	Age	Gender	Number of years self testing	2016 income	Highest level of education	Employment status	Employment industry
PT1	61-65	Male	21-25	35K +	High school diploma or equivalent	Retired	Manufacturing
PT3	71-75	Female	6-10		College diploma	Retired	Educational services
PT4	61-65	Male	11-15	35K +	No certificate, diploma or degree	Retired	Manufacturing / transportation and warehousing
PT5	85-90	Male	0-5		No certificate, diploma or degree - gr.10	Retired	Information, culture and recreation
PT6	56-60	Female	11-15		College diploma	Retired	Business, building and other support services
PT8	66-70	Male	0-5	35K +		Retired	Manufacturing

T. Appendix T - Demographic Description of Physician Participants

Survey of Demographic Information for Physicians

1) Age:

- 18-25 26-30 31-35 36-40 41-45 46-50 51-55
 56-60 61-65 66-70 71-75 76-80 81-85 85-90
 90+ Prefer not to answer

2) Gender:

- Male Female Other-Please specify: _____ Prefer not to answer

3) How many years have you been a practicing physician?

- 0-5 6-10 11-15 16-20 21-25 26-30 31-35
 36-40 40+ Prefer not to answer

Demographic Description of Physician Participants			
	AGE	GENDER	YEARS PRACTICING
PY1	51-55	Male	16-20
PY2	46-50	Male	16-20
PY3	26-30	Female	0-5
PY4	51-55	Female	26-30
PY5	51-55	Male	26-30
PY6	31-35	Female	0-5