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Impact of Community Pharmacists' Care on Self-Management in Type 2 Diabetes

By

Lisa Marian Schapansky 

A thesis submitted to the Faculty of Graduate Studies and Research in partial fulfillment of the requirements for the degree of Master of Science

in

Pharmaceutical Sciences

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Date: March 1, 2000

Abstract

The overall objective of this pilot study was to measure the impact of Certified Diabetes Educator (CDE) pharmacists in the community setting on clinical and humanistic outcomes of people with diabetes.

Sixty-two participants with type 2 diabetes were randomized to an intervention where they received diabetes care from CDE pharmacists or control where they received standard pharmacy services.

Result demonstrated differences in pharmacists' level of education and time to provide care in addition to differences in the intensity of care provided between the study groups. Glycemic control in the intervention group significantly improved ($p<0.001$). However, this improvement was not significantly different from the change in the control group. Small, but positive, differences (effect sizes = 0.1-0.5) were observed for most outcome measures, with small to moderate effect size estimates. Further study is required to determine the full impact of CDE pharmacists on outcomes of care for people with type 2 diabetes.

"My understanding of the role of a pharmacist is one of "dispenser of medication" which has been prescribed by a medical doctor or specialist. Possibly this is "old fashioned" and reason why pharmacy are involved in this and other programs to educate the public and improve health programs. I am sure that views will change drastically after a couple of months of involvement in this research project."

- A participant in the intervention group wrote this unsolicited comment on the back of a baseline questionnaire.

Dedication

I would like to dedicate this thesis to Anita Brown and Pam Davis
for bravely allowing me to design and implement this study to evaluate their practice.

Their vision of pharmacy and commitment to caring for people with diabetes
goes far beyond the job description of a pharmacist.

Acknowledgments

This thesis could not have been completed without the help and support of many individuals.

I would like to express my thanks to my parents, *Ann* and *Gerry Schapansky* and sisters, *Sarah* and *Emma* who have encouraged and supported me in my academic endeavors, whatever they may be.

Thank you, to my supervisor *Jeff Johnson* for accepting and supporting me in my graduate program. You have nurtured my interests and allowed me to grow tremendously. As *Jeff's* first graduate student, I am proud to have been a "guinea pig".

I would also like to thank the members of my committee, *Karen Farris*, *Ross Tsuyuki*, and *Ellen Toth* for sharing you perspectives and broadening my experience. An extra thanks to *Karen* for her open door policy and for gentle reminders about deadlines.

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I would like to acknowledge the *study participants'* for giving up their time to be a part of this study. It was greatly appreciated. I wish them luck in managing their diabetes.

This research was generously supported by a grant from the *Canadian Diabetes Association* in honor of *Alice Minerva Tufteland*, *Shoppers Drug Mart*, and the *Alberta Pharmaceutical Association*. Lastly, I would like to thank the *Institute of Health Economics* for their support.

Table of Contents

List of Tables

List of Figures

Chapter 1

Introduction

1.1.0 Statement of the Problem

Diabetes affects more than one million Canadians and has a significant economic impact in Canada.[1] Ninety percent of people with diabetes have type 2 diabetes. The recent United Kingdom Prospective Diabetes Study (UKPDS) demonstrated that intensive blood-glucose control can reduce microvascular complications in people with type 2 diabetes.[2] The UKPDS results also suggested that for every percentage point decrease in glycoslated hemoglobin (GHb) there was a 35% reduction in diabetes complications.[2]

Diabetes education is recognized as one factor that may contribute to improved self-care activities and, thus, improved metabolic control of diabetes.[3] Health care professionals have sought to teach people with diabetes the knowledge, skills, and attitudes essential to manage this disease and maintain a high quality of life.[3] The importance of diabetes education has been recognized in the literature and the current (i.e., 1998) clinical practice guidelines for the management of diabetes in Canada.[3-6]

While many high quality diabetes education programs exist, diabetes education is not optimally available to people with type 2 diabetes. In Canada, waiting lists for diabetes education programs can be from 6 to 12 weeks.[7,8] The Canadian Diabetes Association estimates that 30 % of people with type 1 diabetes and 70 % of people with type 2 diabetes do not receive appropriate diabetes self-care education.[9]

Pharmacists are ideally positioned in the community to reach people who are not receiving adequate diabetes education. On average, people with diabetes see pharmacists five times more often than other health care workers.[10] Most people with diabetes come into contact with pharmacists when they require testing supplies, syringes, insulin, or other medications. In such situations, pharmacists may help educate people who are unable to attend diabetic education clinics. In addition, the pharmacists' specific focus on drug therapy contributes to the multidisciplinary care of people with diabetes. Pharmacists have been encouraged to become Certified Diabetes Educators (CDE) to better help people with diabetes.[11,12] Pharmacists' prior training provides an excellent background for them to serve as CDEs.[12]

Previous research on the role of the pharmacist in diabetes care has focused on care provided in institutional based ambulatory clinics,[13-16] with prescribing privileges[13] and in selected populations such, as urban African-Americans[13] or Mexican-Americans.[17] Recent studies suggest that pharmacists' support in community settings can help to improve participants' glycemic control over baseline.[18,19] However, both of these community-based studies were conducted in the United States and neither employed a control group.[18,19] These features may limit the internal and external validity of the results. To date, there is no Canadian research examining the effect of pharmacists in the community setting, where the majority of people with diabetes come into contact with pharmacists. Furthermore, researchers have not evaluated the role of pharmacists with diabetes educator certification.

1.2.0 Research Objectives

The overall purpose of this study was to measure the impact of CDE pharmacists in the community setting on clinical and humanistic outcomes of people with type 2 diabetes. Specific research objectives were to determine the effect of CDE community pharmacist patient management on patients':

1) glycemic control,

2) attitudes, beliefs, and confidence in managing diabetes,

3) self-care activities, and

4) expectations and satisfaction with pharmacy services.

It was hypothesized that CDE pharmacists would aid in significantly lowering participants' GHb values and improving participants' beliefs, attitudes, and confidence toward diabetes and self-care activities. Participants' expectations for pharmacy service were anticipated to increase relative to participants not seeing a CDE pharmacist, while satisfaction with pharmacy services was expected to remain high throughout the study.

1.3.0 Significance of the Research

In this research project, CDE pharmacists provided one-on-one patient assessment, teaching, referral to other members of the health care team, and follow-up for people with type 2 diabetes. The evidence generated by this research was intended to explore how CDE pharmacists could affect the outcomes of people with diabetes. Research such as this could be utilized by several audiences including pharmacy-practice researchers, pharmacists, pharmacy chains, health care payers, health care planners, and people with diabetes.

This research may be significant to pharmacy-practice researchers. There is debate on which outcomes should be assessed when looking at the impact of diabetes education.[20] For this reason, both clinical and humanistic outcomes were measured to better elucidate the pharmacists' role in diabetes care, to ascertain which outcomes pharmacists can impact, and to serve to guide future research endeavors.

This research may be useful to pharmacists who wish to evaluate the benefit of providing increased diabetes care to their patients. Similarly, this research may also be useful to pharmacy chains who support their pharmacists to provide these services and advertise these services. If research shows the benefit of the pharmacists care, it may substantiate claims of improved health after receiving pharmacist services.

A positive outcome could be used to support reimbursing CDE pharmacists for diabetes management. Payers such as provincial health plans, private insurance, and employers an interest in improving the health of people with diabetes may use research such as this to assess whether to use pharmacists to provide care for people with diabetes.

Furthermore, if benefits were shown, pharmacist community-based diabetes care may be suggested to have a role in under-serviced areas, such as rural Canada. Health care planners such as regional health authorities may use this research while searching for innovative ways to deliver care to people with diabetes using available health care providers such as pharmacists. Evidence demonstrating the benefits of pharmacists providing community-based diabetes education may encourage pharmacists to provide increased diabetes care.

Finally, the results of this project may be important to people with diabetes. As described in the statement of the problem, diabetes education can improve the health of

people with diabetes, however access to education in not optimal. Research, which evaluates the role of pharmacists in the community, may help patient advocacy groups such as the Canadian Diabetes Association assess how people with diabetes can best receive health services. For people with diabetes, this research may help them consider how the care of pharmacists, a very accessible health care professional whose expertise focuses on medication, may fit into their diabetes management strategy.

