2-20-2019 1:00 PM

Family Physician's Clinical Inertia in the Management of Hypoglycemia

Caroline V. Martignoni Rebicki
The University of Western Ontario

Supervisor
Ryan, Bridget L.
The University of Western Ontario
Harris, Stewart
The University of Western Ontario

Graduate Program in Family Medicine
A thesis submitted in partial fulfillment of the requirements for the degree in Master of Clinical Science

Abstract

Though the management of diabetes is widely documented in scientific literature, little is published about how hypoglycemia is managed by family physicians. The objective of this study was to create a measurement for family physician clinical inertia in managing hypoglycemia, and to determine family physicians' characteristics associated with clinical inertia. The design was a secondary analysis of the data provided by 162 family physicians from the Canadian InHypo-DM Study. The outcome for this thesis was a score for physician clinical inertia. The methods applied were exploratory factor analysis, bivariate analysis and multiple linear regression. Results showed no statistically significant differences in clinical inertia score for any of the independent variables. This study provides evidence that clinical inertia in management of hypoglycemia is not associated with family physicians' characteristics. Further testing this score will provide more information on aspects of clinical inertia and its role in the management of hypoglycemia.

Keywords

Hypoglycemia Management in Family Physicians, Clinical Inertia in Hypoglycemia Management, Clinical Inertia in Family Physicians, Diabetes in Primary Care, Hypoglycemia, Clinical Inertia, InHypo-DM, Exploratory Factor Analysis.

Co-Authorship Statement

This thesis and the associated secondary analysis were developed, planned and performed by the author. Data for the In-Hypo-DM Study were collected by researchers in Dr. Stewart Harris' (Principal Investigator) team at Western University. The exploratory factor analysis, multiple regression and correlation analysis were completed by the author and reviewed with Drs. Bridget Ryan and Stewart Harris. The thesis was written solely by the author, with editorial advice from Drs. Bridget Ryan and Stewart Harris.

Acknowledgments

I must recognize and thank the wonderful people who have helped to make this thesis possible:

Dr. Stewart Harris for his proficient advice, support and guidance along the way.

Dr. Bridget Ryan for her immense patience, graceful guidance and support during the entire process.

Dr. Paul Tremblay for statistical advice.

My father and mother, Waldir and Beatrix Martignoni, for inspiring me to reach higher grounds.

Most importantly, I wish to thank my husband, Rafael, for his encouragement, patience, and never-ending support, and our children, Thomas, Louise, Samuel, Arthur and Daniel for their love and patience.

Table of Contents

List of Tables

List of Figures

List of Appendices

List of Abbreviations

A1C - Glycated Hemoglobin

AB - Alberta

ACCORD – Action to Control Cardiovascular Risk in Diabetes

ADA – American Diabetes Association

ANOVA – Analysis of Variance

BC – British Columbia

CDA – Canadian Diabetes Association

CDE – Certified Diabetes Educator

CPG – Clinical Practice guidelines

DM – Diabetes Mellitus

DOVES – Diabetes Outcomes in Veterans Study

DPP-4 – Dipeptidyl Peptidase-4

EFA – Exploratory Factor Analysis

FP – Family Physician

GLP-1 - Glucagon-like peptide-1

HCP – Healthcare Professionals

IDF – International Diabetes Federation

InHypo-DM – Understanding the Impact of Hypoglycemia on Diabetes Management: A Survey of Perspectives and Practices

IV – Independent Variable

KMO – Kaiser Meyer Olkin

MB - Manitoba

MLR - Multiple Linear Regression

NB – New Brunswick

NL - Newfoundland

NS – Nova Scotia

ON - Ontario

PAF – Principal Axis Factor

PCP – Primary Care Physicians

PEI – Prince Edward Island

PTM – Professional Targeted Marketing

QU - Quebec

SGLT-2 - Sodium-dependent Glucose Co-Transporter-2

SK - Saskatchewan

SO – Significant Others

SPSS – Statistical Package for the Social Sciences

T1DM – Type 1 Diabetes

T2DM – Type 2 Diabetes

TDF – Theoretical Domain Framework

UKPDS – United Kingdom Prospective Diabetes Study

Preface

"Confucius, Buddha, Jesus and Muhammad would have been bewildered if you told them that in order to understand the human mind and cure its illnesses you must first study statistics."

The Discovery of Ignorance, Sapiens - A Brief History of Humankind

Yuval N. Harari, 2014

"Neither evidence nor clinical judgment alone is sufficient. Evidence without judgment can be applied by a technician. Judgment without evidence can be applied by a friend. But the integration of evidence and judgment is what the healthcare provider does in order to dispense the best clinical care."

Hertzel Gerstein, 2012

Chapter 1

Overview

Medical knowledge advances at a fast pace, however some issues remain a perplexing challenge. Even health problems that are old subjects to medical research and are quite familiar to the medical community, such as diabetes, present intriguing limitations in everyday clinical practice.

This thesis explores the factors that may contribute to the relationship between management of hypoglycemia and physician clinical inertia. The starting point for this study was provided by a recent Canadian nation-wide study on hypoglycemia in diabetes. Data from family physician respondents who participated in that study were analyzed for this study. In this first chapter, a brief overview of the steps taken to explore this relationship is laid out.

Chapter two reviews the literature on: diabetes and its relevance in primary care medicine; hypoglycemia management and recent updates; and clinical inertia. This chapter provides preliminary concepts and establishes the current facts, guidelines and definitions for these topics.

The next section, chapter three, describes the objectives and methodologic approaches of both the original InHypo-DM study and the subsequent secondary analysis conducted for the purpose of addressing the objectives of this thesis. The steps taken in the analysis of the original InHypo-DM study Healthcare Provider data set are explained. The sequence of tests and procedures applied to achieve the study objectives is presented.

The results for the analysis conducted are presented in chapter four.

Chapter five reflects upon the findings of this study as to where they differ from the existing knowledge, where they confirm the current knowledge, and where those findings are novel and add to the existing knowledge of clinical inertia in hypoglycemia management in primary care. Recommendations for future research are presented in this concluding section.

Chapter 2

Diabetes, Hypoglycemia and Clinical Inertia

2.1 Diabetes

Diabetes and its related problems are frequent reasons for patient-physician encounters in primary care worldwide. One of the issues that requires special attention from family physicians is the risk and occurrence of hypoglycemia in their patients with diabetes on insulin and/or secretagogues. The ability to appropriately identify and manage this medication-related adverse event is a central competence of diabetes care. Guidelines provide evidence-based recommendations to the fundamentals of diabetes management, and the exemplar physician is capable of individualizing treatment to best achieve patient`s target and well-being accordingly. Literature on family physician's awareness, actions and attitudes towards hypoglycemia and appropriate treatment and intervention in primary care is substantially limited.

2.1.1 Diabetes Prevalence

"Diabetes is one of the largest health emergencies of the 21st century" concluded the latest report of the International Diabetes Federation (IDF).[1] It is estimated that Diabetes Mellitus (DM) affected 415 million adults ages 20 to 79 in 2015 worldwide and another 318 million persons have impaired glucose intolerance and are at a higher risk of developing type 2 diabetes (T2DM). Diabetes, particularly T2DM, is one of the most common chronic diseases in nearly all countries, and continues to increase in numbers and significance, particularly in developing nations. The Brazilian Health Ministry detected in 2018 that the incidence rate of DM increased by 61.8% in the last 10 years, rising from 5.5% of the population in 2006 to 8.9% in 2016.[2]

Following the global trend, Canada's rates of DM are also rising. It is estimated that an increase of 44% will be observed between 2015 to 2025 in the prevalence of DM among Canadians. Diabetes is the leading cause of blindness, end stage renal disease and non-traumatic amputation in Canadian adults.[3]

Possible reasons for this DM epidemic include economic development and urbanization that lead to rapid cultural and social changes in traditional lifestyles characterized by reduced physical activity, ageing populations, increased urbanization, industrialized diet with increased sugar consumption and low fruit and vegetable intake, and consequently, increased obesity.[1]

Globally, one in every 11 adults (8.8%) has DM and half of these are unaware of it[1]. In high-income countries, approximately 87 to 91% of all people with diabetes are estimated to have T2DM, 7% to 12% are estimated to have type 1 diabetes (T1DM) and 1% to 3% to have other types of DM[1].

2.2 Hypoglycemia

2.2.1 Definition

Hypoglycemia is defined biochemically as blood glucose concentration less than 4.0 mmol/L, or 70mg/dL.[4] The Canadian Diabetes Association (CDA), now known as Diabetes Canada, recently published a more sophisticated definition in their Clinical Practice Guidelines (CPG),[5] where hypoglycemia is defined by three components:

- Development of autonomic or neuroglycopenic symptoms (Table 2-a);
- Low plasma glucose level (<4.0 mmol/L for patients treated with insulin or insulin secretagogue); and
- Symptoms responding to the administration of carbohydrate

Table 2-a: Symptoms of Hypoglycemia

Neurogenic (autonomic)	Neuroglycopenic
Trembling	Difficulty concentrating
Palpitations	Confusion
Sweating	Weakness
Anxiety	Drowsiness
Hunger	Vision changes
Nausea	Difficulty speaking
Tingling	Headache Dizziness

Ref.: Yale, JF et al. Diabetes Canada. 2018 Clinical Practice Guidelines, Hypoglycemia. Can J Diabetes. 2018. Cryer, PE et al. Insulin Therapy and Hypoglycemia in Type 2 Diabetes Mellitus. Insulin 2007

Hypoglycemia is clinically classified by the severity of symptoms in the hypoglycemic event and by the individual's ability to self-treat. When blood glucose levels drop below 3.3 mmol/L, most patients experience unpleasant neuroglycopenic or autonomic progressive symptoms (Table 2-a). The first is the result of brain deprivation of glucose, leading to confusion, sensation of warmth, weakness or fatigue, severe cognitive failure, seizure and ultimately, if not reversed, coma. The latter are the result of the perception of physiologic changes caused by the autonomic nervous system's response to hypoglycemia, manifested as tremulousness, palpitations, anxiety, sweating, hunger, paresthesia. This state of physiological discomfort forces the individual to seek an action that normally prevents or rapidly corrects clinical hypoglycemia.[6] Most episodes of lower blood glucose are associated with excessive use of medication, dietary mistakes, and physical exercise[7]; decreased glucose absorption in gastroenteritis and vomiting; or decreased glucose production in liver disease and alcohol intoxication.[8]

In mild to moderate events, the patient can manage hypoglycemia him/her self by identifying the characteristic symptoms and ingesting enough carbohydrates to elevate blood glucose. Severe hypoglycemia happens when the patient is unable to identify the characteristic symptoms and/or is incapable of resolving the problem, needing assistance from others to recover.[9] The severity of hypoglycemia is defined by clinical manifestations and consequences listed in Table 2-b.[5]

Table 2-b: Severity of Hypoglycemia

Mild: Autonomic symptoms are present. The individual is able to self-treat.
Moderate: Autonomic and neuroglycopenic symptoms are present. The individual is able to self-treat.
Severe: Unconsciousness may occur. Plasma glucose is typically <2.8 mmol/L. The Individual requires assistance of another person to treat.

Ref.: Yale, JF et al. Diabetes Canada. 2018 Clinical Practice Guidelines, Hypoglycemia. Can J Diabetes. 2018.

The American Diabetes Association (ADA) recently revised their definitions for hypoglycemia[10].

Table 2-c presents elements that characterize clinical hypoglycemia.

Table 2-c: Classification of Hypoglycemia

Level	Glycemic Criteria	Description
Glucose alert value (level 1)	70 mg/dL (3.9 mmol/L)	Sufficiently low for treatment with fast-acting carbohydrate and dose adjustment of glucose-lowering therapy
Clinically significant hypoglycemia (level 2)	54 mg/dL (3.0 mmol/L)	Sufficiently low to indicate serious, clinically important hypoglycemia
Severe hypoglycemia (level 3)	No specific glucose threshold	Hypoglycemia associated with severe cognitive impairment requiring external assistance for recovery

Ref.: Diabetes Care - Standards of Care, Hypoglycemia, 2019 Suppl.1 S67 American Diabetes Association

2.2.2 Relevance

Hypoglycemia is commonly associated with people with T1DM, but is also seen in T2DM patients managed by insulin and/or, sulfonylureas.[5] Ratzki-Leewing et al[11] analyzed the results of the largest real-world investigation of hypoglycemia epidemiology in Canada and affirmed that the incidence of hypoglycemia among adults with DM taking insulin and/or insulin secretagogues is higher than previously thought. In their paper, the authors stated that, while 83.0% of people with T1DM reported having experienced at least one hypoglycemic event with an overall annualized hypoglycemia rate of 58.1 events per person-year, 62.0% of T2DM individuals experienced at least one hypoglycemia event at a rate of 30.4 events per person-year.

Hypoglycemia is less common in the early stages of T2DM because the glucose plasma counter-regulatory mechanisms tend to be preserved in these patients. However, if patient management at this stage of diabetes includes oral hypoglycemic agents, such as secretagogues, or those on an insulin regimen, hypoglycemia can occur and therefore can be an important complicating factor in efforts to achieve tighter glycemic control.

The United Kingdom Prospective Diabetes Study (UKPDS)[12], was a landmark study in the treatment of T2DM that has influenced standards of care and treatment guidelines throughout the world. That study found that severe hypoglycemia occurred in 11% of subjects on aggressive therapy over a 6-year follow-up period. The Diabetes Outcomes in Veterans Study (DOVES)[13], was another important study which identified clinical and behavioral factors associated with glucose variability in T2DM. It reported 5.5% of subjects experienced severe hypoglycemia over the 8-week observation period[7]. One author has boldly stated that hypoglycemic events are nearly inevitable in patients if tight glycemic control is to be achieved.[15]

Life-threatening, severe hypoglycemia in T2DM patients was believed to be a relatively infrequent event[7], but a recent national epidemiologic study in Canada has challenged that idea. Ratzki-Leewing et al found that, in the InHypo-DM questionnaire answered by patients with diabetes reporting any type of hypoglycemic event, "*the incidence rate of severe hypoglycemia was approximately 37% higher in people with T2DM*" than that found among those respondents who were T1DM.[11 page 6]

2.2.3 Risk Factors for Hypoglycemia

The odds of experiencing hypoglycemia in people with T2DM have been measured by Reichert et al[14] and the authors found that they were highest among younger adults, those with poor glycemic control, those who took multiple daily injections of insulin, and those who lead busy lives (working full time and/or shift work).

Type 2 DM patients are at a higher risk of experiencing severe hypoglycemia when the following factors are present: advancing age, severe cognitive impairment, poor health literacy, food insecurity, hypoglycemia unawareness, prolonged duration of insulin therapy, renal impairment and neuropathy.[4] Another large landmark study for T2DM patients with

elevated risk for cardiovascular disease, the Action to Control Cardiovascular Risk in Diabetes trial (ACCORD)[16], identified additional risk factors for that population including: female gender, African-American race and less than high-school education.[17]

A compilation of major risk factors cited in Diabetes Canada's Clinical Practice Guideline (CPG) for severe hypoglycemia is presented in Table 2-d.

Table 2-d: Risk factors for Severe Hypoglycemia

Diabetic Patients presenting with these conditions are at risk for severe hypoglycemic events
Prior episode of severe hypoglycemia
Current low glycated hemoglobin (<6.0%)
Hypoglycemia unawareness
Long duration of insulin therapy
Autonomic neuropathy
Low economic status
Food insecurity
Low health literacy
Cognitive impairment
Adolescence
Long duration of Insulin therapy
Presence of complications (renal impairment or neuropathy)
Persons unable to detect and/or treat mild hypoglycemia on their own

Ref.: Yale, JF et al. Diabetes Canada. 2018 Clinical Practice Guidelines, Hypoglycemia. Can J Diabetes. 2018.

In the early stages of T2DM, when physiologic defenses against hypoglycemia are intact, the mechanisms for preventing the lowering of blood glucose (down regulation of insulin secretion in β-cell and increase in α-cell glucagon or epinephrine secretion) support euglycemic levels. Over the course of the illness, with progressive beta cell decline hyperglycemia often becomes an issue that patients struggle with. Impairment of sympathetic neural response occurs in consequence of sustained hyperglycemia. At this stage many individuals develop a condition where there is an impairment of the ability to perceive the warning symptoms of hypoglycemia, or even the loss of sympathetic neural response. This impairment of hypoglycemia awareness is mediated by an "*adaptation of the hormonal counter-regulatory response towards low blood glucose levels*"[15 page 229] and it

consists of a reduced ability to perceive the "warning symptoms" due to a lower threshold of these symptoms. A destructive cycle of hypoglycemia induced by previous hypoglycemia is a critical predictive risk factor for severe hypoglycemic episodes[15]. This poses a challenge for aggressive treatment regimens that put patients at risk for hypoglycaemia, for example patients on insulin and/or secretagogues.

In the ADA's recently reviewed guidelines, insulin-treated patients with hypoglycemia unawareness or an episode of clinically significant hypoglycemia (< 3.0 mmol/L) should be advised to raise their glycemic targets to strictly avoid hypoglycemia for at least several weeks to partially reverse hypoglycemia unawareness and reduce risk of future episodes.[18]

According to Heller, strategies to diminish the risk of hypoglycemia from the provider's stand point should be guided by three principles[19]:

- Individual targets adjusted for patient's vulnerability to hypoglycemia;
- Structured education and training for people with diabetes; and
- Team care that is alert to potential problems with hypoglycemia.

2.2.4 Glycemic Goals

Evidence-based guidelines compels the primary care physicians (PCP) to set customized targets for each patient's blood glucose levels after considering several factors. Intensive glucose control, lowering glycated hemoglobin (A1C) values to ≤7% in both T1DM and T2DM, provides strong benefits for prevention of microvascular complications and, if achieved early in the disease, likely provides a significant macrovascular benefit, especially as part of a multifactorial treatment approach. More intensive glucose control, A1C ≤6.5%, may be sought in patients with a shorter duration of diabetes, no evidence of significant cardiovascular disease and longer life expectancy, as long as this does not result in a significant increase in hypoglycemic events. An A1C target ≤8.5% may be more appropriate in T1DM and T2DM with limited life expectancy, higher level of functional dependency, a history of severe hypoglycemia, advanced comorbidities, and a failure to achieve established glucose targets despite treatment intensification.[20]

According to guidelines, if lifestyle and dietary modifications fail to achieve target A1C after two to three months of adjustments, it is recommended that antihyperglycemic pharmacotherapy should be initiated. Unless contraindicated or the patient is intolerant, metformin should be the initial agent of choice. Additional antihyperglycemic agents should be selected on the basis of clinically relevant issues and always tailored to each patient's individual characteristics and glycemic target, such as: contraindication to drug, glucose lowering effectiveness, risk of hypoglycemia and effect on body weight. Timely adjustments to, and/or additions of other antihyperglycemic agents should be made to reach target A1C within three to six months. In patients with marked hyperglycemia (A1C ≥1.5% above individualized target), antihyperglycemic agents should be initiated along with lifestyle modifications, and consideration should be given to initiating combination therapy with two agents, one of which may be insulin.[21]

2.2.5 Hypoglycemia-inducing pharmacologic agents

Glucose lowering agents used to treat T2DM can contribute to a patient's risk for hypoglycemia, with some agents more likely to produce hypoglycemia than others. Biguanides (e.g. metformin) lower blood glucose by mechanisms other than increasing blood level of insulin, working in a glucose-dependent manner. Metformin, for example, decreases hepatic glucose production and increases insulin sensitivity. This group of agents are considered at low-risk for causing hypoglycemia and unlikely to induce hypoglycemia when used as monotherapy.[8] The Diabetes Canada 2018 CPG recommends metformin as a first-line therapy for individuals without metabolic decompensation. However, if metabolic decompensation is present, insulin is the choice for initial treatment.[3]

Secretagogues, a common choice for second-line therapy, stimulate insulin secretion from pancreatic β-cells in a glucose-independent manner, and thus, are associated with a high-risk of hypoglycemia. Recent studies with practice-changing evidence have proven that in adults with T2DM with clinically significant cardiovascular disease in whom glycemic targets are not met, the second antihyperglycemic agent to be added should be one with demonstrated cardiovascular outcome benefit. Some SGLT-2 inhibitors (i.e. empagliflozin and canagliflozin) have shown such benefits without increasing risk of hypoglycemia.[21] Other antihyperglycemic agents, such as glucagon-like peptide-1 (GLP-1) receptor

agonists, have also shown benefits for T2DM patients with cardiovascular risk factors and unmet A1C targets[21] (i.e. liraglutide).

Insulin is generally considered as the third-line therapy and the group of agents most likely to cause hypoglycemia amid the medications in the high-risk category.[22] A combination of oral antihyperglycemic and insulin often effectively control glucose levels. The choice of insulin and insulin regimen should take into consideration multiple type-specific advantages and disadvantages and patient's needs, preferences and context.

Current evidence from a systematic review and meta-analysis by Edridge et al shows that hypoglycemia is considerably prevalent amongst people with T2DM, particularly for those on secretagogues or insulin.[23]

2.2.6 Treatment of Hypoglycemia

Treatment of hypoglycemia can be easily accessed in most settings. Patient education is essential. Orientation may include discussing with patient a plan of action, recognizing hypoglycemic symptoms and identifying available sources of glucose.

Treatment aims at restoring normal blood glucose quickly and safely, avoiding overcorrection. Diabetes Canada CPG suggests that 15g of glucose (equivalent to 3 teaspoons of table sugar; 1 tablespoon of honey; or ¾ cup of orange juice) is efficient in raising glycemia by 2.1mmol/L within 20 minutes. Glucagon 1mg subcutaneously or intramuscularly produces significant blood glucose elevation (up to 12mmol/L) in 60 minutes. Recent alcohol consumption and advanced hepatic disease may impair correction of blood glucose level.[5]

Clinical strategies and revised practice guidelines that accentuate the need to balance effective glycemic control against the risk of hypoglycemia are emerging regularly.[18] Adding to this, newer and safer antihyperglycemic treatments and pharmacologic combinations are becoming more readily available. However, despite these facts, the current burden of hypoglycemia in the real-world context still exists and has been underestimated, especially concerning severe hypoglycemia in T2DM.[11]

In the introduction of the 2018 Diabetes Canada CPG, the author advises: *"People with diabetes are a diverse and heterogeneous group; therefore, it must be emphasized that treatment decisions need to be individualized. Guidelines are meant to aid in decision making by providing recommendations that are informed by the best available evidence. However, therapeutic decisions are made at the level of the relationship between the healthcare professional and the patient. That relationship, along with the importance of clinical judgement, can never be replaced by guideline recommendations."*[3] The cooperation that derives from a solid, genuine patient-provider relationship is indeed of immense clinical value. Yet, sacrificing medical evidence, in the form of clinical guidelines or expert panels for the sake of individualizing care inattentively is not aligned with the principles of the Patient-Centered Clinical Method[24] and such an attitude must not be mistaken for patient-centeredness.

Recommendations from the 2018 CPG on hypoglycemia are listed in Appendix A.

2.2.7 Hypoglycemia Management in Primary Healthcare

Management of the patient with DM embodies the spirit of primary care medicine. Because of the chronic, progressive, and potentially disabling nature of this illness, PCP should be at the cornerstone of diabetes care. This gate-keeping position allows professionals to screen high-risk patients for diabetes, initiate treatment, improve hyperglycemia, monitor and fine-tune pharmacologic therapies, and detect and manage microvascular and macrovascular complications. While patients with complex insulin regimens, or at risk for severe hypoglycemia, or complications often need to be referred to specialists to assist in management, 90% of patients with diabetes can successfully be managed in a primary care setting.[25]

Diabetes is an increasingly common health condition, currently affecting one in every 11 adults globally.[26] It is estimated that three-quarters of people with diabetes live in low and middle-income countries[1]. Ninety percent of these patients have T2DM[7], and most these individuals are cared for by non-specialist PCP.[19] In Brazil, for example, diabetes is among the five major health problems managed by PCP in community health centers.[27] Yet, this

fact also applies to developed nations such as Canada and the United States, where the bulk of diabetes patients are cared for by PCP.[11, 28, 29]

Diabetes is a chronic and complex clinical condition, perhaps more common and complex in the real-world context PCP face daily than what trial-based settings have been able to show.[30] This idea is supported by the findings of a study conducted by Bachimont in 2006 which identified that PCP were aware of the guidelines, however they found that these guidelines sometimes disconnected from everyday practice.[31]

Heller argues that PCP are less confident/less knowledgeable about the risks of insulin management and hypoglycemia when compared to specialists and thus may not be actively and adequately assessing and managing the risk of hypoglycemia for each patient.[19]

Since most of the care of people with diabetes takes place in the primary care setting, there has been a shift toward delivering diabetes care in the primary care setting using the chronic care model.[32] This model comprises an arrangement of the health system in which the primary care provider is properly trained and well-articulated with specialists and other actors of the healthcare system and community. There is evidence that the chronic care model is an effective and efficient model of care for DM. [32, 33]

Dovey also argues that an essential characteristic of primary care is the customization of care to the individual patients' needs, values, and preferences across a broad spectrum of medical care. That author states about primary care practices: "*Its diversity, scope and variation in structure and infrastructure may offer more opportunity for error than more highly regulated and procedure-oriented hospital-based care*."[34]

Though the management of diabetes and its complications are widely investigated and documented in scientific literature, little is published about how one important component of DM, hypoglycemia, is managed in the primary care setting, and even more scarce is the evidence around the factors that affect physician hypoglycemia management behavior and key PCP knowledge gaps.

2.2.8 The Care Gap

Numerous studies have shown that hypoglycemia is an important clinical concern for T1DM patients and those who are T2DM on insulin and/or secretagogue agent therapy. In general, hypoglycemia presents a barrier to starting and adjusting treatment and a challenge in long-term adherence[35, 36]. Despite the evidence that tight glycemic control reduces morbidity and mortality of DM, a significant percentage of patients do not reach treatment goals. In the United States only 40-60% of T2DM patients reach treatment goals. In 2009, The British National Health System (NHS), reported that two-thirds of T2DM patients achieved the goal of 7.5% glycated hemoglobin (A1C). In Canada, the Diabetes Mellitus Status survey[35] highlighted the persistent treatment gap associated with the treatment of T2DM and the challenges faced by primary care physicians to gain glycemic control in these patients. Some evidence shows that the fear of a new hypoglycemic episode can undermine patient compliance to rigorous treatment goals and lead to poor self-management of the disease.[36, 37, 38, 39, 40]

Proper management should include a comprehensive approach and collaboration between patients, primary care, and specialist care when appropriate.[3] In North America, most of chronic illness care, including diabetes as noted previously, occurs within the primary care setting.[29] In Canada, there is a care gap between the clinical goals outlined in evidence-based guidelines for diabetes management and real-life clinical practice.[28]

In summary, despite the recognition of the importance of identifying and managing hypoglycemia as part of an overall diabetes management strategy, very little is known about the factors that influence family physician's attitudes and behavior in managing hypoglycemia. This study will use newly available survey data from family physicians in Canada to explore this prominent issue.

2.3 Clinical Inertia

2.3.1 Overview

Delays in correcting prescribed treatment in T2DM patients when treatment fails to achieve optimal glycemic control, occurs commonly in primary care settings. A substantial proportion of people remain in poor glycemic control for several years before proper adjustment of targets and pharmacologic treatment is initiated [41]. These delays or inertia on the part of physician to fine-tune treatment in the presence of hypoglycemia is perplexing.

2.3.2 Definition

The term *clinical inertia* was coined by Phillips in 2001.[42] It refers to the situation when there is recognition of the clinical problem (e.g. a history of hypoglycemic episodes), but no initiative to act upon it (e.g. reticence to adjust targets or tardiness to review insulin therapy).[41, 42]. O'Connor et al postulate three classes of factors leading to inertia: those related to the patient, those related to the health system and factors related to the physician. They estimate that these three factors contribute 30%, 20% and 50% respectively to the phenomenon of clinical inertia.[44] Factors related to the patient that are believed to be associated with clinical inertia include denial or misconception about the disease and its seriousness; medication nonadherence due to avoidance of expenses and/or side effects; and resistance to adopting lifestyle adjustments that could lead to better health-related outcomes. Factors of the system include availability of technology that optimizes clinical reasoning and prompts specific clinical decision support; organization and planning/prioritizing office visits according to risk, complications, results of tests; active outreach support; availability of continuous medical education. Operationally, the definition of clinical inertia is quite complex and all of these factors may be in play simultaneously.[44]

True clinical inertia may be considered a case of medical error by omission. Dovey conducted a study to understand the nature of medical errors from the perspectives of family physicians.[34] Family physicians were asked to describe deleterious events which should not have occurred and which made them think: "this should not happen in my practice, and I never want this to happen again". He found that clinical inertia, in a broader

sense, was not mentioned as being part of the "taxonomy" of medical errors[34]. In contrast, two other authors, also researching behavior in diabetes treatment, have clearly referred to physician behavior falling under clinical inertia as "medical errors".[44, 45]

True clinical inertia must be distinguished from *watchful waiting*. This attitude is a carefully thought out decision to withhold action. Gerard Reach, in his book Clinical Inertia[46], argues that *the physician behavior falls under this phenomenon of clinical inertia if, and only if:*

1. *a Guideline (G) exists, explicit or implicit*
2. *the doctor (D) knows the Guideline (G)*
3. *the doctor (D) thinks that this Guideline (G) applies to the patient (P)*
4. *the doctor (D) has the resources to apply the Guideline (G)*
5. *conditions 1–4 have been met, yet the doctor (D) does not follow the Guideline (G) in the case of the patient (P).* [46 Page 10]

Clinical inertia has been recognized as an important barrier contributing to inadequate management of chronic diseases, particularly in the context of those with asymptomatic conditions such as diabetes, hypertension, lipid disorders, where treatment decisions are generally influenced by pondering evidence-based clinical outcomes.[47]

2.3.3 Clinical Inertia in Primary Care

A review of the literature concerning diabetes and clinical inertia reveals some relevant research concerning management of hyperglycemia and its associations with physician inertia in primary care settings. However, literature addressing therapeutic inertia in management of DM related hypoglycemia in primary care, to the extent of this researcher's knowledge, is all but non-existent. Therefore, it is only possible to conceptualize clinical inertia for DM care by examining the literature on clinical inertia in hyperglycemia management.

Research with family practices in Ontario, Canada, found that insulin was underused by PCP in patients with T2DM, even though early addition of insulin has long been an

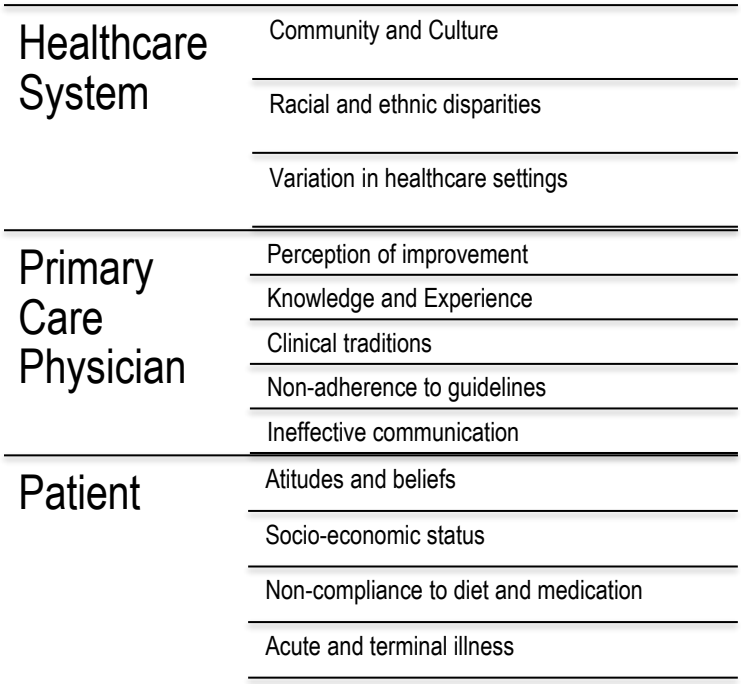
efficient way to quickly and safely achieve glycemic targets and that its use has been recommended by national and international guidelines.[28] Another study in Ontario, this one by Shah et al, identified that "*fewer than one-half of patients with high A1C levels had intensification of their medications, regardless of the specialty of their physicians*."[48]

A nation-wide study in Croatia aimed at understanding clinical inertia in DM management in primary care found that clinical inertia was present in 57.7% of all clinical encounters.[49] They concluded that 100% FPs were clinically inert with *some* patients while 9% of FPs were clinically inert with *all* DM patients. Clinical inertia significantly increased in correspondence with increasing A1C levels. Also, this research found that male family physicians were more likely to be clinically inert than female family physicians. Another researcher identified characteristics of the physicians who were most likely to follow guidelines, and therefore less inclined to clinical inertia: female, recently completed medical studies, frequently used a computer and worked in groups.[50]

Another interesting aspect of physician behavior that could lead to clinical inertia is the impact of competing demands in the patient-physician encounter. Parchman[51] investigated the relationship between clinical inertia and competing demands in primary care. This study found that among patients with an A1C level greater than 7%, each additional patient concern was associated with a 49% reduction in the likelihood of a change in medication. The author concluded that the concept of clinical inertia is limited and does not fully characterize the complexity of primary care encounters.

Ziemer et al. believe that clinical inertia among PCPs is due to limited exposure to education on target-oriented treatment and indications to treatment intensification.[52] Zafar et al. listed other factors that explain clinical inertia, some of which are directly related to the primary care physician.[41] He believes that the phenomenon of clinical inertia should be analyzed apart from patient-related issues: i.e., it is essentially a problem of the physician and the health care system not taking proper action in favor of the patient (Figure 2-b). While patient non-adherence may potentiate clinical inertia on the part of the PCP, failure to improve therapy is essentially related to physician and delivery system issues.[43]

Figure 2-a: Clinical Inertia in DM Care



Ref.: Zafar A, et al. Clinical Inertia in management of T2DM. Primary Care Diabetes, 2010

2.3.4 Theoretic Models of Clinical Inertia

The determinants that potentially explain clinical inertia are numerous and their interactions are sometimes complex and difficult to interpret. For this reason, the construction of theoretical models is needed to allow a more didactic and comprehensive view. Reach[46] mentions five theoretical explanatory models of clinical inertia:

- Knowledge-Attitude-Behavior-Result Model by Cabana et al (1999)[53];
- Awareness-Agreement-Adoption-Adherence by Pathman et al (1996)[54];
- Symmetrical Model involving Physician and Patient by Kim et al (2003)[55];
- Physician Guideline Compliance Model by Maue et al (2004)[56]; and
- The Regulatory Focus Theory Model by Higgins et al (1997)[57].

Cabana argues that physician adherence to clinical guidelines is critical in translating recommendations to improved patient health outcomes. In this comprehensive framework review, the author dissects the process of decision making in guideline adherence and

creates a theoretical framework for the baseline barriers that may undermine it and contribute to the phenomenon of physician clinical inertia.