Chapter 2

Literature Review

2.1.0 Diabetes

2.1.1 Burden of Diabetes

One Canadian is diagnosed with diabetes every eight minutes.[21] It is estimated that more than 1.2 to 1.4 million Canadians have diabetes although only 800,000 of these cases are diagnosed.[1] Previous estimates have shown prevalence rates from 2.4 % to 12.4 % of the population using different methodologies and studying different populations.[1] People aged 65 years and over have three times the prevalence of diabetes compared to people aged 35 to 65.[1] As the population continues to age, the prevalence of diabetes in Canada is expected to increase two percentage points by 2025.[22]

Diabetes is a metabolic disorder characterized by the presence of hyperglycemia due to defective insulin secretion, insulin action or both.[4] The are two primary types of diabetes. Type 1 diabetes accounts for 10 % of diabetes. Type 1 diabetes is thought to be an autoimmune disease where the body destroys the beta cells in the pancreas, thus the body cannot produce endogenous insulin.[4] It has been hypothesized that beta cell destruction is triggered by a viral infection. People with type 1 diabetes are often thin, are prone to developing ketoacidosis, and cannot survive without insulin supplementation.[23] Type 1 diabetes usually develops in children or young adults. Type 1 diabetes has previously been referred to as juvenile onset diabetes, type I diabetes or

insulin dependent diabetes (IDDM).[4] According to United States data, people with type 1 diabetes have a minimum 15-year reduction in life expectancy.[1]

Type 2 diabetes has previously been termed adult onset diabetes, type II, or non-insulin dependent diabetes (NIDDM).[4] The majority of people with type 2 diabetes are obese and display insulin resistance as a main pathophysiologic feature.[23,24] People with type 2 diabetes constitute 90 % of people with diabetes. Risk factors for type 2 diabetes include *modifiable factors* such as obesity and physical inactivity and *non-modifiable factors* such as family history, age (onset after 40 years of age), and ethnic background (higher prevalence rates are observed among Aboriginal, Black and Hispanic populations).[1] The number of people with type 2 diabetes is expected to increase as the population ages and because of new diagnostic criteria. Type 2 diabetes is now defined as a fasting blood glucose level greater than 7.0 mmol/L where previously the threshold was 7.8 mmol/L.[4]

Before the discovery of insulin, diabetes was often a fatal condition. Now with insulin and other therapies, people are living longer and may develop long term complications from diabetes.[25] Complications are classified as microvascular and macrovascular. Microvascular complications are caused by hyperglycemia which damages arterioles and capillaries causing retinopathy, nephropathy, and neuropathy.[26] Diabetes is the leading cause of new cases of legal blindness among working age people, i.e., retinopathy,[1] and is responsible for 40 % of end stage renal disease, i.e., nephropathy.[27] Sixty percent of people with diabetes have some degree of neuropathy which can lead to sensory loss with risk of foot amputation, gangrene, and amputation.[1] Macrovascular complications involve large vessels such as the coronary, cerebral, or

peripheral vessels.[26] People with diabetes are two to six times more likely to have heart disease or stroke.[1]

Not only does diabetes have an immense toll on the health of Canadians, it also has a large economic impact. In 1993, Health Canada estimated the costs associated with diabetes at $1.1 billion.[1] This is likely an underestimate because this figure does not include the costs of complications such as cardiovascular disease and renal failure.[1] In 1992, the costs of diabetes in United States were estimated at $92 billion including direct and indirect costs.[28] It has been approximated that diabetes accounts for one in seven dollars Americans spent on health care.[29] These staggering numbers are predicted to increase in view of improved disease detection,[4] an aging population, and/or increased obesity and sedentary lifestyles.[30]

2.1.2 Treatment of Diabetes

Reducing long-term diabetic complications may significantly decrease costs associated with complications arising from type 1 diabetes.[31] The Diabetes Control and Complications Trial (DCCT) showed that intensive therapy slows the development and progression of retinopathy, nephropathy, and neuropathy by 60 to 70 % in people with type 1 diabetes.[32] By reducing these complications, the high human and economic cost of diabetes can be lessened.[33]

Until recently, it was not clear whether tight glycemic control reduced complications in people with type 2 diabetes. Several authors had suggested that people with type 2 diabetes should strive for tight glycemic control when contraindications such as co-morbidity or advanced age are not present.[34-36] In addition, a randomized trial demonstrated a relationship between improved glucose control and decreased

microvascular complications in lean Japanese people with type 2 diabetes.[37] There was also limited evidence from a 25-year retrospective review of complications and an epidemiological study of diabetic retinopathy demonstrating that poor glycemic control is linked with increased complications in type 1 and 2 diabetes.[38,39] Yet, not all evidence supported tight control of type 2 diabetes. A trial randomized 153 men to intensive or conventional treatment for 27 months, and despite a two percent difference in glycoslated hemoglobin (GHb), there were no statistically significant differences in cardiovascular events.[40]

The recently completed United Kingdom Prospective Diabetes Study (UKPDS) is the largest study on blood glucose control in type 2 diabetes.[2] This large multi-centre study recruited 5,102 people with newly diagnosed type 2 diabetes. At diagnosis, 50 % of patients had signs of diabetes complications including cardiovascular disease, retinopathy, microalbuminuria, absent ankle reflexes, and hypertension.[41] Patients were followed for an average of 10 years to determine whether intensive policies to lower blood glucose would result in clinical benefits and whether sulfonylurea medications, metformin, or insulin had greater therapeutic advantages.[42] The study was originally designed to have four treatment groups. One group was conventionally managed with diet alone while the other three groups were intensively managed with one of the following medications: chlorpropamide, metformin, or insulin. The treatment goal in the intensively managed groups was a fasting blood glucose of 6.0 mmol/L and in the conventional group the treatment goal was a fasting blood glucose level of 15.0 mmol/L. Over time, UKPDS researchers found that monotherapy could not maintain the treatment goal in the intensively managed groups, thus combination therapy was used. Similarly in

the conventional group, diet often was not adequate to maintain blood sugars less than 15.0 mmol/L, thus at least one hypoglycemic medication was initialized in 80 % of patients in the conventional group.

The intensively managed groups were analyzed as a single group. Intensive therapy resulted in a median GHb of 7.0 % compared to conventional therapy with a median GHb of 7.9 %. Microvascular complications were reduced by 25 % in the intensive group. In addition, epidemiological analysis of the UKPDS demonstrated that for every percentage drop in GHb there was a 35 % reduction in microvascular complications. There were no statistically significant differences in cardiovascular outcomes (fatal and non-fatal myocardial infarction and sudden death) between the intensively managed and conventional groups; however, epidemiological analysis showed that for every percentage drop in GHb there was a 25 % reduction in diabetes-related deaths and an 18 % reduction in combined fatal and nonfatal myocardial infarction. Because there were no cardiovascular differences between the study groups, the role of intensive glucose control in cardiovascular disease is still unclear.[42] However, sulfonylurea or insulin therapy did not increase the rate of myocardial infarctions or diabetes-related deaths, reassuring clinicians that intensive therapy may not adversely impact people with type 2 diabetes.[43]

A second arm of the UKPDS evaluated the treatment of hypertension in individuals with type 2 diabetes.[44] Hypertensive patients were randomized to tight blood pressure control (less than 150/85 mm Hg) or less stringent blood pressure control (less than 180/105 mm Hg). Patients randomly assigned to treatment with either an angiotensin converting enzyme (ACE) inhibitor (captopril) or a beta-blocker (atenolol).

The tight control group achieved a mean blood pressure of 144/82 mm Hg compared to the less stringent control group with a mean blood pressure of 154/87 mmHg. Tight blood pressure control significantly reduced the risk of strokes by 44 %, diabetes-related deaths by 32 %, and microvascular complications by 37 %. There were no differences between ACE inhibitor and beta-blocker on any outcome measured including microalbuminuria or protienuria. Patients on beta-blockers had slightly better blood pressure control (1-2 mm Hg).

2.1.3 Feasibility

The message in the both the DCCT and UKPDS is that hyperglycemia should be treated vigorously in people with diabetes.[42] Moreover, the UKPDS supports the systematic treatment of hypertension in people with diabetes. However, clinicians have raised concerns about the feasibility of achieving strict glycemic control in the diabetic population. At issue are a lack of physician expertise and time, financial resources, and patient compliance with complex lifestyle modification.[45] In the DCCT, a team of physicians, nurses, and dietitians educated, monitored, and followed people with diabetes receiving intensive insulin therapy. This specialized multi-disciplinary team is not available to the majority of people with diabetes. Interestingly, it has been noted that non-physician health care professionals had the most involvement with patient education and follow-up in the DCCT.[46]

People who report having a regular provider of diabetes care had improved self-care activities including: following a special diet, monitoring blood glucose levels, and undergoing a GHb test, foot exam, and cholesterol check.[47] However, in 1997 in the United States 10 % of people did not have a regular physician for diabetes care, and 32 %

of people visited their regular physician less than four times a year.[48] A recent study in the United States found that in rural areas the number of primary care physicians were insufficient to meet the national average of visits for required diabetes.[49] Pharmacists were the most prevalent health care workers in these rural areas. It was suggested that pharmacists and other health care professionals could deliver some level of primary care to people with diabetes. While the numbers in Canada may be different, there is a recognized physician shortage in rural areas[50] and this may reduce the feasibility of physician-based intensive treatment policy in diabetes.