This model is based on the premise that the *mechanism of action* by which improved patient care is achieved occurs in steps, as postulated by Woolf in 1993[58]. Before a practice guideline can affect patient outcomes, it must first affect physician knowledge, then attitudes, and finally behavior. Guidelines have been considered effective not only by measuring the outcomes, but also if they improve *knowledge*, making clinicians aware of the recommendations; *attitudes*, getting clinicians to agree with and accept the recommendations as a new *standard of care*; and *behavior*, getting clinicians to change practice patterns to conform with the guidelines.[58] Although behavior can be modified without knowledge or attitude being affected, behavior change based on influencing knowledge and attitudes is probably more sustainable than indirect manipulation of behavior alone.[53]

Clinical inertia is essentially a pattern of behavior. This thesis focused on the creation of a clinical inertia scale comprised of the elements of the actual inertia behavior in practice, and examined potential factors that contribute to inertia.

2.3.5 Barriers to Behavior Change

Table 2-e synthesizes Cabana's rational for the barriers affecting physician's ability to act upon a clinical problem:

Table 2-e: Barriers to Behavior Change

Intrinsic	Knowledge	Awareness	The expanding body of research makes it difficult for any physician to be aware of every applicable guideline and critically apply it to practice.
		Familiarity	Casual awareness does not guarantee familiarity of guideline recommendations and the ability to apply them correctly. Lack of familiarity is more common than lack of awareness.
	Attitude	Agreement	Physicians may not agree with a specific guideline or the concept of guidelines in general.

	Behavior	Self-efficacy	It is the belief that one can actually perform a behavior. It influences whether a behavior will be initiated and sustained despite poor outcomes.
		Outcome Expectancy	Is the expectation that a given behavior will lead to a particular consequence. If a physician believes that a recommendation will not lead to an improved outcome, the physician will be less likely to adhere.
		Inertia of Previous Practices	Physicians may not be able to overcome the inertia of previous practice, or they may not have the motivation to change behavior.
Extrinsic	Guideline		Physicians are less likely to adhere to guidelines they perceive as not easy to use or not convenient, or that modify an established behavior (when compared to ones that introduce a new behavior).
	Patient		The inability to reconcile patient preferences with guideline recommendations is a barrier to adherence.
	Environment/System		Adherence to practice guidelines may require changes not under physician control, such as acquisition of new resources or facilities.

Ref.: Cabana MD, Rand CS, Powe NR, Wu AW, Wilson MH, Abboud P-AC, Rubin HR. Why don't physicians follow clinical practice guidelines? A framework for improvement. JAMA. 1999; 282:1458–67.

2.3.6 The Challenge

Though the management of diabetes and its complications are widely investigated and documented in scientific literature, there is insufficient evidence about how hypoglycemia is managed in a primary care setting. In addition, it seems that what is considered in the literature as clinical inertia (that is, physicians not taking action in clinical circumstances that current guidelines clearly indicate action is recommended) is an acknowledged event in primary care medicine and that its frequency and consequences make it a major public health problem. The objective of this thesis was to develop a measure of clinical inertia specific to hypoglycemia and, by using that measure, gain an understanding about the factors that influence clinical inertia behavior in family physicians in the management of hypoglycemia.

Chapter 3

Methodology

This thesis was a secondary analysis of a sub-set of data collected in the project entitled "*UnderstandINg the impact of HYPOglycemia on Diabetes Management: A Survey of Perspectives and Practices*" (InHypo-DM Study).

3.1 Study Objectives

This study had two objectives.

1. The first objective was to determine the factor structure for the construct of clinical inertia around family physicians' behavior in managing hypoglycemia in their diabetic patients, in the primary care setting.
2. Should a robust factor structure be found for clinical inertia, the second objective was to determine if there was a correlation between physician clinical inertia and family physician characteristics.

3.2 Study Design

This study was an exploratory factor analysis using secondary data from a cross-sectional family physician self-reported survey about hypoglycemia management. Data was obtained from the InHypo-DM Study.

3.3 Data Source: The InHypo-DM Study

3.3.1 InHypo-DM Study Overview

The InHypo-DM Study was the largest hypoglycemia research program conducted in Canada to date.[11] This study was initiated across Canada in 2014 and data analysis is ongoing to the present date. The data used in this thesis were collected from February to April 2016. It was an investigator-initiated research study conducted by Dr. Stewart Harris and collaborators at Western University. It explored clinical and personal perspectives, and practices and behaviors related to hypoglycemia in diabetes, as well as factors influencing hypoglycemia management from the perspectives of three distinct populations: patients with DM, people who have a significant other with DM, and healthcare providers (HCP).

3.3.2 InHypo-DM: Methodology

The InHypo-DM Study used a mixed-methods approach with quantitative and qualitative methods used at distinct stages of the project. Initially, a comprehensive literature review was conducted and 87 questionnaires were identified, from which 2035 questions were extracted and categorized by specific domains.

3.3.3 InHypo-DM: Theoretical Domains Framework Tool

A validated tool, the Theoretical Domains Framework (TDF)[59], was employed in the development of interview guides for a sample of key informants: patients with DM (DM), their significant others (SO) and healthcare providers (HCP). Given the complexity of the management of hypoglycemia, and the limited understanding of it thus far, the TDF tool became especially useful for determining the psychosocial, situational, organizational, and environmental determinants of behavior. Qualitative interviews with DM, SO and HCP were conducted to explore their knowledge, experiences, and opinions regarding hypoglycemia management.

3.3.4 InHypo-DM: Questionnaires

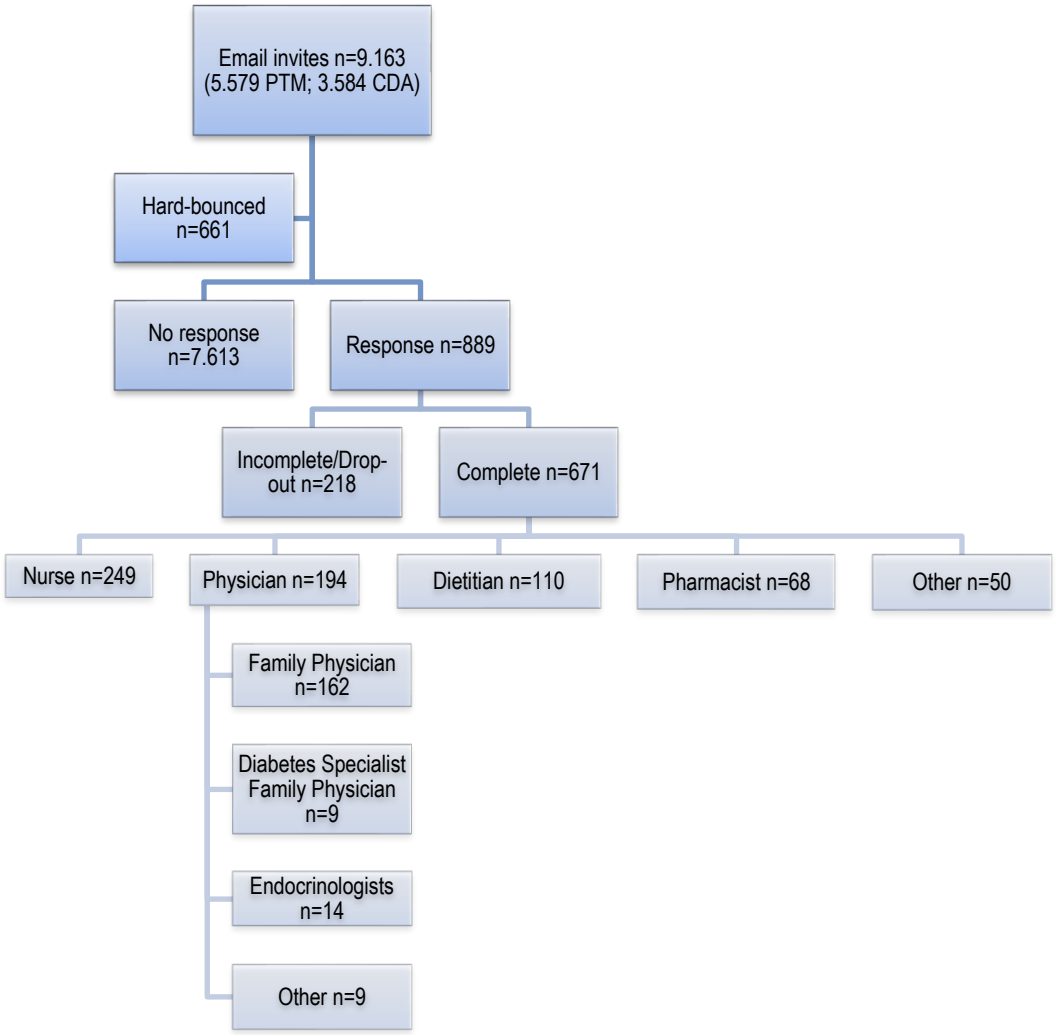
Questionnaires for the three population groups (DM, SO, HCP) were developed using the knowledge from the literature review and the key informant interview, while guided by the TDF. Responses were formulated using 5-point Likert Scales. These questionnaires were piloted for feedback on relevance, clarity, and quality of response options.

The HCP questionnaire (Appendix B) was developed to explore factors that impact HCP potential to effectively help people with diabetes manage hypoglycemia and included a socio-demographic and professional profile segment (section 9) and eight sections on practices and opinions about hypoglycemia management: 1) Knowledge, 2) Capability, 3) Practice, 4) Support, 5) Views, 6) Effects of work life and 7) Effects of social relationships, and 8) Worry/frustration. Respondents included Endocrinologists, Family Physicians, Nurse Practitioners, Registered Nurses, Dietitians, and Pharmacists who provide diabetes care. Appendix contains the entire In-Hypo DM HCP questionnaire.

3.3.5 InHypo-DM: HCP Sampling

A total of 9163 e-mails were sent with an invitation to participate in the study and a link to the HCP questionnaire. The sources for the distribution of the online survey were: a) a panel of physicians and pharmacists who provide diabetes care administered by Professional Targeted Market (PTM), counting 5579 contacts, or 60.9%; and b) the professional section of the Canadian Diabetes Association registered diabetes educators and physicians/researchers (CDA), counting 3584 contacts, or 39.1%. The sampling service utilized multi-source recruitment, quota sampling and quality monitoring. Those who fully completed the questionnaire totalled 671 respondents among physicians and other allied healthcare providers. The diagram in Figure 3-a details the sampling steps:

Figure 3-a: Consort Diagram for the In-HypoDM Study, HCP sampling



N= total number; PTM = Professional Targeted Marketing; CDA = Canadian Diabetes Association
Ref.: Investigating the impact of hypoglycemia on diabetes management: A survey of perspectives and practices. (InHypo-DM Study) Final report phase I & II, 2016.

3.3.6 InHypo-DM: HCP Respondents – Descriptive Results

The respondents included: physicians (28.9%) and other healthcare providers: nurse (nurse practitioners and registered nurses) (37.1%), dietitians (16.4%), and pharmacists (10.1%). The profile of HCP respondents overall was as follows: the majority were female (75%), the average age was 53 years, they were practicing for an average of 16 years, the majority (69.4%) practiced in an urban setting and the majority (65.7%) were Certified Diabetes Educators (CDE or, in this paper, also referred to as Diabetes Educator designation).

Respondents saw an average of 28 patients with diabetes per week and 15.7% of these people had been diagnosed with T1DM.

One hundred and ninety-four physicians completed the questionnaire: 162 family physicians, 14 endocrinologists, 9 diabetes specialist family physicians, 4 internal medicine and 5 respondents from other medical categories. The physician respondents' (28.9%) profile was: male (57%), average age of 56.7 years, few (6%) were Certified Diabetes Educators, practicing for an average of 26 years, in an urban setting (77.3%), seeing an average of 31 patients with diabetes per week. Only 6% of the physicians were CDE.

Table 3-a shows a comparison of HCP respondent profile and the physician respondent profile.

Table 3-a: Comparison of Other Health Care Provider and Physician Characteristics

	HCP Respondents (n=671)	Physician Respondents (n=194)
Sex (%)	75	57
Age in years (mean)	53	56.7
Diabetes Educator designation (%)	65.7	6
Years in practice (mean)	16	26
# DM pt/week (mean)	28	31

N = total number; DM = Diabetes Mellitus; pt = patient
Ref.: Investigating the impact of hypoglycemia on diabetes management: A survey of perspectives and practices. (InHypo-DM Study) Final report phase I & II, 2016.

3.4 Sample

The sample for this thesis consisted of the sub-set of 162 family physicians who completed the InHypo-DM HCP questionnaire.

3.5 Variables

3.5.1 Dependent Variable

The first objective of this thesis was to create a clinical inertia scale. The potential items for inclusion in the scale were the 13 questions in section 3 that asked family physicians about what they believed to be true about their actual *practices and behavior*. The heading for this section of the questionnaire read: "*These are questions about what you do when*

helping your patients manage their hypoglycemia. Remember that management refers to both treatment and prevention. Please select the answer that you believe is true most of the time:"

Table 3-b reproduces the 13 items in Section 3 from the questionnaire. The response categories in the 5-point Likert scale were: "Never"; "Rarely"; "Sometimes"; "Often"; and "Always".

Table 3-b: Potential Items for the Clinical Inertia Scale

Section 3 – These are questions about what you actually do when helping your patients manage their hypoglycemia. Remember management refers to both treatment and prevention. Please select the answer that you believe is true most of the time: **In general,**	**Name of variable for this thesis**
10) …I make an effort to keep track of my patients' progress with regard to managing their hypoglycemia.	**effort track progress**
11) …I advise my patients to increase the frequency of blood glucose monitoring when they are at increased risk for hypoglycemia.	**advice increase monitor**
12) …I make sure that I am prepared to help my patients manage their hypoglycemia.	**prepared to help**
13) …I am confident that I can help my patients manage their hypoglycemia even when there is little time.	**time management**
14) …addressing the specific appointment issue takes priority over discussing their hypoglycemia management.	**specific issue priority**
15) …helping my patients manage their hypoglycemia is something I do routinely.	**routine help**
16) …the way I help my patients manage their hypoglycemia is informed by current evidence and guidelines.	**guideline informed**
17) …I take the initiative to help my patients improve their hypoglycemia management.	**take initiative**
18) …I explain how to manage hypoglycemia to my patients.	**explain how manage**
19) …I discuss hypoglycemia-related guidelines regarding driving or operating heavy machinery with my patients.	**discuss guidelines**
20) …I solicit patients' input when discussing their hypoglycemia management.	**solicit input**

21) …I use motivational strategies to help my patients manage their hypoglycemia.	**motivational strategy**
22) …my professional liability, according to my specific regulatory body, directs the way I manage patients' hypoglycemia.	**professional liability**

3.5.2 Independent Variables

Ref.: Investigating the impact of hypoglycemia on diabetes management: A survey of perspectives and practices. (InHypo-DM Study) Final report phase I & II, 2016. InHypo-DM HCP questionnaire, Section 3

The independent variables used in this analysis were:

a) Age in years,

b) Sex (male, female),

c) Years in practice,

d) Practice location (rural or urban setting),

e) Canadian province where the practice was located (recoded into the following categories: Ontario (ON); Quebec (QU); Newfoundland (NL); Alberta (AB); Western/Prairie Provinces – British Columbia (BC), Manitoba (MB) and Saskatchewan (SK); and Maritime Provinces – Prince Edward Island (PEI), New Brunswick (NB) and Nova Scotia (NS).

f) Practice type (response options in the questionnaire were Hospital, Family Health Team or Other. The answers for the open-text option *Other* included: Family Health Organizations or Groups; Primary Care Network, solo/private office; Community Health Clinic/walk-in clinic, corporate clinic, military Clinic, long-term care and palliative facilities, and retirement homes. All responses were recoded as "Hospital", "Team-based practice" and "non-Team based practice"),

g) Diabetes Educator designation (yes or no),

h) Country where the respondent obtained the most recent professional degree, (Canada or other)

i) Mean number of diabetes patients the respondent physician usually sees in an average week (# DM pt/week),

j) Personal diagnosis of diabetes (yes or no).

3.6 Descriptive Analysis

A descriptive analysis examined the distribution of all variables. The frequencies and percentages for the response for each of the 13 potential clinical inertia items were run, and missing values were identified. For the independent variables, the mean and standard deviation were calculated for age, years in practice and number of DM patients per week. For the remaining independent variables, sex, practice type, practice location, province of practice, country of medical degree, DM educator designation, and personal diagnosis of diabetes, frequencies and percentages were run. All analyses were conducted using SPSS statistics version 25.

3.7 Exploratory Factor Analysis

Exploratory Factor Analysis (EFA) was the chosen statistical technique to address the first objective of this study, to create a clinical inertia scale. There are two main purposes or applications of factor analysis: data reduction and exploring theoretical underlying structures. It allows the researcher to examine all relationships between individual variables (items on a scale), grouping together variables that are correlated in order to extract latent factors. These factors should reflect the underlying processes that have created the correlations among variables. "*Exploratory factor analysis is usually performed in the early stages of research, when it provides a tool for consolidating variables and for generating hypothesis about underlying processes*."[60] EFA is normally the first step in building scales or new metrics.[61] Exploratory factor analysis was used in this thesis in an iterative process to identify correlations among the 13 potential clinical inertia items that could contribute to a clinical inertia scale.

The following sections 3.7.1 and 3.7.2 outline the assumptions that were explored before determining whether the data set was suitable for EFA.

3.7.1 Adequacy of Sample

Exploratory Factor Analysis requires a robust sample size and a strong correlation among variables in the data set. Adequacy of the sample was verified by the Bartlett´s test of Sphericity and the Kaiser-Meyer-Olkin (KMO) measures. The strength of the intercorrelations among items (referred to as factorability) was verified by examining the correlation matrix.

Bartlett's test of Sphericity tests whether the data comes from multivariate normal distribution with zero covariances or, in other words, the correlation matrix is an identity matrix. This would indicate that the factor model is inappropriate. It is appropriate if $p < 0.05$.[60] The KMO measure of sampling adequacy ranges from 0 to 1. A minimum value suggested for a good factor analysis is 0.6.[60]

For a data set to be suitable for EFA, or to achieve factorability, the items in the sample must have strong correlations. The correlation matrix was used to identify the value of correlations between variables. Strong correlations are indicated by coefficients greater than 0.3.[60]

3.7.2 Data Verification

The missing values were treated using the exclude case listwise option in SPSS. With this option, cases were included in the analysis only if they had full data on all the variables listed for that analysis.

Normality assessment was performed with the Kolmogorov-Smirnov and Shapiro-Wilk tests. The Kolmogorov-Smirnov statistic assesses the normality of the distributions of the scores. A non-significant result (value greater than 0.05) indicates normality. On the other hand, a significant value less than 0.05 suggests a violation of the assumption of normality. The Shapiro-Wilk test rejects the hypothesis of normality when the p-value is less than or equal to 0.05.

3.7.3 Extraction and Rotation Methods

The extraction method for this study was the Principal Axis Factors (PAF) technique, chosen because the 13 potential clinical inertia items included in the EFA were not normally distributed. Maximum likelihood extraction method is preferred when multivariate normality of the variables is observed and PAF for when that assumption is violated.[61, 62]

Rotations were performed after extraction in an attempt to find the clearest and simplest structure for ease of interpretation. This is achieved by maximizing high correlations between factors and minimizing low ones through mathematical procedures. The types of rotations are distinguished in terms of whether they are orthogonal, used when it is believed that factors are uncorrelated, or oblique, used when it is believed that the factors are correlated.[63] According to Osborne, "*In the social sciences we generally expect some correlation among factors, particularly scales that reside within the same instrument/questionnaire, …, and oblique rotation should theoretically render a more accurate, and perhaps more reproductible solution*."[62 page 33]

In this EFA, the SPSS output for Oblique rotations (correlated items), provided two tables of loadings: A Pattern Matrix and a Structure Matrix. The structure matrix disregards the fact that the factors are correlated and the differences between high and low loadings are more apparent in the pattern matrix. The greater the loading, the more the variable is a pure measure of the factor. Some authors suggest that loadings over 0.71 are excellent, over 0.63 are very good, over 0.55 are good, over 0.45 are fair and under 0.32 are poor.[60] For this thesis, based on statistical advice from supervisors, values above 0.40 were considered adequate loadings. When no rotation is performed, only one matrix is presented, a Factor Matrix.

3.7.4 Factor Retention

The decision on how many of the extracted factors to keep was guided by the scree plot and the Kaiser's criterion (eigenvalue and the total variance explained). Some authors recommend using the scree test in conjunction with the eigenvalues to determine the number of factors to retain.[61, 62]

The Scree test involves plotting the eigenvalues of each factor and inspecting the plot to find a point where the shape of the curve changes direction or inclination abruptly. Factors that should be retained are those that lie above the point where the line changes inclination.[64]

The Kaiser's criterion, or the eigenvalue rule, is the most commonly used technique to decide how many factors to retain.[64] Using this rule, only factors with an eigenvalue of 1.0 or higher are retained for further investigation. The eigenvalue of a factor represents the amount of the total variance explained by that factor.

Once the number of factors was defined, investigation continued with interpreting the findings to make clinical sense. This is an essential step in EFA. The interpretation is conducted to understand the underlying dimensions that unify the group of variables that load on each factor.[60]

The strength of the relationship between the factors is measured by the value on the Factor Correlation Matrix. Values above 0.3 are considered strongly correlated. Values above 0.8 may be considered, in fact, too highly correlated, suggesting that they are indistinct and might actually fit better as a sub-scale of one single factor.[65]

One of the most commonly used indicators of internal consistency is Cronbach's alpha coefficient. Internal consistency for each factor was assessed by checking the coefficient value of each factor's Cronbach's alpha. Ideally, the Cronbach's alpha coefficient should be above 0.7.[64]

3.8 Clinical Inertia Score

3.8.1 Factor Score

A factor score is a useful outcome of EFA. Factor scores can be calculated in various forms. They are estimates of the scores that subjects would have received on each of the factors had it been possible to measure them directly. The simplest procedure for achieving this is to calculate the mean value of each responses in the questionnaire for each respondent.[60] This method was used to calculate a clinical inertia score which was then treated as a continuous outcome variable.

3.9 Examining the Relationship between the Clinical Inertia Score and Physician Characteristics

3.9.1 Bivariate Analysis

The relationship between the clinical inertia score and physician characteristics was examined first using bivariate statistics and then using multiple linear regression. The independent variables used to compare physician characteristics to the factor score were: age, sex, years in practice, country of medical degree, practice location (urban or rural), Province of practice, practice type (team-based or non-team-based), Diabetes educator designation, number of DM patients per week and personal diagnosis of DM.

Normality for continuous variables and Outcome variable (12-item Score) was assessed by Shapiro-Wilk and Kolmogorov-Smirnov tests and verified by examining in the Quartile (Q-Q) Plots. When distribution of points on the scatterplot form a linear trace, it is presumed that the assumption of normality was not violated.

For the bivariate analysis, the procedures were Pearson correlation for continuous independent variables (age, years in practice, number of DM patients per week), independent-samples t-test for dichotomous independent variables (sex, practice location, country of medical degree, Diabetes educator designation), and ANOVA for categorical independent variables with more than two response categories (practice type, Province of practice).

3.9.2 Multiple Linear Regression

The primary goal of regression analysis is to investigate the relationship between a dependent variable (in this case, the clinical inertia score) and several independent variables.

Standard multiple regression was performed to explore the relationship between the clinical inertia factor score and all independent variables in the model. Assumptions underpinning multiple linear regression were tested as follows:

The adequacy of the sample size was assessed by applying the formula ($n \geq 20 + 5m$) where m = number of Independent variables (IV).[64]

Absence of multicollinearity was determined by examining the correlation matrix and variables with a bivariate correlation of 0.7 or more were considered collinear and removed from the regression.[64]

Absence of Outliers was verified by inspecting the standardised residual scatterplot for values beyond ± 3.3.[64]

Normality, linearity and homoscedasticity of residuals refer to aspects of distribution of scores and the nature of the underlying relationship between variables. The assumptions of linearity and normality were checked by visually inspecting the Normal Probability (P-P) Plot of the regression standardised residuals for a reasonably straight diagonal line from bottom left to top right, indicating no major deviations from normality.[64]

Homoscedasticity was assessed by inspection of the scatterplot. When the residuals were roughly rectangularly distributed with most scores concentrated in the center, it determines that the variance of the residuals about the predicted outcome variable scores were the same for all predicted scores and the assumption of homoscedasticity was met.[64]

The mode ENTER was the model choice, and only entries with full data were included.

Chapter 4

Results

This chapter first describes the sample of family physician respondents. Next, results from the Exploratory Factor Analysis are reported. Finally, the resulting clinical inertia score is compared to the characteristics of the family physicians in both bivariate and multivariate analyses.

Important note: Data analysis was processed by SPSS with Brazilian Portuguese (European) convention for punctuation, where decimals points are represented by commas, not by periods, as in the English convention. Most tables in this chapter must be read with this understanding.

4.1 Family Physician – Descriptive Results

One hundred and sixty-two family physician (FP) or primary care physicians (PCP) (hereafter referred to as family physicians or FPs) completed the questionnaire. Table 4-a and Table 4-b report on the continuous and the categorical variables respectively. These respondents were 56.2% males, 43.8% females with a mean age of 57.5 years. Respondents had been practicing medicine for a mean of 26 years. The number of DM patients seen by these FP was, on average, 27 DM patients per week. One family physician respondent reported seeing an average of 250 DM patients per week. This respondent also informed that he/she is not a diabetes educator and works in a Family Health Team. That number of DM patients/week was deemed highly improbable and was considered an error and it was excluded from the analysis. Nine respondents (5.6%) affirmed having a Diabetes Educator designation.

Table 4-a: Family Physician Respondent Characteristics – Continuous Variables

	Mean	SD	Min	25th percentile	Median	75th percentile	Max
Age in years	57.55	9.65	31	50	57	64	85
Years in practice	26	11	3	17	25	33	55
# DM pt/week	27	24	1	12	20	30	101

SD = Standard Deviation; Min = Minimum; Max = Maximum; DM = Diabetes; pt = patient

The majority, 75.3%, of FPs were in urban areas and 24.7% in rural areas. FPs reported that they practiced in Hospitals (4.9%), Family Health Teams (30.9%) or Other settings (64.2%). Nine respondents did not specify the type of their practice. After recoding this variable into Hospital, Team-based and not-Team based, the distribution was Hospitals (5.4%), Team-based practice (42,3%) and Non-Team-based practice (46.3%).

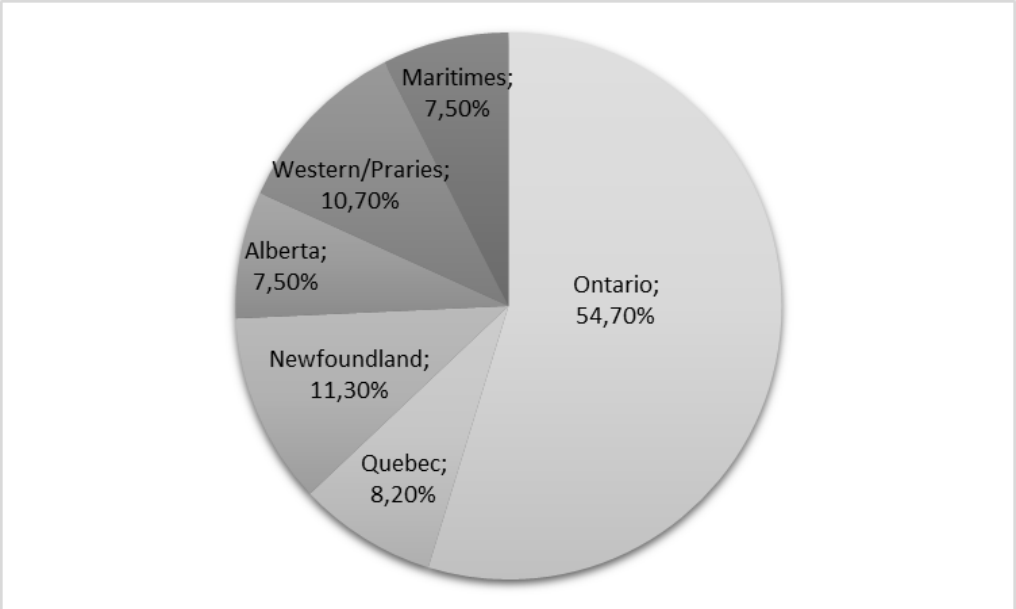
Most FP respondents practiced in Ontario (54.7%), Canada's most populated province. The distribution of FP respondents (159 valid responses) across Canada is represented in Figure 4-a.

The majority of respondents obtained their degree in Canada (84.5%). Fifteen per cent of the FP obtained their degree in other countries including respondents from the United Kingdom, India, Ireland, South Africa, Slovakia, Uganda, Hong Kong, USA, Jordan, Bangladesh, Pakistan and Libyan Arab Jamahiriya.

Nine percent of the FP respondent had a personal diagnosis of DM, of which 46% reported having experienced a diabetes-related hypoglycemic event.

The distribution for each categorical variable, including re-coded Province and Practice type variables, are presented in Table 4-b.

Figure 4-a: Distribution of FP Respondents across Canada (%)



Note: Decimals in this graph are represented by commas, not periods. Western/Prairies = British Columbia, Manitoba and Saskatchewan; Maritimes = Prince Edward Island, New Brunswick and Nova Scotia

Table 4-b: Family Physician Respondent Characteristics – Categorical Variables

		Count	% of N
Location	Urban	122	75,3%
	Rural	40	24,7%
Province	ON	87	54,7%
	QU	13	8,2%
	NL	18	11,3%
	AB	12	7,5%
	Western/Prarie Provinces	17	10,7%
	Maritimes Provinces	12	7,5%
Practice Type	Hospital Practice	8	5,4%
	Team-based Practice	63	42,3%
	Not Team-based Practice	69	46,3%
	Missing	9	6,0%
Country of Degree	Canada	136	84,5%
	Other Country	25	15,5%
CDE	Yes	9	5,6%
	No	153	94,4%
Personal DM	Yes	14	8,6%
	No	148	91,4%

Note: Decimals in this table are represented by commas, not periods. N= total number; CDE = Diabetes Educator designation; ON = Ontario; QU = Quebec; NL = Newfoundland; AB = Alberta; WP = Western Prairies (British Columbia, Manitoba and Saskatchewan); MP = Maritime Provinces (Prince Edward Island, New Brunswick and Nova Scotia); DM = Diabetes

4.2 Exploratory Factor Analysis

4.2.1 Adequacy of Sample

Prior to performing EFA, the suitability of the data for factor analysis was assessed. Inspection of the correlation matrix revealed the presence of many coefficients of 0.3 and above indicating the factorability of the items (Table 4-c). The KMO index was 0.923, achieving the recommended value of 0.6 or higher, and Bartlett`s test of Sphericity reached

statistical significance ($p < .001$), supporting the adequacy of sample size and factorability of the correlation matrix (Table 4-d).

Table 4-c: Correlation Matrix

	effort track progress	advice increase monitor	prepared to help	time management	specific issue priority	routine help	guideline informed	take initiative	explain how manage	discuss guidelines	solicit input	motivational strategy	professional liability
effort track progress	1,000												
advice increase monitor	0,447	1,000											
prepared to help	0,563	0,557	1,000										
time management	0,521	0,418	0,645	1,000									
specific issue priority	-0,061	-0,121	-0,183	-0,172	1,000								
routine help	0,550	0,388	0,650	0,575	-0,224	1,000							
guideline informed	0,470	0,415	0,551	0,570	-0,118	0,585	1,000						
take initiative	0,532	0,488	0,691	0,596	-0,105	0,739	0,628	1,000					
explain how manage	0,561	0,461	0,645	0,551	-0,142	0,655	0,545	0,689	1,000				
discuss guidelines	0,405	0,397	0,424	0,459	-0,124	0,475	0,477	0,511	0,524	1,000			
solicit input	0,531	0,409	0,507	0,517	-0,206	0,491	0,507	0,608	0,571	0,539	1,000		
motivational strategy	0,417	0,317	0,485	0,617	-0,048	0,485	0,433	0,579	0,535	0,521	0,581	1,000	
professional liability	0,286	0,131	0,300	0,314	0,111	0,302	0,344	0,419	0,265	0,376	0,344	0,404	1,000

Note: Decimals in this table are represented by commas, not periods.
Values > |0.30| considered well correlated

Table 4-d: Sample Adequacy tests

KMO and Bartlett Tests		
Kaiser-Meyer-Olkin Measure		**0,923**
Bartlett`s Sphericity Test	Aprox. Qui-squared	1076,646
	Sig.	**0,000**

Note: Decimals in this table are represented by commas, not periods. Sig = Significance

4.2.2 Data Verification

The cases were inspected for missing data. Two cases of missing data were found, where respondents chose not to answer a question that was expected to be answered by all respondents. These two cases were excluded from the factor analysis.

The Kolmogorov-Smirnov and Shapiro-Wilk statistic tests assess the normality of the distribution of scores. For these tests, the significance value across the table is 0.000, suggesting violation of the assumption of normality. Table 4-e reports the test for each of the 13 potential items. This result dictated the choice of extraction method as outlined in next section, 4.3.1.

Table 4-e: Normality Tests

	Kolmogorov-Smirnov[a]			Shapiro-Wilk		
	Statistic	df	Sig.	Statistic	df	Sig.
effort track progress	0,253	160	0,000	0,860	160	0,000
advice increase monitor	0,248	160	0,000	0,804	160	0,000
prepared to help	0,274	160	0,000	0,808	160	0,000
time management	0,277	160	0,000	0,849	160	0,000
specific issue priority	0,201	160	0,000	0,901	160	0,000
routine help	0,247	160	0,000	0,870	160	0,000
guideline informed	0,311	160	0,000	0,831	160	0,000
take initiative	0,338	160	0,000	0,815	160	0,000
explain how manage	0,285	160	0,000	0,830	160	0,000
discuss guidelines	0,253	160	0,000	0,874	160	0,000
solicit input	0,289	160	0,000	0,831	160	0,000
motivational strategy	0,281	160	0,000	0,862	160	0,000
professional liability	0,189	160	0,000	0,909	160	0,000

Note: Decimals in this table are represented by commas, not periods. Df = degrees of freedom; Sig = significance

4.3 Factor Analysis – Round 1

4.3.1 EFA-1 Extraction and Rotation Methods

Based on the assessment described in Section 4.2, the data were considered suitable to proceed with the EFA. The chosen extraction method was the Principal Axis Factors (PAF) technique, due to the observation that there was not a normal multivariate distribution.

Rotation was performed for achieving a simpler structure, for ease of interpretation. Because the 13 potential clinical inertia items were correlated, the oblique technique of rotation Oblimin was chosen. The Pattern and Structure matrices report all factor loadings

for each of the 13 potential clinical inertia items on each factor (Table 4-f). Factor loading values of 0.40 and above are considered relevant.