2.2.0 Diabetes Education

Diabetes education has been defined as "the teaching and the learning of the body of knowledge and skill [related to the management of this chronic disease], with the ultimate goal being to promote the behavior changes necessary for optimal health outcomes, psychosocial adaptation, and quality of life."[3]

Diabetes education is recognized as one factor that contributes to improved self-care of diabetes and thus improved control in diabetes[51,52] A meta-analysis of 82 studies on educational interventions in adults with diabetes illustrated that diabetes education improves patient outcomes.[5] Patient education had a moderate to large effect on knowledge, a small to moderate effect on self-care behaviors, a moderate effect on GHb and blood sugars, and a small effect on psychological outcomes.[5]

2.2.1 Access to Diabetes Education

"[P]eople affected by diabetes have the right to access diabetes education and the diabetes team."[6] While the importance of diabetes education has also been recognized in

the literature and the 1998 Canadian Clinical Practice Guidelines for the Management of Diabetes[4], not all people have equal access to diabetes education. A review of the literature revealed that 50 to 80 % of people with diabetes have severe deficits in knowledge about self-care activities.[8] In the United States, it has been estimated that only 35 % of people with diabetes have attended a diabetes class or program.[53] The lowest rate of education was among those who are not taking insulin, having lower socioeconomic status, or living outside urban areas.[53]

The Canadian Diabetes Association (CDA) estimates that 30 % of people with type 1 diabetes and 70 % of people with type 2 diabetes do not receive appropriate diabetes self-care education.[9] However, these statistics are based on a chart review in one Canadian hospital, and consequently may not be generalizable across Canada. In Canada, waiting lists for diabetes education programs can be from 6 to 12 weeks.[7,8] Some regions have duplications of diabetes educational services while others completely lack services.[7]

Concern has also been raised about the follow-up of people with diabetes.[54] Most diabetes education programs are short-term and information-based without continued enforcement of new behaviors. Programs without reinforcement are less likely to influence participant's behavior.[54]

With an aging population the number of people with type 2 diabetes is expected to increase. Older adults may have greater difficulty achieving glucose control because they have less access to education and an increased number of co-morbidities.[51,55] A meta-analysis of diabetes education interventions found that older participants had fewer improvements in outcomes, especially those related to knowledge.[5] The reason for the

lack of effect in this population is unknown[5] and few studies assess the educational needs of older adults.[55,56] Research is needed to determine what education techniques are most effective in older adult with diabetes.[56]

2.2.2 Diabetes Educator Certification

Certified Diabetes Educators (CDEs) are health care professionals including registered nurses, registered dietitians, pharmacists, physicians, registered psychologists, physiotherapists, and social workers, who have a sound knowledge base in both diabetes care and educational processes, in addition to good communication skills and a dedication to excellence in diabetes education.[58] Certification is voluntary through the Canadian Diabetes Educator Certification Board. In order to be certified, health care professionals must write a competency exam on areas including pathophysiology, nutrition, self-care management with medications, hypoglycemia, hyperglycemia, blood glucose monitoring, activity, psychosocial/lifestyle, and education theory. In addition, applicants are required to have two years of full-time work experience in their field, and spend at least one day per week or 400 hours per year in direct diabetes education.[58]

Certification as a CDE recognizes competencies in specialized area and requires performance in knowledge, skill, and patient care.[59] Certifications differs from certificate programs. A certificate program allows pharmacists to acquire knowledge and skills in a new practice area whereas certification assesses the performance of pharmacists in that area.[59] Health care professionals may not need CDE designation to provide excellent care to people with diabetes, however a CDE designation affords several advantages. First, certification allows recognition for excellence in diabetes care[57] and ensures a minimum level of care in diabetes. CDE certification is recognized by other health care

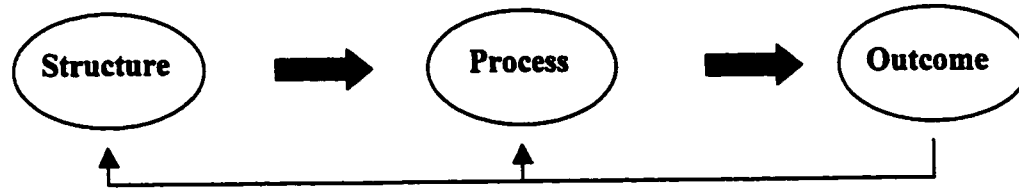
disciplines and may help to establish an individual's credibility in providing care to people with diabetes.[60] Lastly, a national recognized program may help health care professionals seeking reimbursement for diabetes care provided to people with diabetes. A survey at the Canadian Diabetes Association Conference in 1998 asked 250 CDEs what they perceived as benefits of certification.[61] They listed increased job security, a cohesiveness among team members with certification, and an increase in self-confidence as a diabetes educator.

2.2.3 Evaluating Diabetes Education

2.2.3.1 Quality of Care Assessment

When assessing the quality of patient care, researchers often use frameworks to guide them. Donabedian first proposed the structure, processes, and outcomes (SPO) framework in 1967 to assess at the quality of medical care.[62] This framework assesses structures which support the processes or the actions of care which in turn influence patient outcomes (Figure 2.1). Both the pharmacy [63] and diabetes education literature[64,65] propose the application of the SPO model. McLeod described a modified version of SPO to examine diabetes education. This model includes the first three elements of SPO plus a fourth variable, impact, which looks at the effect of a diabetes education program on the community.[7]

Figure 2.1 Structure, Process, and Outcome Model.



It is important to collect information simultaneously on all elements of SPO, in order to examine the relationship amongst the elements. This could help to establish the link between a pharmacist's processes and patient outcomes. Without attention to all three levels of indicators, it would be more difficult to attribute changes in patients' health outcomes to enhanced pharmacy services. Of course, there still remains the possibility that patients receive care from other health professionals that would impact their health outcomes.

The first element of the SPO model, structure, refers to the resources in place to provide care to patients. Examples include pharmacist training, e.g.: certification, physical layout of the pharmacy, stock, and staffing.[63] Additional structures have been used to describe the structures of diabetes education centres[64] including documentation forms, education aids, amenities in the facility, and facility accessibility. While structures do not guarantee quality care, they are vital to the provision of quality care.

Processes are the actual activities of care provided. Pharmacists often evaluate the process of care they provide as these indicators are convenient and relevant. Process indicators that pharmacist use include gathering patient information, providing education, identifying and resolving drug related problems, meeting with other health care professionals, and developing patient relationships.[63] Process indicators that apply to diabetes education include teaching strategies, centre philosophy whether it be mainly educational or clinical, and use of non-medical terminology.[64]

The final component of the SPO model is outcomes. Donabedian broadly defined outcomes as "changes in the current or future health status of patients that occur as a

result of antecedent medical care."[62] When evaluating the outcomes of a pharmacist's care, Farris and Kirking recommended the goals of pharmaceutical care (PC).[63] These include cure of disease, elimination or reduction of symptoms, slowing of disease processes, and prevention of disease or symptoms.[66] In the health outcomes and diabetes education literature, there is discussion on what are the optimal outcomes to assess the quality of patient care.[67,68]

2.2.3.2 Outcomes

The economic, clinical, and humanistic outcomes (ECHO) model was developed to address the question, which outcomes should be measured?[67] Traditionally, clinicians have been interested in clinical outcomes, payers have been focused on economic outcomes, and patients have been concerned about humanistic outcomes. Economic outcomes assess the total cost of treatment including medical, non-medical, and indirect costs. Clinical outcomes include medical events that occur as a result of disease treatment. Finally, humanistic outcomes refer to the impact of a treatment on a patient's life.[67] By combining these in the ECHO model, research will heed society's perspective on the value of medical services.

Glasgow and Osteen reviewed the diabetes education literature through 1990 and concluded that evaluations were too narrowly focused on clinical outcomes and were not addressing patient and economic outcomes.[68] They concluded that most studies have evaluated patient knowledge and GHb (Table 2.1).[68] Studies have shown that knowledge is weakly related to other outcomes such as self-management or glucose control.[68,69]

Table 2.1 Processes and Outcomes in Diabetes Education Research [68]

Processes and Mediating Variables	Diabetes Management
Knowledge	Lifestyle Change
Attitudes	Dietary
Self-Efficacy*	Eating Behaviors*
Problem Solving/Coping Skill*	Exercise
Social Support	Medical Self-Care
Personal Models*	Glucose Testing
Health Beliefs/Intentions	Medication Adherence
Short Term Outcomes	Insulin Self-Regulation*
	Foot Care
GHb	Patent-Provider Interactions**
Glucose Variability*	**Long Term Health Outcomes**
Hypoglycemic Episodes*	
Cardiac-Cholesterol Levels*	Complications*
Blood Pressure, Smoking,*	Retinopathy*, Neuropathy*, Renal
Weight	Failure, Sexual Dysfunction*, Stroke*
Health Related Quality of Life**	Mortality*
Functional Limits, Psychological*	Cost-Effectiveness**

* Variables that have not been studied sufficiently

** Variables that have been studied less often that are more important to assess

Patient's attitudes, beliefs, and confidence in managing diabetes have been shown to impact diabetes management. A patient's attitude toward diabetes has been shown to be positively associated with their level of self-care activities.[70] A change in patient's score on an attitude instrument may indicate the first stage in behavior modification according to the Theory of Reasoned Action.[71] This theory states that behavior is best predicted by one's intentions, which are in turn influenced by attitudes and social norms. Improved attitudes have been related to increased self-care behaviors including maintaining diet, monitoring blood glucose, and recording of test results, all of which subsequently lead to improved glucose control.[70] However, attitudes are not the only influence on behavior.

The health beliefs of people have also been shown to affect behavior.[72] The Health Belief Model states that people are more likely to take health action when the perceived threat of the disease outweighs the perceived risks involved with treatment. In the case of diabetes, people who believe that they are susceptible to diabetes

complications and also believe the risk of complications is decreased by self-care, would be more likely to perform self-care behaviors.[7] Health beliefs such as perceived severity of the disease have been related to glycemic control, but not directly to self-care activities.[73,74]

Finally, people with higher level of self-efficacy or confidence are more likely to better manage their diabetes self-care activities.[75-77] Self-efficacy was first described as part of Bandura's social cognitive theory.[78] Self-efficacy is achieved through personal experience or by observing behaviors modeled by others.[79] The Transtheoretical model (TTM) is another theory to explain behaviors, and also includes self-efficacy as part of its framework. TTM has been used to help predict, explain, and change human behavior such as smoking cessation, drug abuse, and self-care behaviors in diabetes.[80,81] People with a higher levels of self-efficacy may progress through the stages of the TTM from unwillingness to change (precontemplation), considering change in the next six months (contemplation), planning change in the near future (preparation), performing change behaviors (action), and continuing the change for a prolonged period (maintenance).[81] This staged model is not necessarily linear and people may repeat stages. TTM may be useful in diabetes management because it helps educators design stage-specific interventions for people with diabetes.[82,83] It also allows for quicker recognition of success as people with diabetes progress through the stages of change, instead of waiting for improvements in health outcomes to mark success.[80]

Many short-term outcomes address the clinical health of people with diabetes (Table 2.1). Mortality, of course, is the ultimate health outcome; however GHb may be viewed as a surrogate outcome. Large lengthy research trials, such as the DCCT and

UKPS, have clearly established the links between the intermediate outcomes of glycemic control and the long-term diabetes complications.[2,32] GHb is commonly used as measure of glycemic control because it reflects changes over the previous few months and is not subject to rapid fluctuations in blood glucose. A GHb less the 115 % of normal (e.g. 4.1 to 6.1) is the customary treatment goal for type 2 diabetes.[4]

HRQL "represents those parts of life that relate to an individual's health [and] conceptually, HRQL includes domains of physical, psychological, social, spiritual, and role function, as well as general well being."[84] It has been suggested that health-related quality of life (HRQL) should be measured whether or not it relates to diabetes control.[68] Some authors have found that glycemic control varies with HRQL,[85-88] while other researchers have found no relationship between diabetes control and HRQL in either type 1[89,90] or type 2 diabetes.[91]

There are two approaches to quality of life, generic instruments which look at HRQL in any population and specific instruments which focus on a disease or population.[92] The Diabetes Quality of Life (DQOL) instrument is an example of one diabetes specific instrument that was used in the DCCT.[93] Using this instrument, researchers found that HRQL did not deteriorate with intensive insulin therapy in people with type 1 diabetes.[94] HRQL was also assessed in the UKPDS using both a generic instrument and a disease specific instrument.[95] In the UKPDS, HRQL did not vary with different treatment policies for glycemic control or hypertension. However, HRQL was reduced in people who had a diabetes-related complications and people who reported frequent hypoglycemic episodes.

In the area of diabetes self-care management (Table 2.1), lifestyle change, medical self-care, and patient-provider interaction are commonly assessed outcomes. All three of these outcomes may be considered processes or intermediate outcomes, as they do not directly impact health. Diabetes is a chronic disease whose management entails substantial lifestyle modification. People are expected to follow complex regimens that include exercising, restricting diet, taking medications, injecting insulin, and measuring blood sugars. Researchers have referred to these activities as self-care.[96] A high level of self-care is likely to improve glycemic control and decrease long term diabetic complications.[32,97] Researchers have recognized the importance of measuring changes in self-care in addition to glycemic control,[51] though many studies assessing self-care activities have not used validated instruments.[68] The Summary of Diabetes Self-Care Activities (SDSCA) was developed and validated as a brief, and reliable instrument to measure changes in the level of self-care activities. Instruments such as this have been used to show improvements in self-care activities after diabetes education.[51]

Glasgow identified patient-provider interaction as an important understudied area in diabetes education.[68] Unsatisfactory interaction between patients and providers has been shown to negatively affect patient behaviors.[76,98,99] Furthermore, in one study, patients who reported positive physician relationships had improved metabolic control.[100] Golin and DiMatteo described a model of determinants of patient adherence, whereby they hypothesized that increased patient participation in the patient-provider interaction may improve patient satisfaction with diabetes care, which may in turn, increase patient adherence to self-care activities.[76]

Patient satisfaction with general medical, diabetes, and pharmacy care has been used to evaluate the patient-provider interaction. In the medical literature, patient satisfaction serves as an indicator of the quality of care and a predictor of adherence. [101] "Satisfied patients are more likely than unsatisfied ones to continue using health care services, maintain relationships with providers, and comply with care regimens."[76,101] Furthermore, people with diabetes have been shown to be satisfied with the care they receive from nurse educators,[102] hospital affiliated clinics,[103] physicians in hospital affiliated clinics,[104] general practitioners,[105] and the diabetes team in the community setting.[106] However, satisfaction with diabetes care has been shown to vary with an individual's level of education or type of health care system.[103] Physicians who viewed their patient relationships as partnerships had patients who were more satisfied with diabetes care compared to physicians who viewed the relationship as physician controlled.[104]

Satisfaction with pharmacy services has been shown to be high, particularly when expectations are being met.[101,107-110] In one study, patients with diabetes have higher expectations of traditional pharmacy activities such as counseling and documenting necessary information than of PC activities such as patient assessment and monitoring.[111] It is not known if people with diabetes have higher expectations of CDE pharmacists or if these expectations would be met with the care provided by pharmacists with a CDE designation.

Glasgow stressed the measurement of long term health outcomes (Table 2.1).[68] While these are seldom feasible, they help to provide answers to what care best helps people with diabetes. Finally, Glasgow concluded that future diabetes education

evaluations should broaden the range of outcomes assessed. Yet, within a given outcome, he recommended that researchers should employ a limited set of efficient, validated instruments.[68]

2.3.0 Role of the Pharmacist

2.3.1 Role of the Pharmacist in Patient Care

While there are numerous examples of pharmacists' care for people with diabetes, historically, pharmacists did not fulfill on this role. Pharmacists have traditionally assumed the role of preparing medication pursuant to a physician's prescription, however this role has expanded in the past four decades.[112] In the 1960s, clinical pharmacy originated where pharmacists performed enhanced functions such as monitoring drug therapy, pharmacokinetic dosing, and provision of drug information.[113] Clinical pharmacy was similar to traditional pharmacy in that it placed drugs and drug delivery at the centre of pharmacy practice. In 1975, Mikeal et al. first described pharmaceutical care (PC) as "the care that a given patient requires and receives which assures safe and rational drug usage."[114] This new concept of patient focused care was elaborated on by Brodie et al. in 1980 when he stated that "PC includes the determination of the drug needs for a given individual and the provisions not only of the drug required but also of the necessary services (before, during, or after treatment) to assure optimally safe and effective therapy.[115]

Helper put forward a more reflective definition of PC in 1987 when he stated that PC is a "convenantal relationship between a patient and a pharmacist in which the pharmacist performs drug-use-control functions (with appropriate knowledge and skill)

governed by awareness of and commitment to the patient's interest."[116] In 1990, Hepler and Strand authored the most common definition of PC. "PC is the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient's quality of life."[66]

Hepler and Strand have since developed different approaches toward PC. Strand, along with Cipolle and Morley, have further defined PC in a holistic manner where "the practitioner takes responsibility for patient's drug-related needs, and is held accountable for this commitment."[117] Helper has taken a more technical approach to PC, referred to as Therapeutic Outcomes Management (TOM), whereby a pharmacist manages patient's outcomes in one or more targeted diseases.[118] Hepler explained that pharmacists may be more comfortable learning PC with this approach. Regardless of whether pharmacists favour a holistic or TOM approach to PC, it is clear that pharmacists' professional responsibility now focuses on caring for the patient.