This first round of Exploratory Factor Analysis revealed the presence of two factors with eingenvalues above 1; and one factor with eigenvalue inferior to 1. The eingenvalues for the three factors found were 4.582 (factor #1), 1.356 (factor #2) and 0.824 (factor #3). It is recommended that only factors with eingenvalues of 1 or above should be retained.[61] These 3 factors explained 46.36%, 13.726%, 8.34% of the variance, respectively, and 68.43% cumulatively. Table 4-g presents these results.

An inspection of the scree plot (Figure 4-b) revealed a break in the inclination of the graphic line after the second factor (#2), further corroborating that factor #3 should be left out of the analysis.

Table 4-h reports the factor correlation values in the 3-factor solution, showing a strong negative correlation between factor #1 and factor #3 and a weak negative correlation between factor #1 and factor #2. Factors #2 and #3 had a weak positive correlation.

Table 4-f: Pattern and Structure Matrix for EFA-1 with Oblimin Rotation

Variable	Pattern coefficients			Structure coefficients			Communalities
	Factor 1	Factor 2	Factor 3	Factor 1	Factor 2	Factor 3	
effort track progress	**0,666**	-0,053	0,074	**0,684**	**-0,548**	-0,120	0,475
advice increase monitor	**0,603**	0,049	-0,064	**0,585**	-0,403	-0,238	0,348
prepared to help	**0,966**	0,158	0,026	**0,840**	**-0,563**	-0,250	0,716
time management	**0,521**	-0,254	-0,077	**0,733**	**-0,645**	-0,235	0,564
specific issue priority	-0,018	0,020	**0,563**	-0,197	0,049	**0,569**	0,325
routine help	**0,766**	-0,022	-0,065	**0,801**	**-0,596**	-0,288	0,646
guideline informed	**0,557**	-0,199	0,009	**0,703**	**-0,615**	-0,157	0,512
take initiative	**0,735**	-0,180	0,094	**0,842**	**-0,726**	-0,124	0,738
explain how manage	**0,701**	-0,107	-0,045	**0,793**	**-0,631**	-0,251	0,634
discuss guidelines	0,076	**-0,630**	-0,132	**0,584**	**-0,690**	-0,170	0,501
solicit input	0,134	**-0,617**	-0,246	**0,667**	**-0,724**	-0,301	0,611
motivational strategy	0,117	**-0,661**	-0,021	**0,617**	**-0,749**	-0,072	0,569
professional liability	0,020	**-0,570**	0,258	0,371	**-0,578**	0,237	0,398

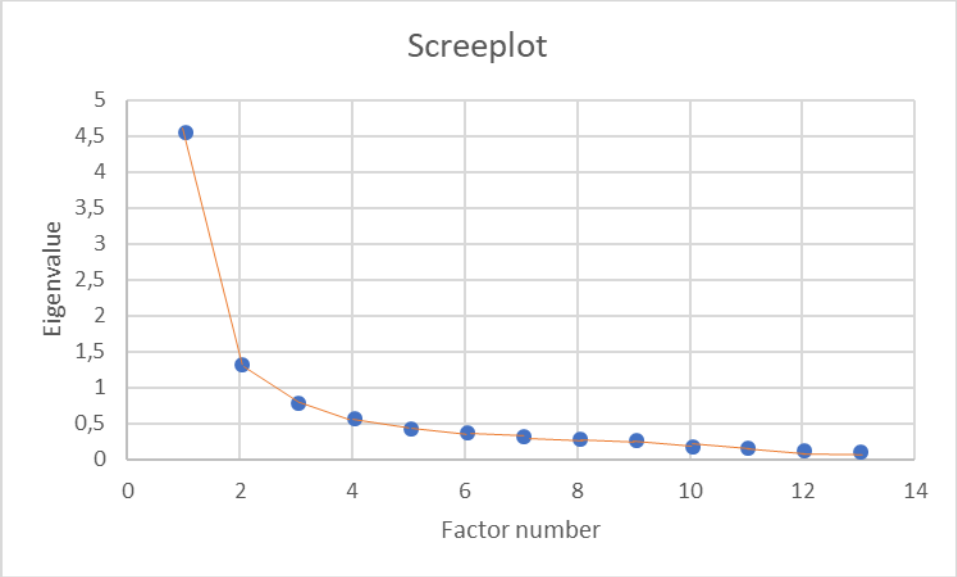
Note: Decimals in this table are represented by commas, not periods. Values > |0.40| are considered adequate loadings

Table 4-g: Total Variance Explained EFA-1

Factor	Initial Eigenvalues			Rotation Sums of Squared Loadings
	Total	% of Variance	Cumulative %	Total
1	**4,582**	**46,362**	**46,362**	**4,215**
2	**1,356**	**13,726**	**60,088**	**2,258**
3	**0,824**	**8,342**	**68,430**	**0,511**
4	0,598	6,049	74,479	
5	0,457	4,620	79,099	
6	0,403	4,081	83,180	
7	0,355	3,588	86,768	
8	0,150	3,188	89,956	
9	0,303	3,063	93,019	
10	0,205	2,074	95,093	
11	0,199	2,011	97,104	
12	0,155	1,566	98,671	
13	0,131	1,329	100,000	

Note: Decimals in this table are represented by commas, not periods.

Figure 4-b: Scree plot EFA-1



Note: Decimals in this graph are represented by commas, not periods.

Table 4-h: Factor correlation Matrix EFA – 1

Factor Correlation Matrix			
Factor	1	2	3
1	1,000	-0,290	-0,747
2	-0,290	1,000	0,026
3	-0,747	0,026	1,000

Note: Decimals in this table are represented by commas, not periods.

4.3.2 Retaining Factors

With the support of the results of these tests, it was decided to retain factor #1 and factor #2 for further investigation. The third factor was composed of one variable, item #14 of the questionnaire. This variable was separated from the analysis and was the subject of further examination, reported at the end of this study.

4.4 Factor Analysis – Round 2

4.4.1 EFA -2 Extraction and Rotation Methods

A second factor analysis was run, without the one variable that composed factor #3, leaving 12 items. In order to maximize high correlations between factors and potential clinical inertia items and minimize low correlations between them, rotation was performed and, again, the oblique technique Oblimin allowed for a better clustering of items and therefore better interpretation. The rotated solution revealed the presence of simple structure, with both factors showing a number of strong loadings predominantly on only one factor on the Pattern Matrix. All factors were internally consistent and well defined by the variables. In Table 4-i, good loading values, 0.45 or above, are bolded for ease of interpretation.

The two-factor solution explained a total of 63.7% of the variance (Table 4-j), with factor 1 contributing to 52.4% and factor 2 contributing to 11.3%, as shown in the Table 4-j.

The scree plot on for this second round of factor analysis confirmed the two-factor solution.

After rotation, the Factor Correlation Matrix, also referred to as Component Correlation Matrix (Table 4-k) showed a strong negative correlation between the two factors, at -0.707.

Internal reliability for each factor was calculated and found to be satisfactory with a value of 0.910 for Factor #1 and 0.762 for Factor #2. The Cronbach Alpha`s value for the 12 items together was 0.915. (Table 4-l)

Table 4-i: Pattern and Structure Matrix for EFA-2 with Oblimin Rotation

Variable	Pattern coefficients		Structure coefficients		Communalities
	Factor 1	Factor 2	Factor 1	Factor 2	
effort track progress	**0,636**	-0,074	**0,698**	**-0,605**	0,476
advice increase monitor	**0,682**	0,112	**0,790**	**-0,588**	0,369
prepared to help	**0,908**	0,101	**0,836**	**-0,541**	0,705
time management	**0,550**	-0,251	**0,688**	**-0,523**	0,560
routine help	**0,748**	-0,059	**0,828**	**-0,719**	0,625
guideline informed	**0,541**	-0,222	**0,602**	-0,370	0,512
take initiative	**0,639**	-0,267	**0,727**	**-0,639**	0,721
explain how manage	**0,741**	-0,083	**0,800**	**-0,607**	0,644
discuss guidelines	0,204	**-0,534**	**0,582**	**-0,679**	0,482
solicit input	0,340	**-0,462**	0,358	**-0,546**	0,551
motivational strategy	0,141	**-0,661**	**0,608**	**-0,761**	0,589
professional liability	-0,057	**-0,587**	**0,666**	**-0,702**	0,300

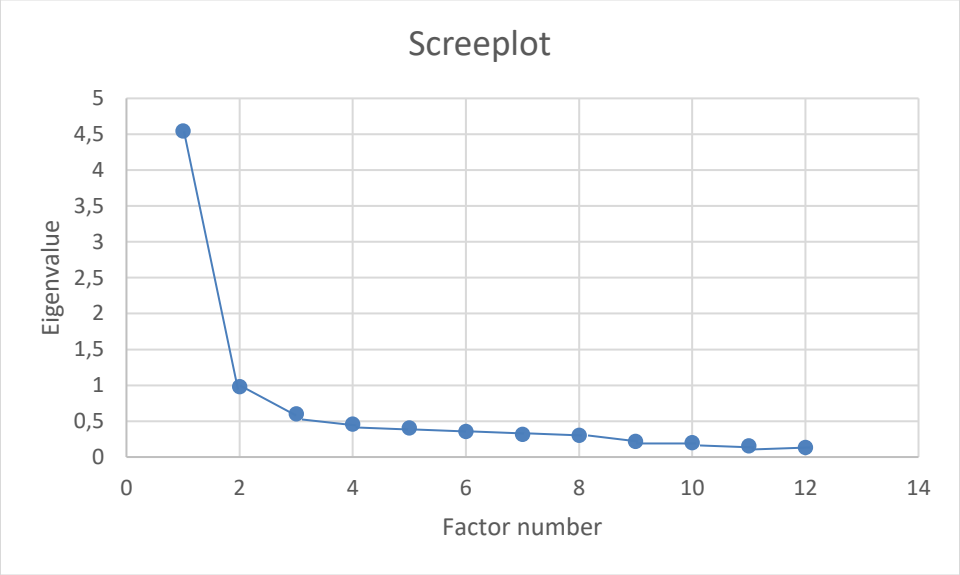
Note: Decimals in this table are represented by commas, not periods. Values > |0.40| are considered adequate loadings

Table 4-j: Total variance Explained EFA-2

Factor	Initial Eigenvalues			Rotation Sums of Squared Loadings
	Total	% of Variance	Cumulative %	Total
1	**4,543**	**52,403**	**52,403**	**4,336**
2	**0,979**	**11,297**	**63,699**	**2,439**
3	0,602	6,947	70,646	
4	0,457	5,266	75,912	
5	0,406	4,684	80,597	
6	0,355	4,095	84,692	
7	0,317	3,660	88,352	
8	0,303	3,495	91,847	
9	0,215	2,484	94,332	
10	0,200	2,312	96,643	
11	0,156	1,801	98,444	
12	0,135	1,556	100,000	

Note: Decimals in this table are represented by commas, not periods.

Figure 4-c: Scree plot EFA-2



Note: Decimals in this graph are represented by commas, not periods.

Table 4-k: Factor Correlation Matrix EFA-2

Factor Correlation Matrix		
Factor	1	2
1	1,000	-0,707
2	-0,707	1,000

Note: Decimals in this table are represented by commas, not periods.

Table 4-l: Cronbach`s Alpha EFA -2

Reliability			
	Cronbach's alpha	Cronbach's alpha (standardized items)	Number of items
Factor 1	0,910	0,910	8
Factor 2	0,762	0,773	4
2-Factor solution	0,915	0,921	12

Note: Decimals in this table are represented by commas, not periods.

4.4.2 Factors in EFA - 2

Table 4-m lists variables that composed factor #1, in order of importance (highest to lowest loading values, on the pattern matrix).

Table 4-m: Loading values (Pattern coefficients) for variables in EFA-2 Factor #1

Loading Value	Item
0.908	I make sure that I am prepared to help my patients manage their hypoglycemia.
0.748	helping my patients manage their hypoglycemia is something I do routinely.
0.741	I explain how to manage hypoglycemia to my patients.
0.682	I advise my patients to increase the frequency of blood glucose monitoring when they are at increased risk for hypoglycemia.
0.639	I take the initiative to help my patients improve their hypoglycemia management.
0.636	I make an effort to keep track of my patients' progress with regard to managing their hypoglycemia.
0.550	I am confident that I can help my patients manage their hypoglycemia even when there is little time.
0.541	the way I help my patients manage their hypoglycemia is informed by current evidence and guidelines.

Table 4-n lists variables that composed factor #2, in order of importance (highest to lowest loading values, on the pattern matrix).

Table 4-n: Loading values (Pattern coefficients) for variables in EFA-2 Factor #2

Loading Value	Item
-0,661	I use motivational strategies to help my patients manage their hypoglycemia.
-0.587	My professional liability, according to my specific regulatory body, directs the way I manage patients' hypoglycemia.
-0.534	I discuss hypoglycemia-related guidelines regarding driving or operating heavy machinery with my patients.
-0.462	I solicit patient' input when discussing their hypoglycemia management.

Although the two factors found were statistically distinguished, they were not clinically distinct; they did not describe two different concepts within the overarching theme of clinical inertia. With that in mind, this overlap in construct was discussed with the clinician supervisor and we determined that it was appropriate to evaluate the use of a scale with all the items as one factor, instead of a two-factor scale.

4.5 Factor Analysis – Round 3

In Round 3, another EFA was conducted restricting the analysis to one factor. Note that with a one-factor solution, there is no rotation. When there are several loadings on the factor matrix that have adequate values (greater than 0.40), it is evidence that one-factor scale is reasonable.

4.5.1 One Factor Solution – 13 item scale

This 13-item solution (Table 4-p) explained 50.1% of the variance (Table 4-p). However, the item that was found inconsistent in previous EFA-1 for loading on a factor alone, in this round of EFA also showed inappropriate loading value, that is, smaller than 0.30. This item, #14 "*appointment issues take priority*", had a loading value of – 0.174, and it was removed from the analysis and therefore not used in the scale. Another round of EFA was run without that item.

Table 4-o: Factor Matrix EFA – 3 (One-factor, 13-item)

Factor Matrix	
	Factor
	1
effort track progress	**0,680**
advice increase monitor	**0,566**
prepared to help	**0,792**
time management	**0,755**
specific issue priority	-0,174
routine help	**0,781**
guideline informed	**0,715**
take initiative	**0,839**
explain how manage	**0,791**
discuss guidelines	**0,642**
solicit input	**0,726**
motivational strategy	**0,681**
professional liability	**0,431**

Note: Decimals in this table are represented by commas, not periods.
Values > |0.40| are considered adequate loadings

Table 4-p: Total Variance Explained EFA -3 (One-factor, 13-item)

Total Variance Explained						
	Initial Eigenvalues			Sum of Squared loadings		
Factor	Total	% variance	% cumulative	Total	% variance	% cumulative
1	**6,517**	**50,129**	**50,129**	**6,052**	**46,554**	**46,554**
2	1,185	9,114	59,242			
3	0,868	6,676	65,918			
4	0,696	5,351	71,269			
5	0,608	4,680	75,949			
6	0,557	4,284	80,234			
7	0,547	4,207	84,440			
8	0,486	3,741	88,182			
9	0,436	3,358	91,539			
10	0,331	2,549	94,088			
11	0,303	2,327	96,415			
12	0,252	1,936	98,352			
13	0,214	1,648	100,000			

Note: Decimals in this table are represented by commas, not periods.

4.6 Factor Analysis – Round 4

4.6.1 One Factor Solution – 12 item scale

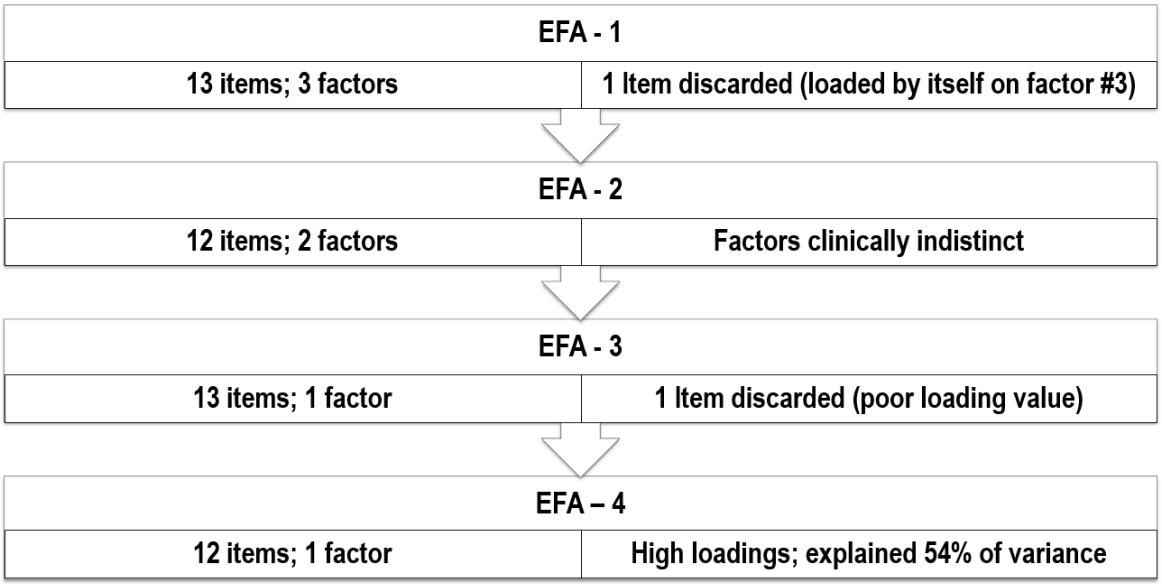
The fourth iterative round of EFA was a solution with a 12-item scale, excluding the item described above in Round 3. All items loaded on the factor with values superior than 0.40. (

Table 4-q). This 12-item solution explained 54% of the total variance (

Table 4-r). An illustration of the successive iterative rounds of EFA is presented on Figure 4-d.