2.3.2 Role of the Pharmacist in Diabetes Education

The need for increased diabetes education presents an excellent opportunity for pharmacists to become more involved in the education and follow-up of people with diabetes. On average, people with diabetes see pharmacists five times more often than other health care workers.[10] Most people with diabetes come into contact with pharmacists when they require insulin, syringes, testing supplies, or other medications. In this way, pharmacists may have the occasion to reach people that are less likely or unable to attend diabetic education clinics. In addition, many pharmacies in urban centres are opened with extended hours that provide people with more flexible access to

pharmacists. However, it is unknown if individuals with diabetes consider pharmacists as a source for diabetes education.[119]

According to 1997 IMS Canadian data, medications for diabetes therapy comprised 3.2 % of the market share by total prescriptions accounting for 7,667,000 million prescriptions.[120] Because diabetes management usually requires multiple medications, pharmacists have the ideal training in medication use and disease management to help people with diabetes.[121] This training provides an excellent background for them to serve as CDEs.[12]

Pharmacists have been encouraged to obtain certification through the CDE program, in order to better educate people with diabetes on their disease and medication.[11] In a survey performed in Alberta, two percent of pharmacists indicated that they had a CDE designation and another two percent indicated that they were interested in becoming a CDE.[122]

A CDE pharmacist recently described her role which includes the following: 1) counseling and monitoring on medication, 2) training and on-going assessment on blood glucose monitors 3) supplying diabetes care products and literature, 4) advising on acute complications, 5) ensuring third-party coverage, 6) identifying needs and referral to the diabetes care team, and 7) providing support and encouragement.[123]

In survey of 661 pharmacists in the United States registered with the American Diabetes Association, 118 pharmacists who were CDEs provided more nutritional education and had more years' experience providing education than did pharmacists without CDE.[124] Pharmacists charged equal amounts for their services whether they were

a CDE or not, however further results show that CDEs may have more success in billing for their services.

While most pharmacists are not CDEs, pharmacists in Mississippi are paid for diabetes management if they have been accredited by the state.[125] In a recent survey of Canadian private payers, 53 % said that they would reimburse pharmacists if pharmacist services could be linked to reductions in long term disability, absenteeism, or improved productivity.[126]

Five primary roles have been identified for pharmacists in the care of individuals with diabetes including: 1) identification of people with diabetes, 2) assessment of the patient's needs, 3) education, 4) monitoring, and 5) patient referral to other health care professional for eye, foot, dietary, and other care.[10] There are several descriptive reports of pharmacists in these roles. In 1977, Schilling described a program where pharmacists provided primary care for people with diabetes which included monitoring of lab values, assessment of patient's glucose control, refill of prescriptions, and referral to a physician when necessary.[127] In a second example published in 1983, pharmacists were reimbursed for assessing patients' educational needs, providing individualized treatment plans, and monitoring glucose control for people with diabetes in an ambulatory-care setting for 10 years.[128]

Recently, there are more reports of pharmacists providing care to people with diabetes. Early in 1999, the Wall Street Journal published "Not Just a Pill Pusher" which described the day of a pharmacist who met with 16 people with diabetes.[129] This article suggested that there is a "turf war" over care of the patient between pharmacists and physicians, yet the American Pharmaceutical Association reported that pharmacists only

modify medication treatments when a collaborative relationship has been established with physicians. At the American Pharmaceutical Association Conference in 1999, Rodriguez de Bitter described the implementation of diabetes care program in a busy pharmacy[130] and Nau described the diabetes care provided by a network of five community pharmacies.[131]

While pharmacists have excellent access to people with diabetes and an in-depth understanding of medications, they need the expertise of the diabetes team to best deliver diabetes care. The Canadian Diabetes Association suggests interdisciplinary teams as the best way to deliver care to people with diabetes.[4,6] A team usually consists of the person with diabetes at the centre supported by a primary care physician, diabetes specialist, and diabetes educator (nurse or dietitian). The team may also consist of medical specialists such as ophthalmologists and nephrologists and other professionals such as social workers, podiatrists and pharmacists.[4]

Ideally, pharmacists would work directly with the diabetes team to help optimize medication use. However, diabetes care teams are customarily affiliated with a hospital or large care centre whereas the majority of pharmacists work in the community. Still, pharmacists have found ways to connect with the diabetes team by sending letters to the physicians about care provided,[130] establishing a referral network from other health care providers to pharmacists,[16,128,131] referring patients to diabetes centres,[19] and working with other health care providers to establish care guidelines.[127,128] The Canadian Medical Association and the Canadian Pharmacists Association have developed a joint statement on approaches to enhancing the quality of drug therapy.[132] While this document is not specific to diabetes, it does provide a framework for physician and pharmacist

collaboration on medication therapy. There is international interest in team care and pharmacists as noted by a Japanese article on the pharmacist's role on the diabetes education team.[133]

2.3.3 Evaluations of Pharmacist Role in Diabetes

In a review of the literature, twelve studies were found evaluating the impact of pharmacists' care for people with diabetes (Table 2.2).[13-15,17,134,16,18,19,135-138] These studies were identified by a MEDLINE and EMBASE search using the key terms diabetes, pharmacy, and pharmacist. Articles were also identified through the dissertation abstracts and colleague referral. These studies primarily focused on clinical outcomes, but also included measures of self-care management and quality of life. More recently, economic outcomes and resource utilization have been included.

In 1977, Sczupak and Conrad first investigated the effect of patient-oriented pharmaceutical services on 40 ambulatory people with diabetes in a 12 month randomized controlled study at a hospital affiliated clinic.[15] In the intervention group, pharmacists monitored drug profiles, provided additional drug information, consulted with other health care workers on the patient's behalf, resolved financial problems related to drug therapy, and provided refill reminders. The control group received standard care which included dispensing of medication and clarification of physicians' orders. After twelve months, people in the intervention group had statistically significantly fewer hospitalizations, fewer hypoglycemic episodes, and fewer medication errors as determined by the physician. This study established that pharmacists could have an impact on outcomes of people with diabetes.

In 1979, Hawkins et al. evaluated clinical pharmacists' intervention on the management of hypertensive and diabetic patients in a hospital setting.[17] The pharmacist provided primary care to 349 patients with diabetes which was compared to the care provided by physicians for 280 patients. The Department of Family Practice supervised pharmacist care. Patients who had received care from the pharmacist had an increased number of kept clinic visits, and no changes in emergency and hospital visits. The fasting blood glucose levels were equal in both the physician and pharmacist managed groups. Pharmacists' care was considered equivalent to physician care; however, this study did not ascertain if pharmacists can improve the health of people with diabetes.

Brown et al. looked at the outcomes of PC in 54 people with diabetes in a randomized controlled trial.[134] Five pharmacists received training on PC and diabetes care. These pharmacists met with patients in the intervention group monthly for six months, but details of the pharmacists' care were not reported. The intervention group had significant improvements in the mean preprandial blood glucose concentrations and HRQL at the end of the study when compared with the start. There were no differences between the treatment and control group on the summary of self-care activities, health-related hardiness scale, diabetes specific quality of life, health-related quality of life or mean blood glucose concentrations on pretest or posttest intervention scores. The authors felt that the small sample size and short study duration did not allow the study to detect small improvements in diabetes management affected by the pharmacists.

Table 2.2 Evaluations of Pharmacist Care

	Sample	Design	Structure	Process	Outcome
Scupak & Conrad, 1977	-40 Pts -female -type 1&2	-RCT -12 months	-Diabetes clinic affiliated with hospital -Rx reviewed diabetes/clinic before study	-Rx monitored drug therapy, provide info, training about diabetes (monthly) -control-basic Rx services	-↑ compliance with clinic visits -↓ medication errors, symptoms, -↓ hospitalization, therapeutic changes -↓ urine glucose, PBG, X FBG
Hawkins et al., 1979	-629 Pts -↑ BP &/or type 1&2 -90% Mex/Amer	-RCT -29 months	-medical follow-up clinic, teaching hospital -Rx was a PharmD	-Rx managed all care for people with diabetes, monitored by dept. of family practice -physician care for control group	-↑ compliance with clinic visits -X emergency/ hospital visits -X FBG
Brown et al., 1996	-54 Pts -type 1&2	-RCT -6 months	-Rx attended 2 day clinic on diabetes care & PC -Rx sites were a variety of community Rx	-5 Rx with Pt met monthly -Rx provided PC & meter training	-X HRQL, self care, health related hardiness, PPG -↓ PBG (when initial BG>6.6 mmol/l)
Van-Veldhui-zen Scott et al., 1995	-41 Pts -type 1&2	-RCT -2 months -2 Rx Groups -1 Control Group	-regional diabetes centre -all Pt attend 3 day diabetes course (multidisciplinary)	-Rx reviewed diabetes/ medication & answered questions -Group 1 -one session -Group 2 -one session & 4 follow-up phone calls Control -did not meet with Rx	-X between group 1&2 -Group 1&2 vs. control: ↓ improved average weekly BG, hypoglycemic episodes -X knowledge, ↑ perceptions/ attitudes toward Rx & diabetes

↑ = increased effect ↓ = decreased effect X = no effect
BG = Blood Glucose, BP = blood pressure, FBG = fasting blood glucose, GHb = glycoslated hemoglobin, HDL = high density lipids, HMO = health maintenance organization LDL = low density lipids, PBG = preprandial blood glucose Pt = patient, HRQL = health related quality of life, RCT = randomized controlled trial, Rx = pharmacist, SMBG = Self-monitoring blood glucose

Table 2.2 Evaluations of Pharmacist Care (cont.)

	Sample	Design	Structure	Process	Outcome
Jaber et al.., 1996	-39 Pts African Amer. -type 2	-RCT -4 months	-university outpatient clinic -Rx had prescribing rights for hypoglycemics	-Rx managed all aspects of diabetes care (every 2-4 weeks) -control came to clinic at start/end	-↓ GHb, -X FBP, BP, lipids, renal function, weight, HRQL
Fincham & Lofhom, 1998	-51 Pts -type 1&2 -10 Rx	-Single group pre/post measurement -2 months	-Rx completed diabetes management programs -Rx sites were not described	-Rx teaching on diabetes, SMBG & medications -Rx monitored diabetes	-↓ GHb ↑ # of monthly foot exams -↑ HRQL, Pt compliance, Pt satisfaction -cost savings $4295 per pt/yr
Coast-Senior et al., 1998	-23 Pts -type 2 -Referred by primary caregiver	-Single group pre/post measurement -mean 27 wks	-university-affiliated veterans affairs medical centre -established Rx referral system -All Pt received BG monitors	-Rx education, counseling, insulin adjustment, teaching on SMBG (monthly)	-↓ FBG, RBG, & GHb
Gerber et al., 1998	-812 Pts -on insulin & pills -HMO Pt	-retrospective database -2 tx & 1 control group -3 years	-9 pharmacies located in a medical centre campus in triplets	-control –counseling at Rx discretion -state –Mandatory counseling -HMO -PC, diabetes monitoring & referral to education clinic	-↓ costs 7.8% for Pt on insulin in state model -↓ costs 29% for Pt on pills/insulin in HMO model

↑ = increased effect ↓ = decreased effect X = no effect
BG = Blood Glucose, BP = blood pressure, FBG = fasting blood glucose, GHb = glycoslated hemoglobin, HDL = high density lipids, HMO = health maintenance organization LDL = low density lipids, PBG = preprandial blood glucose Pt = patient, HRQL = health related quality of life, RCT = randomized controlled trial, Rx = pharmacist, SMBG = Self-monitoring blood glucose

Table 2.2 Evaluations of Pharmacist Care (cont.)

	Sample	Design	Structure	Process	Outcome
Cranor, 1998	46 Pts type 1&2 -payer identified Pt	-single group pre/post measurement -14 months	-community pharmacies -Rx had 4 day training program from local Dr/diabetes centre -patients BG monitors	-Rx assessed Pt needs, & communication styles -Rx education focused on insulin & SMBG -Pt attended diabetes education	-↓ GHb, ↑HDl, ↓LDL, X total cholesterol, TG -↑ Pt Satisfaction, HRQL -program saved payer $20250
Sarkadi & Rosenqvist, 1999	60 Pts -Sweden -39 evaluated -type 2	-single group pre/post -approx. 1 yr	-held in community pharmacy -groups of 8-10 -lead by trained Rx & diabetes specialist nurse	-initial 2 day general education with Rx/nurse -10-12 monthly session lead by Rx on SMBG & complications	-↑of Pt with good GHb at 6 month, but X at 12 months over baseline -in interviews, Pt appreciated program
Baran et al., 1999	88 Pts -10-69 evaluated -type1&2	-single group pre/post measurement -6 months	-10 Rx recruited in & completed training approved by American Diabetes Assoc. -3 Rx were CDEs -Rx sites were variable	-Rx met with Pt at least every 2 months -Rx educated on diabetes, monitored & record diabetes progression -detected 23 drug-related events	-↑ HRQL & diabetes management skills rated by Rx -↓ cholesterol, GHb, RBG, & BP (n= 10-50) -↓ health care utilization (n=69) -81% of Pt reported education as excellent or very good
Berringer et al., 1999	52 Pts -type2 -23-27 evaluated	-single group pre/post measurement -12 months	-2 independent pharmacies -10 Rx (2 CDE/all with diabetes training)	-disease & drug monitoring with dispensing, chart review, & quality assessment -15/20 drug recommendations accepted by physician	-↓SMBG from baseline at 6 & 12 months -X in frequency of SMBG -maintained 90% medication adherence

↑ = increased effect ↓ = decreased effect X = no effect
BG = Blood Glucose, BP = blood pressure, FBG = fasting blood glucose, GHb = glycoslated hemoglobin, HDL = high density lipids, HMO = health maintenance organization LDL = low density lipids, PBG = preprandial blood glucose Pt = patient, HRQL = health related quality of life, RCT = randomized controlled trial, Rx = pharmacist, SMBG = Self-monitoring blood glucose

More recently, Van Veldhuizen-Scott et al. investigated the effect of PC in an ambulatory setting for patients with diabetes.[14] Forty-one participants attended a three day multidisciplinary diabetes clinic and then were randomized to three study groups: 1) control, 2) group pharmacist intervention, or 3) one-on-one pharmacist intervention with four telephone follow-ups. Participant education in the intervention groups focused on medication and accessories used by people with diabetes. Participants were evaluated on differences in blood glucose control and humanistic outcomes such as knowledge, perception, and attitudes which were measured by a questionnaire developed for this study. Statistically significant changes in blood glucose were reported. However, this result may be due to the method of analysis whereby all non-compliant participants were removed from the intervention group only. There were no significant changes between the treatment and control group in the knowledge portion of the questionnaire. The intervention groups had improved scores on the following perception and attitude scales: diabetes in general, diabetes medications, medications for other health conditions, and pharmacist as a care provider. There were no differences between the group and one-on-one pharmacist interventions on any measures. This study is an important step as it recognizes that pharmacists may influence humanistic outcomes in people with diabetes.

Jaber et al. evaluated the impact of a PC model on ambulatory diabetes management.[13] Thirty-nine urban African-American patients with type 2 diabetes were randomized to either an intervention group that received PC or the control group, which received standard care for four months provided by physicians. In this disease specific model of PC, pharmacists monitored medications and self-care activities, adjusted hypoglycemic medications, and educated participants on diabetes and its complications,

diet, and exercise. For the duration of the study, pharmacists were delegated prescribing privileges for oral hypoglycemic medications. Significant differences in the change scores for GHb were achieved. In the treatment group, GHb decreased from 11.5 to 9.2 % (a change of 2.3) whereas the control group had a change of 0.1 in GHb. There were no significant differences in the change scores for fasting blood glucose and secondary outcomes including blood pressure, lipid profile, renal function, weight, and health-related quality of life. This study established that a PC intervention could improve glycoslated hemoglobin.

Jaber et al. followed up with 14 of 17 patients from the intervention group two to nine months after the original study was completed to determine if improvements in glycemic control were maintained after the PC intervention.[139] Patients' post study GHbs were similar to baseline and significantly higher than those at study exit. They concluded that the benefits of PC on GHb were short-lived after the pharmacists' intervention.