Given the clinical sense of this version and the high loadings resulting, the 12 items from this 12-item one-factor solution were chosen to create the clinical inertia score as described in Section 4.7 below.

Figure 4-d: Illustration of the Iterative Process for EFA



EFA = Exploratory factor analysis

Table 4-q: Factor Matrix EFA – 4 (One-factor, 12-item)

Factor Matrix	
	Factor 1
effort track progress	0,682
advice increase monitor	0,565
prepared to help	0,791
time management	0,754
routine help	0,778
guideline informed	0,716
take initiative	0,840
explain how manage	0,791
discuss guidelines	0,642
solicit input	0,724
motivational strategy	0,684
professional liability	0,437

Note: Decimals in this table are represented by commas, not periods.
Values > |0.40| are considered adequate loadings

Table 4-r: Total Variance Explained EFA – 4 (One-factor, 12-item)

Total Variance Explained						
	Initial Eigenvalues			Sum of Squared loadings		
Factor	Total	% variance	% cumulative	Total	% variance	% cumulative
1	**6,484**	**54,034**	**54,034**	**6,021**	**50,178**	**50,178**
2	1,007	8,394	62,428			
3	0,697	5,805	68,233			
4	0,634	5,284	73,516			
5	0,569	4,741	78,257			
6	0,551	4,593	82,850			
7	0,489	4,074	86,924			
8	0,437	3,646	90,570			
9	0,331	2,762	93,332			
10	0,324	2,701	96,033			
11	0,256	2,130	98,163			
12	0,220	1,837	100,000			

Note: Decimals in this table are represented by commas, not periods.

4.7 Clinical Inertia Score

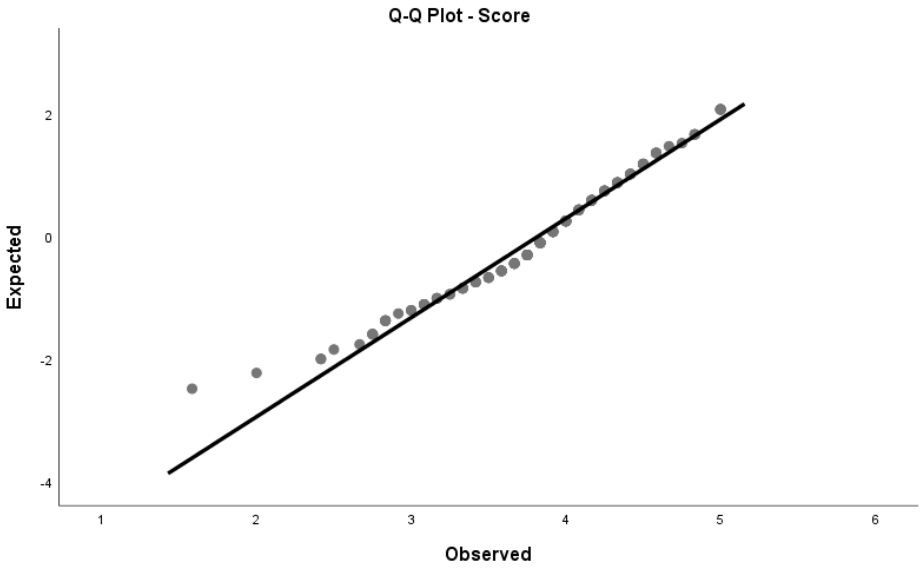
A Clinical Inertia Score variable was created by calculating the mean of the response for each of the 12 items for each respondent. Descriptive statistics and normality assessment for this outcome variable are presented in Table 4-s and Figure 4-ef, respectively.

Table 4-s: Descriptive Results

Clinical Inertia Score		
N	Valid	160
	Missing	2
Mean		3,8234
Median		3,8333
Standard Deviation		0,61140
Percentile	25	3,5000
	50	3,8333
	75	4,1667

Note: Decimals in this table are represented by commas, not periods. N= total number

Figure 4-e: Outcome normality assessment



4.8 The Relationship between the Clinical Inertia Score and Family Physician Characteristics

A comparison of the outcome, the Clinical Inertia Score, to physician characteristics was performed.

4.8.1 Bivariate Analysis

Comparison of the continuous independent variables with the clinical inertia score outcome, using Pearson's correlations coefficient (Table 4-t), showed that none of the comparisons achieved statistical significance.

An independent-samples t-test was conducted to compare the clinical inertia scores for each group of respondents in the dichotomous variables of: sex (male/female), practice location (rural/urban), country of medical degree (Canada/other countries), Diabetes Educator designation (yes/no), personal diagnosis of DM (yes/no). None of the differences in scores for these variables achieved statistical significance. Results are presented in Table 4-u.

Categorical variables with more than two response categories after recoding were analyzed using one-way between groups ANOVA with post-hoc tests when appropriate. Mean, minimum, maximum and standard deviation of scores for province and practice type categories are presented on Table 4-v and Table 4-w respectively. There was no statistically significant association between either province (Table 4-x) or type of practice (Table 4-y) and clinical inertia score.

Table 4-t: Correlation for Continuous Variables and Clinical Inertia Score

	score	Years in Practice	Age	# DM pt/week
Pearson's r	1	0,093	0,066	0,059
Sig.		0,245	0,408	0,46
N	160	157	157	159

Note: Decimals in this table are represented by commas, not periods. DM = Diabetes; pt = patient; Sig. = Significance; N=total number

Table 4-u: Clinical Inertia Scores and T-test Results for Dichotomous variables

			Average	Standard Deviation	Mínimum	Median	Maximum	Sig.
12-item score	Sex	Male	3,90	0,56	2,42	4,00	5,00	0,067
		Female	3,72	0,66	1,58	3,83	5,00	
	Practice Location	Urban	3,82	0,62	1,58	3,83	5,00	0,760
		Rural	3,84	0,59	2,42	3,83	4,83	
	Country of Medical Degree	Canada	3,81	0,60	1,58	3,83	5,00	0,640
		Other Country	3,87	0,66	2,42	4,00	5,00	
	Diabetes Educator Designation	Yes	3,97	0,48	3,42	3,75	4,75	0,660
		No	3,81	0,62	1,58	3,83	5,00	

Note: Decimals in this table are represented by commas, not periods.

Table 4-v: Clinical Inertia Score for Province Categories

Province	Mean	Min	Max	Std Dev
ON	3,792	1,583	5,000	0,646
QU	3,847	2,417	4,833	0,645
NL	3,889	2,833	4,750	0,522
AB	3,958	2,750	5,000	0,769
Western/Prarie Provinces	3,975	3,333	5,000	0,468
Maritimes Provinces	3,618	2,667	4,167	0,457

Note: Decimals in this table are represented by commas, not periods. Min = Minimum; Max= Maximum; Std Dev = Standard Deviation; ON = Ontario; QU = Quebec; NL = Newfoundland; AB = Alberta; WP = Western Prairies (British Columbia, Manitoba and Saskatchewan); MP = Maritime Provinces (Prince Edward Island, New Brunswick and Nova Scotia)

Table 4-w: Clinical Inertia Score for Practice Type Categories

Type of Practice	Mean	Min	Max	Std Dev
Hospital	4,094	3,583	5,000	0,533
Team-based	3,858	2,417	5,000	0,564
Not Team-based	3,808	1,583	5,000	0,657
Missing	3,491	2,417	4,083	0,541

Note: Decimals in this table are represented by commas, not periods. Min = Minimum; Max = Maximum; Std Dev = Standard Deviation

Table 4-x: ANOVA for Province Variable

Clinica Inertia Score					
	Sum of Squares	df	Mean Square	Z	Sig.
Between Groups	1,287	5	0,257	0,682	0,638
Within Groups	56,976	151	0,377		
Total	58,263	156			

Note: Decimals in this table are represented by commas, not periods. df = Degrees of freedom; Z = standard deviation; Sig. = Significance

Table 4-y: ANOVA for Practice Type Variable

Clinica Inertia Score					
	Sum of Squares	df	Mean Square	Z	Sig.
Between Groups	1,672	3	0,557	1,518	0,212
Within Groups	52,507	143	0,367		
Total	54,18	146			

Note: Decimals in this table are represented by commas, not periods. df = Degrees of freedom; Z = standard deviation; Sig. = Significance

4.8.2 Multiple Linear Regression

Multiple linear (MLR) regression was used to assess the ability of nine independent variables (age in years, years in practice, average number DM patients per week, sex, urban or rural practice location, province, personal diagnosis of DM, diabetes educator

designation, practice type recoded) to predict the score on a Clinical Inertia Scale. This is referred to as MLR-1.

Analyses were conducted on MLR-1 to ensure no violation of the assumptions of normality, linearity, multicollinearity and homoscedasticity. Normal Probability (P-P) Plots were inspected and the residuals rested well along the line indicating that both normality and linearity assumptions were met for MLR-1.

Multicollinearity was verified by examination of the correlation matrix. The variable Age was highly collinear with variable Years in Practice, with a bivariate correlation of 0.826, with statistical significance (p value < 0.001).

Therefore, the independent variable Age was excluded from the regression and a second multiple linear regression analysis (MLR -2) was performed. The correlation matrix for MLR-2 is presented on Table 4-z. There was no evidence of multicollinearity for MLR-2.

The normal Probability (P-P) Plot was inspected and the residuals rested well along the line indicating that both normality and linearity assumptions were met for MLR-2 (Figure 4-ff). In the Scatterplot examination the standardised residuals for MLR -2 were distributed in a rough rectangular shape, indicating that the assumption of homoscedasticity was met (Figure 4-gg).

After examination of the relationships in MLR – 2, it was observed that none of the variables were predictive of the Clinical Inertia Score. (

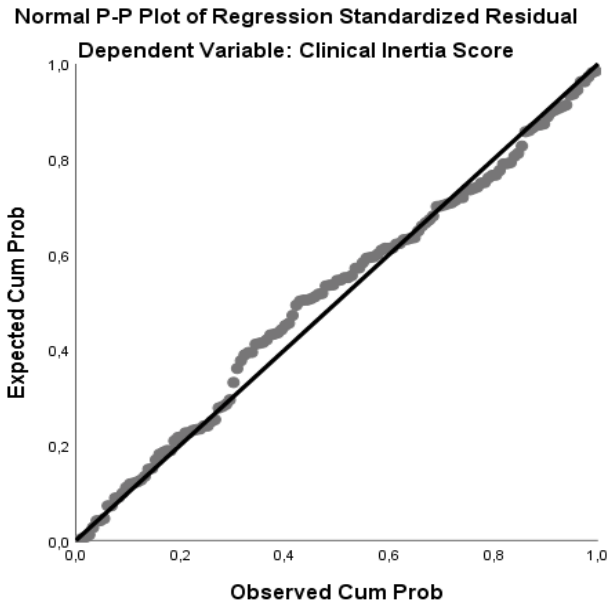
Table 4-aa).

Table 4-z: Correlation in MLR -2

	Pearson's Correlation	Sig.	N
Clinical Inertia Score	1,000		160
Years in Practice	0,093	0,122	157
# DM pt/week	0,059	0,230	159
Sex	-0,150	0,029	160
Location	0,019	0,405	160
CDE	-0,060	0,227	160
Personal diagnosis DM	-0,075	0,174	160
Province (recoded)	0,029	0,358	157
Pratice Type (recoded)	-0,151	0,034	147

Note: Decimals in this table are represented by commas, not periods. Sig.= Significance; N = total number; DM = Diabetes; pt = patient; CDE = Diabetes Educator designation

Figure 4-f: P-P Plot MLR - 2



Note: Decimals in this graph are represented by commas, not periods.
Cum Prob = Cumulative Probability

Figure 4-g: Scatterplot MLR -2

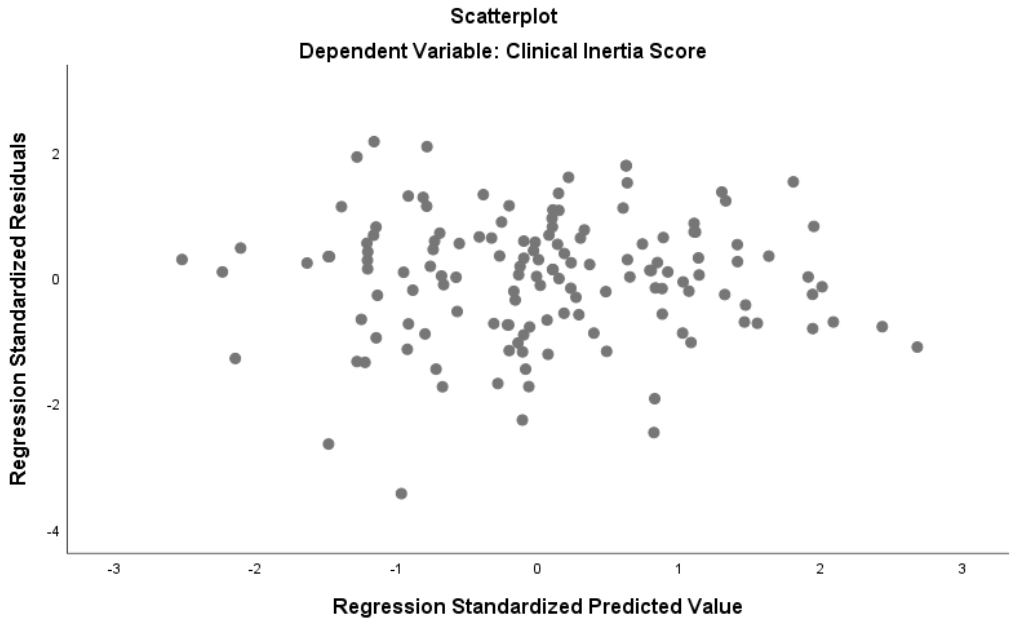


Table 4-aa: Coefficients MLR – 2

Model	Unstandardized Coefficients		Standardized Coefficients	t	Sig.	Confidence Interval for B 95,0%	
	B	Std Error	Beta			Lower Limit	Upper Limit
(Constant)	4,324	0,67		6,455	0	3	5,648
Years in practice	0,002	0,005	0,044	0,485	0,629	-0,008	0,012
# DM pt/week	0,001	0,002	0,029	0,321	0,749	-0,004	0,005
Sex (Reference=Male)	-0,179	0,115	-0,146	-1,559	0,121	-0,406	0,048
Location (Reference - Urban)	-0,014	0,127	-0,01	-0,112	0,911	-0,265	0,236
CDE (Reference - Not a CDE)	-0,009	0,24	-0,003	-0,036	0,971	-0,482	0,465
Personal DM (Reference - Do not have DM)	-0,18	0,184	-0,083	-0,977	0,33	-0,543	0,184
Province (Reference – Ontario)							
Quebec	0,04	0,196	0,018	0,203	0,84	-0,347	0,426
Newfoundland	0,148	0,178	0,076	0,834	0,406	-0,203	0,499
Alberta	0,151	0,196	0,065	0,769	0,443	-0,237	0,538
Western provinces	0,217	0,175	0,109	1,241	0,217	-0,129	0,563
Maritime provinces	-0,206	0,201	-0,089	-1,024	0,307	-0,605	0,192
Practice Type (Reference – Hospital)							
Family Health Team	0,013	0,146	0,01	0,089	0,929	-0,276	0,301
Other Practice Type	0,021	0,14	0,017	0,15	0,881	-0,256	0,298

Note: Decimals in this table are represented by commas, not periods.
Ref = Reference; Avg = average; CDE = Diabetes Educator Designation; DM = Diabetes Mellitus; WP = Western Prairies (British Columbia, Manitoba and Saskatchewan); MP = Maritime Provinces (Prince Edward Island, New Brunswick and Nova Scotia); Hosp = Hospital; FHT = Family Health Team.

Chapter 5

Discussion

In this chapter, an overview of the findings is presented and is put into context by situating it within the existing literature. The implications of these findings, and the strengths and limitations of this study is also discussed. Finally, recommendations for future research are highlighted.

5.1 Summary of Findings

The main contribution of this thesis to the literature is the creation, for the first time, of a clinical inertia scale around hypoglycemia management. As a result of multiple iterations of factor analysis, it is recommended that the scale be used in the form of a one 12-item scale. While sub-scales were identified statistically, there was no conceptual distinction among the sub-scales identified, and therefore it is not suggested that they be used without further research. The results found in the standard multiple regression analysis showed that, for this population, none of the differences in the clinical inertia score found in the family physician characteristics variables achieved statistical significance. The characteristics compared to the score were: age, sex, years in practice, average number of DM patients seen per week, country of medical degree, practice type, practice location, DM educator designation and personal diagnosis of diabetes.

5.2 Implication of Findings

A review of recent literature indicates that the management of hypoglycemia in primary care setting by family physicians lacks thorough investigation. In fact, measuring clinical inertia in family physicians' management of hypoglycemia was an absent subject in the extensive literature search that anticipated this research. The only available information referred to research on similar topics, such as guideline adherence for the care of hyperglycemia, clinical inertia related to other chronic problems and other general aspects of DM management.