In 1998, Fincham and Lofholm, evaluated the costs of pharmacists' care for patients with diabetes.[135] Ten pharmacists were recruited from a sample of 1000 pharmacists who had completed a diabetes education program. These pharmacists recruited 51 patients total. Pharmacists' interventions spanned a two month period and included teaching on diabetes and its complications, diet, exercise, testing devices, and medications. Clinical and economic outcomes were collected by the pharmacists. GHb levels were reported to decrease by 22 % although not all patients had GHb recorded over the study period. The number of people having monthly foot exams increased from 18 to 36 and self-reported compliance increased from 82 % to 88 %. For the humanistic

outcomes, there were significant improvements in patient satisfaction with pharmacists' services, and the health-related quality of life dimensions except physical functioning. There were no differences in diabetes-specific quality of life. Pharmacists estimated direct and indirect cost saving to the health care system at $4,295 per person per year. These results may be limited in their applicability because of poor research design (outcomes were not measured for all patients in the study, lack of a control group, and limited time frame) and the method of cost determination.

Coast-Senior et al. evaluated the glycemic control of patients with type 2 diabetes who received pharmacists' diabetes care in Veterans Administration primary care clinics in the United States.[16] Members of the primary team referred 23 veterans who had started on insulin to one of four clinical pharmacists for diabetes management. The clinical pharmacists assessed patients' diabetes management, blood glucose self-monitoring, and glycemic control. Patients were provided with a blood glucose meter and a testing schedule. At monthly phone or in-person visits, pharmacists adjusted insulin doses according to a protocol and monitored patients' glycemic control, symptoms, and hypoglycemia episodes.

After an average of 27 weeks follow-up, patients had significantly lower fasting blood glucose (219 to154 mg/dL), random blood glucose (236 to 154 mg/dL), and GHb (11.1 % to 8.9 %) when compared with baseline. While the results suggest that pharmacists working with interdisciplinary primary care teams can improve glycemic control, this study did not have a control group. Thus, it is hard to determine if the improvement in glycemic control is due to the pharmacist intervention, patients starting

insulin, or patients receiving free self-testing supplies. It may be combination of all three that resulted in the observed changes.

Gerber et al. examined the effect of pharmacist consultation on costs of diabetes in a health maintenance organization (HMO).[19] Three models of pharmacists' care were compared including basic counseling when the pharmacist considered it necessary (control pharmacy), counseling for all new prescriptions (state model), and complete counseling on disease, medication use, compliance assessment, and referral to diabetes education centre when necessary (HMO model). A computerized database was used to gather data on patients' characteristics and health care utilization. Researchers used a regression model to control for patient characteristics while examining the effects of each pharmacy model on direct medical costs associated with hospitalizations, office visits, and medications. Patients who were on insulin and were classified in the state model had 7.8 % lower total costs when compared to patients in the control model. Costs were 29 % lower for people on oral hypoglycemics and/or insulin who filled their new prescriptions at the HMO pharmacies when compared with control model. In this HMO, authors recommended at least counseling with every prescription to decrease health care costs.

The Asheville Project has recently been described as a model for pharmacists partnering with a third party payer to manage diabetes in a defined population.[18] The city of Asheville, North Carolina partnered with local pharmacists, physicians, and academics in a 14-month before and after evaluation of pharmacists' interventions. Pharmacist were provided four days of training in diabetes care by a local diabetes centre, physicians, and universities in the form of group lectures, discussions, and hands-on experience.[140]

Forty-six people with diabetes participated in the study. Patients first attended the diabetes education centre if they had not previously done so. Patients then met with a pharmacist one-on-one for a one-hour assessment of the patients' needs, goals, and communication style as well as initial teaching on the use of a blood glucose meter or mixing insulin. Pharmacists then met with patients at least once a month to provide additional training, review blood glucose levels, or address patient concerns.[60]

There was a 1.4 point (e.g., 11.4 % to 10 %) decrease in GHb from study start to 14 months. High density lipoproteins and low density lipoproteins improved significantly at both 8 and 14 months, however there were no changes in triglycerides or LDL/HDL ratios. Patient satisfaction scores in all areas (general satisfaction, technical competence, consideration, and explanation) appeared to improve from 7 % to 8 % over baseline, however no statistical analysis was presented. HRQL, as measured by the SF-36, significantly improved over baseline in six of eight domains (general health perception, energy, role emotional, pain, role physical, and physical function) at eight-months, and two domains (general health perception and energy) at 12 months. Economic outcomes were assessed for the 12 months before and after baseline, including claims for inpatient and outpatient care, pharmacist fees, glucose monitors, and diabetes education. Overall, the program saved the City of Asheville $20,250 after accounting for the costs of the program.

Because the Asheville study lacked a control group, it is again hard to identify the relationship as causal. The improvements in glucose control may be due to the pharmacists' intervention, free diabetes supplies or education that was received at the diabetes clinic. Quality of life scores were only available for 34 of 46 patients, thus not

representative of the entire sample. Despite these limitations, the payer was greatly satisfied with the pharmacist's intervention and consequently has continued the program and intends to extend it to include care for people with asthma.[141]

Sarkadi and Rosenqvist assessed the feasibility of a group education model called 'study circles' held in Swedish pharmacies.[136] People with type 2 diabetes were recruited from the community and placed in groups of eight to ten. Groups first attended a two-day session hosted by a pharmacist and diabetes nurse specialist to learn the basics of diet, exercise, and blood glucose self-monitoring. Groups then met monthly for sessions with a pharmacist who facilitated learning on the management of blood glucose monitoring and diabetes complications.

Eight study circles (60 participants) that met for five months or more were evaluated. At six-months there was an increase in the number of patients (n=39) who had good control (GHb less than 6.6 %) when compared with baseline but at twelve months fewer patients had good control. No statistical analysis was conducted. Questionnaires on the program and diabetes in everyday life indicated that patients (n=22) appreciated the diabetes circles and more than half stated their perception of diabetes had changed as a result of participating. Finally, six participants who were interviewed felt more secure, experienced social support, and appreciated the peer help in a non-medical setting. Study circles lead by pharmacists were shown to be a feasible model for delivering diabetes education. Further research may be required to assess the effectiveness of study circles in a controlled trial with multiple standardized outcomes such as metabolic control, quality of life, and diabetes self-care. As before, there were problems with casual inference due to the singe group design and high attrition rate.

Recently, Baran et al. reported the impact of community pharmacist counseling on the outcomes of people with type 2 diabetes.[137] Ten pharmacists were provided with an abbreviated program on diabetes education standards. These pharmacists then met with 88 patients at least every two months for a period of six months and provided education on diabetes with materials from the American Diabetes Association and industry. The pharmacists were also encouraged to monitor and record diabetes progression.

Pharmacists intervened on 23 drug-related events and made 39 drug recommendations. Significant improvement was seen between pretest and posttest cholesterol, GHb, random blood sugar, and blood pressure values using the data available (n=10 to 50). Pharmacists rated their patients (n=71) significantly higher on their mastery of diabetes management skills. HRQL, as measured with the Medical Outcomes Study Short Form 20, improved in three of eight areas: general health perception, mental health, and well being. Patients (n=69) reported fewer physicians visits and hospitalizations. Baran et al. concluded that non-intensive follow-up of patients with diabetes in the community can result in improve patient outcomes. However, as before in other studies, researchers did not consistently use standardized measures and compare against a control group to ensure that the intervention was the cause of patient improvement.

Berringer et al. evaluated the outcomes of people with type 2 diabetes in a community pharmacy-based diabetes-monitoring program. This program took place in two community pharmacies.[138] Two pharmacists were CDEs and they trained the remaining pharmacists. This intervention was termed Point of Dispensing (POD) PC and had three components: routine monitoring, chart review, and quality assessment.

Routine monitoring occurred with dispensing. Pharmacists were prompted to review patient charts with each fill while technicians asked the patient to complete a checklist on signs and symptoms, blood glucose levels, and patient concerns. A chart review occurred weekly to assess the patient information gathered at POD and develop a care plan. As well, a complete medication review was conducted every 6 months. Quality assessment ensured that pharmacists reviewed the chart with dispensing and that chart and medications reviews occurred.

Sixty-two patients completed the six months of follow-up and 52 complete the entire 12 months of follow-up. Physician accepted 15 of 20 drug-related recommendations. Participants' blood glucose levels as measured by self-monitoring improved over baseline (9.91 mmol/L) at 6 (8.84 mmol/L) and 12 months (8.31 mmol/L). There was no change in the frequency of self-monitoring blood glucose. Compliance as calculated by refill records over one year did not improve, but remained high at 90 %. This practical model of PC demonstrated that pharmacists could improve the short-term health of people with diabetes.