The major and novel contribution of this study to gain a better understanding of family physician management of hypoglycemia, is the development of a practical measure for

clinical inertia. The author believes that development of a clinical inertia score can be an important and useful tool for family physicians and primary care services that wish to improve the delivery of care to DM patients, specifically in the management of hypoglycemia. It enables medical leaders, service managers and policy makers to assess the measurement of clinical inertia in hypoglycemia management in physicians in primary care. This in turn will enhance and increase awareness of this under-studied issue in family medicine. Awareness may prompt discussions and reflection about hypoglycemia management guidelines. This may, in turn, precipitate physician behavior modification towards critically applying guideline recommendations to their practice and ultimately improving outcomes for people with DM. The creation of a clinical inertia measure is a novel contribution to the literature on hypoglycemia management that can guide future research on the topic of physician behavior influencing management of hypoglycemia in primary care settings.

At this point in the research, no reference values were identified for the scale. Higher scores are intended to reflect less clinical inertia because higher scores reflect more positive and proactive behaviors described in the items. Reference values concerning what constitutes clinical inertia will be determined only after testing different populations of family physicians and assessing the relationship between the scores and clinical hypoglycemia on hypoglycemia management.

After creating the clinical inertia scale and calculating scores, this study examined potential relationships between these scores and family physician characteristics that could be associated with the phenomenon of clinical inertia in hypoglycemia management. Findings from this analysis diverged from limited existing knowledge in three areas: sex, years of practice and working in groups. Lang in 2015, affirmed that males were more prone to clinical inertia[49], and Sammer in 2008 stated that recent medical school graduates, women, minorities, physicians who use computers for information in their practices, and physicians in non-solo practice types were significantly less inclined to depart from guidelines.[50] Yet, this study found no difference in the clinical inertia score results between male or female physicians. The existing literature also indicated that physicians with fewer years of practice were more likely to follow guidelines[50], but the results for the sample of family

physicians in this study showed no tendency across years of practice. The same study by Sammer in 2008 [50] found that those physicians who worked in groups were more adherent to guidelines, and therefore, less clinically inert. The analyses of the clinical inertia score within the practice type variable (Hospital, Team-based or not team-based) did not find such disparity in the current study.

No findings in this study corroborated with the limited existing knowledge on hypoglycemia management in primary care that focus on the issue of clinical inertia. One reason for this may be that the majority of the existing studies that examined physician behavior towards clinical inertia in management of DM related problems, evaluated other aspects of DM care, more consistent with hyperglycemia, such as failure to increase pharmacologic treatment in the presence of off-target, elevated A1C hemoglobin.[28, 48, 49] These fundamental differences in the objects of the cited studies and this research made it difficult to compare results.

While this study would need to be replicated in larger and different populations, the new evidence generated about clinical inertia around management of hypoglycemia suggests a consistency in propensity to clinical inertia behavior across Canadian provinces or whether the family physician worked in a rural or urban setting; inertia on the part of the physician did not vary inversely to the volume of DM patients seen per week; a designation of DM educator was not an advantage in preventing clinical inertia; and a personal diagnosis of DM did not lessen nor encourage physician clinical inertia behavior in hypoglycemia management. Given that some physician characteristics are not amenable to change, such as age, sex, nationality of medical degree and personal diagnosis of diabetes, they do not provide opportunities for interventions to change behaviour, and so would be of limited practical value in tackling the problem of clinical inertia. Optimistically then, this may suggest that other facets of care amenable to change, such as knowledge and support to family physicians, may be the most strategic approach for interventions.

5.3 Strengths and Limitations

The strength of this study is that it raises awareness and addresses an issue relevant to primary care and family medicine world-wide, that of clinical inertia in hypoglycemia management in primary care settings.

The preference for this statistical method, exploratory factor analysis, allowed for observation of underlying constructs where no specific theory was available to explain the phenomenon. This makes it an appropriate choice of statistical analysis for a primer study.

Data for the analysis were supplied by a major study designed and executed under a rigorous scientific method. Respondents were from across Canada, representing a nation-wide sample.

Recognizing possible limitations of this study is key to improving future research. One limitation is that the survey used in this study was based on physicians' self-report of their behaviour and may not reflect actual behavior. Because of the secondary data analysis nature of the study's design, key aspects that could measure clinical inertia were not present in the original questionnaire, such as attitudes and behavior of the physician in relation to patient's results on glycemic target or glycosylated hemoglobin levels; or questions about the use of electronic medical records, telehealth and other technology-driven clinical intelligence tools that could aid physicians in protocols and practice guidelines. Further research could investigate and lead to expansion of the clinical inertia scale to include these more behavioural components.

The original question about practice type ("*Type of Practice: Hospital, Family Health Team, Other: please specify*_____") was not precise enough to classify the team-based characteristics of the physician's practice. Re-classification was conducted to mitigate this problem but the recoding criteria were not free from subjectivity. Practices considered as "team based" for the purpose of re-classification were those entries that specifically mentioned a team or multi-professional model of care, such as Primary Care Network, Long-term and Palliative Care Institutions, Chronic Care Model. Entries considered as "not team-based" were those that did not mention collaborative work with any other health

professions such as solo or private practices, clinics comprised exclusively of physicians and those that do not mention team work. However, a large number of entries were not clear about the professional arrangement in the practice. In future research employing physician surveys, a specific question about team-based practice, along with a clear definition of what was being considered a team-based practice should be added to the survey to improve the precision for measuring this construct, and perhaps improve the prediction power of that item.

The item that was deleted for loading on a factor by itself, #14 of the InHypo-DM HCP questionnaire, "*addressing specific appointment issues take priority over discussing their hypoglycemia management*" refers to demands from the patient that compete for the physician's time and attention during a patient-physician encounter. This is a problem that could explain in part the attitude of the physician for not acting when guidelines would indicate an action is in order.[51] So while the decision to delete this item from the current clinical inertia scale was driven by statistic analysis, conceptually, the presence of competing demands is an issue that should be explored in future research in order to better understand its contribution to the phenomenon of physician clinical inertia in managing hypoglycemia in primary care.

The interplay between patient and system factors influencing clinical inertia must not be ignored. While this research was designed to understand the role of physician behaviors in clinical inertia, future studies should also investigate physician clinical inertia behavior in comparison to their patient's characteristics, such as non-adherence status, A1C levels, presence of comorbidity. The knowledge that will derive from such a comprehensive understanding of the multi-factorial and complex topic of clinical inertia in primary care will undoubtedly improve outcomes for DM patients.

5.4 Conclusion

This study is the first of its kind that explores a clinical inertia measurement for hypoglycemia management in primary care and, as such, it serves as a primer, a basic foundation for future research to test, validate and build upon. The creation of the clinical inertia scale for hypoglycemia management is the first step in the development and

validation of a scale to measure an important and largely under-studied clinical issue. It is hoped that further validation of the scale will happen over time, as it is tested in other family physician populations.

References

1- IDF Diabetes Atlas, 7th edition. 2015

2- Brazilian Ministry of Health, Health editorial, February 15th, 2018. Chronic Disease Vigilance data. Available in Portuguese on-line at: http://www.brasil.gov.br/editoria/saude/2017/11/numero-de-brasileiros-com-diabetes-cresceu-61-8-em-10-anos

3- Houlden, RL. Diabetes Canada. 2018 Clinical Practice Guidelines Introduction, Can J Diabetes. 2018;42(Suppl 1): S1-S325.

4- Clayton, Dale et al. Hypoglycemia. 2013 Canadian Journal of Diabetes, Volume 37, S69 - S71

5- Yale, JF et al. Diabetes Canada. *2018* Clinical Practice Guidelines, Hypoglycemia. Can J Diabetes. 2018;42(Suppl 1): S1-S325.

6- Cryer, PE et al. Insulin Therapy and Hypoglycemia in Type 2 Diabetes Mellitus. Insulin 2007. July; vol2(3): 127-133

7- Murata G, et al. Hypoglycemia in type 2 diabetes: a critical review. Biomedic & Pharmacotherapy 58 (2004) 551-559.

8- Tenzer-Iglesias, P. et al. Managing Hypoglycemia in Primary Care. Journal of Fam Practice. 2012. Oct; Vol 61(10): S1-S6.

9- Graveling AJ, Frier BM. Impaired awareness of hypoglycemia: a review. Diabetes & Metabolism. 2010. 36(2010) S64-S74

10- Standards of Care, Diabetes Care. Hypoglycemia, American Diabetes Association 2019 Suppl.1 S67

11- Ratzki-Leewing, A et al. Real-world crude incidence of hypoglycemia in adults with diabetes: Results of the InHypo-DM Study, Canada. BMJ Open Diab Res Care 2018;6: e000503. Doi:10.1136/bmjdrc-2017-000503

12- King P, Peacock I, Donnelly R. The UK Prospective Diabetes Study (UKPDS): clinical and therapeutic implications for type 2 diabetes. Br J Clin Pharmacol. 1999 Nov; 48(5): 643–648.

13- Murata GH, et al. Intensified Blood Glucose Monitoring Improves Glycemic Control in Stable, Insulin-Treated Veterans With Type 2 Diabetes. The Diabetes Outcomes in Veterans Study (DOVES). Diabetes Care 2003 Jun; 26(6): 1759-1763.

14- Reichert SM, Harris S, Ryan B, Mequanint S, Webster-Bogaert S, Ratzki-Leewing A, Brown J.B. A population-based study on incidence and associated risk factors for hypoglycemia in Canada: the INHYPO-DM study, University of Western Ontario, London, Canada. EASD InHypo-DM Abstract, 2016

15- Kubiak T, et al. Evaluation of a self management-based patient education program for the treatment and prevention of hypoglycemia-related problems in type 1 diabetes. Patient Educ Couns. 2006; 60 228-234.

16- Gerstein HC, Miller ME, Byington RP, Goff DC Jr, Bigger JT, Buse JB, Cushman WC, Genuth S, Ismail-Beigi F, Grimm RH Jr, Probstfield JL, Simons-Morton DG, Friedewald WT. Action to Control Cardiovascular Risk in Diabetes Study Group (ACCORD), Effects of intensive glucose lowering in type 2 diabetes. N Engl J Med. 2008 Jun 12;358(24):2545-59. doi: 10.1056/NEJMoa0802743. Epub 2008 Jun 6.

17- Miller ME, et al. ACCORD Investigators. The effects of baseline characteristics, glycaemia treatment approach, and glycated hemoglobin concentration on the risk of severe hypoglycemia: post hoc epidemiological analysis of the ACCORD study. BMJ. (2010) 340: b5444.

18- American Diabetes Association, Standards of Care. Diabetes Care Volume 41, Supplement 1, S61-62, January 2018.

19- Heller, S et al. 2015, Hypoglycemia: A Global cause for concern, page 16.

20- Imran, SA. et al. Canadian Diabetes Association, Clinical Practice Guidelines, Target for Glycemic Control. Can J Diabetes. 2018;42(Suppl 1): S1-S325.

21- Lipscombe L, et al. Diabetes Canada 2018 Clinical Practice Guidelines, Pharmacologic Glycemic Management of Type 2 Diabetes in Adults: Can J Diabetes 2018;42(Suppl 1): S88-S103

22- Rodbard HW, et al. Statement by an American Association of Clinical Endocrinologists/American College of Endocrinology consensus panel on type 2 Diabetes: an algorithm for glycemic control. *Endocr Pract*. 2009;15(7):768-770

23- Edridge CL, Dunkley AJ, Bodicoat DH, Rose TC, Gray LJ, Davies MJ, Khunti K Prevalence and Incidence of Hypoglycaemia in 532,542 People with Type 2 Diabetes on Oral Therapies and Insulin: A Systematic Review and Meta-Analysis of Population Based Studies. PLoS One. 2015 Jun 10;10(6): e0126427. doi: 10.1371/journal.pone.0126427.

24- Stewart, M. et al. 2014. Patient-Centered Medicine: Transforming the Clinical Method. 3rd ed. Radcliffe Publishing, London, UK. Chapter 16.

25- Davidson JA. The Increasing Role of Primary Care Physicians in Caring for Patients With Type 2 Diabetes Mellitus. Mayo Clin Proc. 2010 Dec; 85(12 Suppl): S3-S4.

26- Diabetes Canada Clinical Practice Guidelines Expert Committee. Diabetes Canada 2018 Clinical Practice Guidelines for the Prevention and Management of Diabetes in Canada. Can J Diabetes. 2018;42(Suppl 1):S1-S325.

27- Gusso G. Tratado de Medicina de Família, Chapter 162, Type 1 and 2 Diabetes, p. 1436. 2012. Ed. Artmed, São Paulo.

28- Harris S et al. 2010. Clinical inertia in patients with T2DM requiring insulin in family practice. *Canadian Family Physician* Vol 56: Dec. 2010, e418-24

29- Stellefson M, Dipnarine K, Stopka C. The Chronic Care Model and Diabetes Management in US Primary Care Settings: A Systematic Review. Prev Chronic Dis 2013;10: 120180.

30- Elliot L, Fidler C, Ditchfield A et al. Hypoglycemia Event Rates: A Comparison Between Real-world Data and Randomized Controlled Trial Populations in Insulin-Treated Diabetes. Diabetes Ther 2016; 7:45-60.

31- Bachimont J et al. Pourquoi les médecins généralistes n'observent-ils pas les recommandations de bonnes pratiques cliniques? L'exemple du diabète de type 2. In: Sciences sociales et santé. Volume 24, n°2, 2006. pp. 75-103.

32- Clement, M. et al. Diabetes Canada *2018* Clinical Practice Guidelines, Organization of Diabetes Care. Can J Diabetes. 2018;42(Suppl 1): S1-S325.

33- Bodenheimer T, et al. 2002. Improving Primary Care for Patients with Chronic Illness. JAMA (2002)1779-1775:(14)288;

34- Dovey S M, et al. A preliminary taxonomy of medical errors in family practice. Qual Saf Health Care 2002;11: 233–238

35- Lawrence A L, et al. Type 2 diabetes mellitus management in Canada: is it improving? Canadian Journal of Diabetes 2013, 37 (2): 82-9

36- Wild D, et al. A critical review of the literature on fear of hypoglycemia diabetes: implications on diabetes management and patient education. Patient Educ Couns. 2007;68 (1):10-15

37- Anderbro T, Amsberg S, Adamson U, et al. Fear of hypoglycaemia in adults with Type 1 diabetes. Diabet Med 2010;27:1151e8.

38- Belendez M, Hernandez-Mijares A. Beliefs about insulin as a predictor of fear of hypoglycaemia. Chronic Illn 2009;5:250e6.

39- Barnard K, Thomas S, Royle P, et al. Fear of hypoglycaemia in parents of young children with type 1 diabetes: a systematic review. BMC Pediatr 2010;10:50.

40- Di Battista AM, Hart TA, Greco L, Gloizer J. Type 1 diabetes among adolescents: reduced diabetes self-care caused by social fear and fear of hypoglycemia. Diabetes Educ 2009;35:465e75.

41- Zafar A, et al. 2010. Clinical Inertia in management of T2DM. Primary Care Diabetes 4 (2010)203–207

42- Phillips LS, Branch WT, Cook CB et al. Clinical inertia. Ann Intern Med. 2001; 135:825-34

43- Shaefer C.F. 2006. Clinical Inertia: Overcoming a Major Barrier to Diabetes Management. Insulin, page 61-64.

44- O'Connor PJ, Sperl-Hillen JAM, Johnson PE, et al. Clinical Inertia and Outpatient Medical Errors. In: Henriksen K, Battles JB, Marks ES, et al., editors. Advances in Patient Safety: From Research to Implementation (Volume 2: Concepts and Methodology). Rockville (MD): Agency for Healthcare Research and Quality (US); 2005 Feb.

45- Kennedy AG, Maclean CD. Clinical inertia: Errors of omission in drug therapy Am J Health-Syst Pharm. 2004; 61:401-4

46- Reach G. Clinical Inertia – A Critique of Medical Reason. 2013. Springer-Verlag France, Paris, 2013; ISBN 978-2-8178-0312-8. Translation by Claudia Ratti

47- Aujoulat I, Jacquemin P, Rietzschel E, Scheen A, Tréfois P, Wens J, Darras E, Hermans MP. Factors associated with clinical inertia: an integrative review. Adv Med Educ Pract. 2014 May 8;5:141-7.

48- Shah BR, Hux JE, Laupacis A, Zinman B, van Walraven C. Clinical inertia in response to inadequate glycemic control: do specialists differ from primary care physicians? Diabetes Care. 2005 Mar;28(3):600-6.

49- Lang VB, Marković BB, Kranjčević K. Family Physician Clinical Inertia in Glycemic Control among Patients with Type 2 Diabetes Med Sci Monit. 2015; 21: 403–411.

50- Sammer CE, Lykens K, Singh KP. Physician characteristics and the reported effect of evidence-based practice guidelines. Health Serv Res. 2008 Apr;43(2):569-81.

51- Parchman ML, Pugh JA, Romero RL, Bowers KW. Competing demands or clinical inertia: the case of elevated glycosylated hemoglobin. Ann Fam Med. 2007;5(3):196-201.

52- Ziemer DC et al. 2005. Clinical Inertia contributes to poor diabetes control in primary care settings, Diabetes Educ vol 31: July-August (4) 2005 pages 564-571

53- Cabana MD, Rand CS, Powe NR, Wu AW, Wilson MH, Abboud P-AC, Rubin HR. Why don't physicians follow clinical practice guidelines? A framework for improvement. JAMA. 1999; 282:1458–67.

54- Pathman DE, Konrad TR, Freed GL, Freeman VA, Koch GG. The awareness-to-adherence model of the steps to clinical guideline compliance: the case of pediatric vaccine recommendations. Med Care. 1996; 34:873–89.

55- Kim C, Hofer T, Kerr EA. Review of evidence and explanations for suboptimal screening and treatment of dyslipidemia in women. A conceptual model. J Gen Intern Med. 2003; 18:854–63.

56- Maue SK, Segal R, Kimberlin CL, Lipowski EE. Predicting physician guideline compliance: an assessment of motivators and perceived barriers. Am J Manag Care. 2004;10: 383–91.

57- Higgins ET. Beyond pleasure and pain. Am Psychol. 1997; 52:1280–300

58- Woolf SH. Practice guidelines: a new reality in medicine, III: impact on patient care. Arch Intern Med. 1993;153: 2646–55.

59- Cane J, O'Connor D, Michie S. 2012. Validation of the theoretical domains framework for use in behaviour change and implementation research. Implement Sci. (2012) Apr 24;7: 37.

60- Tabachnick, BG. and Fidell, LS. Using Multivaried Statistics, 2014, 6th ed, p. 662

61- Yong G. and Pearce S. A Beginner's Guide to Factor Analysis: Focusing on Exploratory Factor Analysis, *Tutorials in Quantitative Methods for Psychology* 2013, Vol. 9(2), p. 79-94.

62- Osborne J. 2014. Best Practices in Exploratory Factor Analysis, 2014

63- Grimm LG, Yarnold PR. Reading and Understanding Multivariate Statistics. American Psychological Association, Washington, DC. 2010. P. 99 - 136

64- Pallant J. SPSS Survival Manual, 4th edition, 2010.

65- Costello AB, Osborne JW, Exploratory Factor Analysis, *Practical Assessment Research & Evaluation*, 2005, Vol 10, No 7; 4

Appendices

Appendix A: Recommendations from the 2018 CPG for Hypoglycemia in T2DM

Reference: Yale, JF et al. Diabetes Canada. *2018* Clinical Practice Guidelines, Hypoglycemia. Can J Diabetes. 2018;42(Suppl 1): S1-S325.

1. All people with diabetes currently using or starting therapy with insulin or insulin secretagogues and their support persons should be counselled about the risk, prevention, recognition and treatment of hypoglycemia. Risk factors for severe hypoglycemia should be identified and addressed [Grade D, Consensus].
2. The DHC team should review the person with diabetes' experience with hypoglycemia at each visit, including an estimate of cause, frequency, symptoms, recognition, severity and treatment, as well as the risk of driving with hypoglycemia [Grade D, Consensus].
3. In people with diabetes at increased risk of hypoglycemia, the following strategies may be used to reduce the risk of hypoglycemia:

a. Avoidance of pharmacotherapies associated with increased risk of recurrent or severe hypoglycemia [Grade D, Consensus]
b. A standardized education program targeting rigorous avoidance of hypoglycemia while maintaining overall glycemic control [Grade B, Level 2]
c. Increased frequency of SMBG, including periodic assessment during sleeping hours [Grade D, Consensus]
d. Less stringent glycemic targets with avoidance of hypoglycemia for up to 3 months [Grade D, Level 4]
e. A psycho-behavioral intervention program (blood glucose awareness training) [Grade C, Level 3]
f. Structured diabetes education and frequent follow up [Grade D, Consensus for T2DM].

4. In people with diabetes with recurrent or severe hypoglycemia, or impaired awareness of hypoglycemia, the following strategies may be considered to reduce

or eliminate the risk of severe hypoglycemia and to attempt to regain hypoglycemia awareness:

a. Less stringent glycemic targets with avoidance of hypoglycemia for up to 3 months [Grade D, Level 4]

5. Mild-to-moderate hypoglycemia should be treated by the oral ingestion of 15 g carbohydrate, preferably as glucose or sucrose tablets or solution. These are preferable to orange juice and glucose gels [Grade B, Level 2]. People with diabetes should retest BG in 15 minutes and re-treat with another 15 g carbohydrate if the BG level remains <4.0 mmol/L [Grade D, Consensus]. *Note*: This does not apply to children.
6. Severe hypoglycemia in a conscious person with diabetes should be treated by oral ingestion of 20 g carbohydrate, preferably as glucose tablets or equivalent. BG should be retested in 15 minutes and then re-treated with another 15 g glucose if the BG level remains <4.0 mmol/L [Grade D, Consensus].
7. Severe hypoglycemia in an unconscious person with diabetes:

a. With no intravenous access: 1 mg glucagon should be given subcutaneously or intramuscularly. Caregivers or support persons should call for emergency services and the episode should be discussed with the DHC team as soon as possible [Grade D, Consensus]
b. With intravenous access: 10–25 g (20–50 mL of D50W) of glucose should be given intravenously over 1–3 minutes [Grade D, Consensus].

8. Once the hypoglycemia has been reversed, the person should have the usual meal or snack that is due at that time of the day to prevent repeated hypoglycemia. If a meal is >1 hour away, a snack (including 15 g carbohydrate and a protein source) should be consumed [Grade D, Consensus].
9. For people with diabetes at risk of severe hypoglycemia, support persons should be taught how to administer glucagon [Grade D, Consensus].

Abbreviations: A1C, glycated hemoglobin; *BG*, blood glucose; *CVD*, cardiovascular disease; *CGM*, continuous glucose monitoring; *CSII*, continuous subcutaneous insulin infusion; *DHC*, diabetes health-care team; *SMBG*, self-monitoring of blood glucose.

Appendix B: InHypo-DM HealthCare Provider Questionnaire

Investigating Hypoglycemia: Your Perspectives on Diabetes Management Questionnaire (InHYPO-DM_HCPQ)

Many people with diabetes experience hypoglycemia now and then. The following series of questions will explore your thoughts, feelings, beliefs, and actions around helping your patients manage their hypoglycemia. Please be as honest and accurate as possible. There are no correct answers. We are interested in your opinion. There are 9 sections in total and other participants have taken 15 minutes to complete the survey. You may refuse to answer any question you do not want to answer. All responses will be kept completely confidential.

PLEASE READ BEFORE STARTING:

Questions will apply to *both* the treatment and prevention of hypoglycemia. We will refer to this as **hypoglycemia management**, unless specified. In addition, questions will refer to *all* "types" of hypoglycemia: mild or moderate as well as severe hypoglycemia. Please refer to the definitions provided below, which describe each of these "types" of hypoglycemia.

Mild or moderate hypoglycemia: When your patient has symptoms of hypoglycemia such as sweatiness, hunger, anxiety, weakness, confusion, heart palpitations, difficulty speaking, and/or loses his/her train of thought but is still able to take action to reverse these symptoms (for example by drinking a glass of juice, eating something, or taking a sugar pill).

Severe hypoglycemia: When your patient absolutely needs assistance from someone else because he/she is either unable to help him/herself or is not aware that he/she needs help.

SECTION 1 The following questions ask about your understanding of hypoglycemia and its management. Remember that **management refers to both treatment and prevention**. Please select the answer that you believe is true most of the time:

a) Please rate your level of knowledge:

		Very low	***Low***	***Moderate***	***High***	***Very high***
1.)	I would rate my level of knowledge about hypoglycemia as:	○	○	○	○	○
2.)	I would rate my level of knowledge about hypoglycemia management as:	○	○	○	○	○

a) Please indicate your agreement with the following items:

	In general…	***Strongly disagree***	***Disagree***	***Neither agree nor Disagree***	***Agree***	***Strongly agree***
3.)	…I have enough knowledge to help my patients manage their hypoglycemia.	○	○	○	○	○
4.)	…I know where to go to find information about managing hypoglycemia. Examples may be printed materials (such as guidelines), trusted websites, or conferences.	○	○	○	○	○
5.)	…I know where I can find support to help my patients manage their hypoglycemia. Examples may be consulting with another healthcare provider or team member, or referring a patient to another healthcare provider, team member, or care centre.	○	○	○	○	○
6.)	…I can access additional training or learning programs if I want to in order to help my patients manage their hypoglycemia.	○	○	○	○	○

	In general, I believe…	***Strongly disagree***	***Disagree***	***Neither agree nor Disagree***	***Agree***	***Strongly agree***
7.)	…I have the skills to help my patients manage their hypoglycemia.	○	○	○	○	○
8.)	…I tailor the delivery of my hypoglycemia care based on my knowledge of my patients' lifestyles and contexts.	○	○	○	○	○
9.)	…I am not as good as I could be at helping my patients' manage their hypoglycemia.	○	○	○	○	○

SECTION 3 These are questions about what you actually do when helping your patients manage their hypoglycemia. Remember that **management refers to both treatment and prevention**. Please select the answer that you believe is true most of the time:

	In general…	***Never***	***Rarely***	***Sometimes***	***Often***	***Always***
10.)	…I make an effort to keep track of my patients' progress with regard to managing their hypoglycemia.	○	○	○	○	○
11.)	…I advise my patients to increase the frequency of blood glucose monitoring when they are at increased risk for hypoglycemia.	○	○	○	○	○
12.)	…I make sure that I am prepared to help my patients manage their hypoglycemia.	○	○	○	○	○
13.)	…I am confident that I can help my patients' manage their hypoglycemia even when there is little time.	○	○	○	○	○
14.)	…addressing the specific appointment issue takes priority over discussing their hypoglycemia management.	○	○	○	○	○
15.)	…helping my patients manage their hypoglycemia is something I do routinely.	○	○	○	○	○
16.)	...the way I help my patients manage their hypoglycemia is informed by current evidence and guidelines.	○	○	○	○	○
17.)	…I take the initiative to help my patients improve their hypoglycemia management.	○	○	○	○	○
18.)	…I explain how to manage hypoglycemia to my patients.	○	○	○	○	○
19.)	…I discuss hypoglycemia-related guidelines regarding driving or operating heavy machinery with my patients.	○	○	○	○	○
20.)	…I solicit patients' input when discussing their hypoglycemia management.	○	○	○	○	○
21.)	…I use motivational strategies to help my patients manage their hypoglycemia. Examples may be praising, encouraging, reminding, or warning.	○	○	○	○	○
22.)	…my professional liability, according to my specific regulatory body, directs the way I manage patients' hypoglycemia.	○	○	○	○	○

SECTION 4 The following questions ask about what supports you in helping your patients manage their hypoglycemia. Remember that **management refers to both treatment and prevention**. Please select the answer that you believe is true most of the time:

	In general…	***Strongly disagree***	***Disagree***	***Neither agree nor Disagree***	***Agree***	***Strongly agree***
23.)	…I am committed to helping my patients manage their hypoglycemia.	○	○	○	○	○
24.)	…I know what helps me stay motivated to help my patients' care for their hypoglycemia.	○	○	○	○	○
25.)	…I believe that I have enough time to help my patients manage their hypoglycemia.	○	○	○	○	○
26.)	…I know how to help motivate my patients to manage their hypoglycemia.	○	○	○	○	○
27.)	…I have clear goals for managing my patients' hypoglycemia.	○	○	○	○	○
28.)	…my goals regarding hypoglycemia management align with my patients' goals.	○	○	○	○	○

SECTION 5 Healthcare providers may differ in their general outlook toward their management of hypoglycemia. We are interested in how *you* view helping your patients manage their hypoglycemia. Remember that **management refers to both treatment and prevention**. Please select the answer that you believe is true most of the time:

	In general, I believe that…	***Strongly disagree***	***Disagree***	***Neither agree nor Disagree***	***Agree***	***Strongly agree***
29.)	…I share responsibility with my patients for helping them manage their hypoglycemia.	○	○	○	○	○
30.)	…it is my responsibility to society to help my patients manage their hypoglycemia.	○	○	○	○	○
31.)	…managing hypoglycemia is consistent with my professional role.	○	○	○	○	○
32.)	…I am optimistic about managing my patients' hypoglycemia in the future.	○	○	○	○	○
33.)	…there is not much use in trying to help my patients avoid hypoglycemia because hypoglycemia will happen anyway.	○	○	○	○	○
34.)	…the benefits of helping my patients manage their hypoglycemia outweigh the effort I put forth.	○	○	○	○	○
35.)	…my patients' health will benefit if I help them manage their hypoglycemia.	○	○	○	○	○
36.)	...helping my patients manage their hypoglycemia is challenging.	○	○	○	○	○
37.)	…my patients adhere to my advice with regard to hypoglycemia management.	○	○	○	○	○
38.)	…helping my patients' manage their hypoglycemia takes too much of my energy.	○	○	○	○	○

SECTION 6 Healthcare providers may have different ideas about what is and is not supportive when it comes to helping their patients manage their hypoglycemia. Remember that **management refers to both treatment and prevention**. We are interested in whether your everyday professional life hinders or supports *your* ability to help your patients manage their hypoglycemia. Please select the answer that you believe is true most of the time:

	In general, to what extent do/does…	***Strongly hinders***	***Hinders***	***Neither hinders nor supports***	***Supports***	***Strongly supports***
39.)	…your **work environment** affect your ability to help your patients manage their hypoglycemia? Examples may be materials, staff support, etc.	○	○	○	○	○
40.)	…the **resources** provided to you affect your ability to help your patients manage their hypoglycemia? Examples may be from local authorities, employers, government, etc.	○	○	○	○	○
41.)	…the **media** affect your ability to help your patients manage their hypoglycemia? Examples may be the news, health advertisements, professional networking websites, publications, patient posters/handouts, etc.	○	○	○	○	○
42.)	…your **professional role(s)** affect your ability to help your patients manage their hypoglycemia?	○	○	○	○	○
43.)	…your **scope of practice** affect your ability to help your patients manage their hypoglycemia.	○	○	○	○	○

SECTION 7 We are also interested in how your social relationships affect your ability to help your patients manage their hypoglycemia. Remember that **management refers to both treatment and prevention**. Please select the answer that you believe is true most of the time:

	In general, to what extent do/does your relationship(s) with…	***Strongly hinders***	***Hinders***	***Neither hinders nor supports***	***Supports***	***Strongly supports***
44.)	…**other healthcare providers with whom you frequently work** affect your ability to help your patients manage their hypoglycemia? Examples may be physicians, nurses, pharmacists, etc.	○	○	○	○	○
45.)	…**other healthcare providers in the broader professional community** affect your ability to help your patients manage their hypoglycemia? Examples may be physicians, nurses, pharmacists, etc.	○	○	○	○	○

SECTION 8 Healthcare providers may experience worry and frustration regarding their patients' risk and management of hypoglycemia. Remember that **management refers to both treatment and prevention**. We are interested in knowing to what extent these emotions affect how *you* help your patients manage their hypoglycemia. Please select the answer that you believe is true most of the time:

a) Worry about your patients' hypoglycemia risk and management:

		Strongly hinders	***Hinders***	***Neither hinders nor Supports***	***Supports***	***Strongly supports***
46.)	In general, how does worrying about helping patients manage their hypoglycemia affect your ability to do so?	○	○	○	○	○

		Never	***Rarely***	***Sometimes***	***Often***	***Always***
47.)	Does this worry cause you to modify recommended guidelines when helping your patients manage their hypoglycemia?	○	○	○	○	○

a) Frustration about your patients' hypoglycemia risk and management:

		Strongly hinders	***Hinders***	***Neither hinders nor Supports***	***Supports***	***Strongly supports***
48.)	In general, how does your frustration about helping patients' manage their hypoglycemia affect your ability to do so?	○	○	○	○	○

		Never	***Rarely***	***Sometimes***	***Often***	***Always***
49.)	Does this frustration cause you to modify against recommended guidelines when helping your patients manage their hypoglycemia?	○	○	○	○	○

SECTION 9 This section contains questions related to your background and management of patients' mild/moderate or severe hypoglycemia events.

1. Sex:

   Male ☐
   Female ☐

2. Year of birth: _____

3. Location of practice:

   Urban ☐
   Rural ☐

4. Location of practice:

   Province (pick from the list): (ON, QC, NS, NB, MB, BC, PE, SK, AB and NL)

5. Type of practice:

   Hospital ☐
   Family Health Team ☐
   Other, please specify: _____

6. What is your current profession?

   ☐ Endocrinologist
   ☐ Internal Medicine
   ☐ Family Physician – Diabetes Specialist
   ☐ Family physician
   ☐ Nurse practitioner
   ☐ Pharmacist
   ☐ Nurse
   ☐ Dietitian
   ☐ Other _____

7. Are you a diabetes educator?

   Yes ☐
   No ☐

8. How long have you been practising in your current role (years)? _____

9. Where did you obtain your most recent professional degree?

Type in name of country: _____

1. How many people with diabetes do you see in an average week?

Type in the number of people: _____

2. Of these people, approximately what proportion have been diagnosed with Type 1 diabetes

Type in the percentage of people: _____ %

3. Of these people, approximately what proportion are taking medication for their diabetes that risks hypoglycemia (for example insulin or sulyphonureas)?

Type in the percentage of people: _____ %

4. Have you been diagnosed with diabetes?

Yes ☐
If yes, Type 1 ☐
Type 2 ☐
No ☐

5. Have you ever experienced a diabetes-related hypoglycemia event?

Yes ☐
No ☐

6. Do you want to be entered in a drawing to win a prize?

Yes ☐ → Q 15.
No ☐ →End of Survey

7. If yes, please enter your email address below so that you can be included in a drawing for a prize. This information will not be associated with your survey responses.

Email address [ ]

Curriculum Vitae

Name:	Caroline Villa Martignoni Rebicki
Post-secondary Education and Degrees:	Universidade Federal do Paraná *Federal University of Paraná* Curitiba, Brazil 1999-2006
	Sociedade Brasileira de Medicina de Família e Comunidade *Brazilian Society of Family and Community Medicine* São Paulo, Brazil 2012, Family Medicine Specialist
Related Work Experience	Medical Coordinator for Primary Care United Health Group Brazil 2018
	Teaching Assistant Positivo University Curitiba, Brazil 2015-2018
	Family Physician São José dos Pinhais, Brazil 2006-2016