In summary, a number of research studies have examined the role of pharmacist care in diabetes management, however the results of these projects have been mixed and may be limited in their internal and external validity. Studies have limited descriptions of the structures and a process used by pharmacists to deliver care. Earlier studies focused on clinical outcomes with the more recent studies looking at humanistic and economic outcomes. Most studies have shown a benefit in glycemic control over the short term with the exception of two studies.[17,134] The latest studies demonstrated that pharmacist management improved participants' glycemic control over baseline, however these

studies lacked control groups.[16,18,18,135,135,136,136,137,137,138,138] Thus, it is impossible to determine if improvements in glycemic control were due to pharmacists' interventions, the blood glucose monitors provided to patients, or other influences in the communities. There have been discrepancies in other short term clinical outcomes such as lipids and blood pressure.

Pharmacists' interventions have positively affected humanistic outcomes such as HRQL,[18,135,135,137] attitudes,[14] and patient satisfaction[18,137] with the exception of one study.[134] However, it is difficult to draw strong conclusions about the impact of pharmacists on self-care activities.[137] Finally, some studies have supported the economic benefit of the pharmacist activities, though their methodologies may be weak.[18,19,135,135]

In Glasgow's review of the diabetes education literature, several understudied variables were identified (Table 2.1). The literature assessing pharmacists' interventions has addressed two important understudied variables, HRQL and cost-effectiveness, however it has not explored social support, self-efficacy, problem solving, personal models, smoking, insulin-self regulation and long-term complications of diabetes.

Published research on the impact of pharmacists in diabetes may not be generalizable to Canadian community pharmacists. Generalizability refers to the ability to apply the results of a given study across populations, setting, and time.[142] Previous research has focused on care in the United States provided by pharmacist in the clinic setting,[13-17] with prescribing privileges,[17;13] or in selected populations such as urban African-Americans[13] or females.[15] The majority of these studies were set in hospital affiliated clinics, yet people with diabetes are more likely to contact pharmacists in community pharmacies where pharmacists usually do not have prescribing authority.

2.4.0 Summary

Diabetes education and lifestyle modifications have the potential to reduce the high human and economic impact of diabetes. However, diabetes education is not optimally available for people with diabetes. A lack of expert and financial resources may prevent the wide spread implementation of the intensive treatment policies advocated in the DCCT and UKPDS. Pharmacists are more readily available in the community than other health care professionals and are trained to provide care for people with chronic medical conditions. This provides an opportunity for pharmacists to increase care for people with diabetes.

The current literature addressing the role of pharmacists in diabetes care is almost exclusively United States-based and has primarily studied pharmacists in clinics affiliated with hospitals or with prescribing authority. While these studies have shown some benefits of pharmacists in caring for people with diabetes, they may not be generalizable to Canada and community pharmacists. To our knowledge, researchers have not evaluated the effect of pharmacists with diabetes educator certification in Canada.

Likewise, previous research has lacked strong internal validity because of single group design, incomplete data collection, and high attrition rates. Thus, it is difficult to attribute pharmacists' intervention to improvements in the outcomes of people with diabetes. These methodological shortcomings could be overcome by an improved study design which uses a control group, assesses outcomes for all participants, and carries out a complete participant follow-up.

Donabedian's structure, process, and outcomes model has been suggested as a framework to assess the quality of care. Furthermore, researchers have emphasized

assessing a variety of clinical and humanistic outcomes with standardized measures. These approaches will assist researchers in discovering the best way for pharmacists to help people manage diabetes.

Chapter 3

Methods

3.1.0 Research Objectives

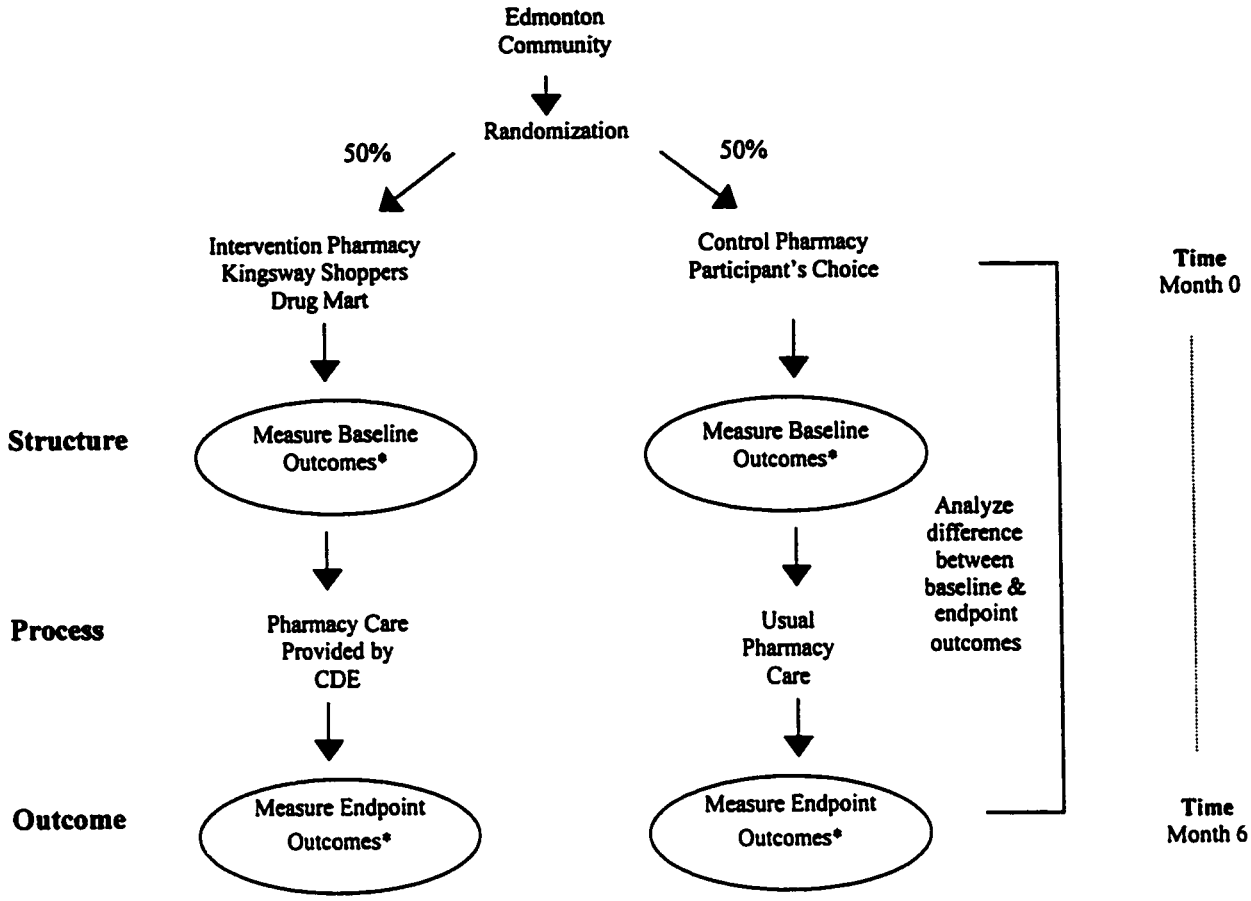
The overall objective of this study was to measure the impact of CDE pharmacists in the community setting on clinical and humanistic outcomes of people with diabetes. Specific research objectives were to determine the effect of CDE community pharmacist patient management on patients':

1) glycemic control,
2) attitudes, beliefs, and confidence in managing diabetes,
3) self-care activities, and
4) expectations and satisfaction with pharmacy services.

3.2.0 Study Design

This study was a prospective, randomized, controlled trial. It compared the outcomes of people with type 2 diabetes who were randomized to receive care from a pharmacy with CDE pharmacists or care from their usual pharmacy (Figure 3.1). One pharmacy with two CDE pharmacists served as the intervention pharmacy. Individuals in the control group were asked to name their usual pharmacy as their control pharmacy.

Figure 3.1 Study Design



*Outcomes –1) Glycoslated hemoglobin, 2) Diabetes Attitude Scale, 3) Summary of Diabetes Self-Care Activities, 4) Diabetes Lifestyle Form and 5) Patient Expectations & Satisfaction with Pharmacy Services, and 6) Health-Related Quality of Life

3.2.1 Study Duration

Recruitment took place over five months starting in January 1999. Participant follow-up was carried out for a further six months. The follow-up duration was selected to allow CDE pharmacists time to provide care to participants. In addition, the study duration allowed time to detect changes in glycemic control via glycoslated hemoglobin (GHb) after pharmacists' invention, as previously shown by Jaber.[13] Bringing glucose levels under control for 4-6 weeks will result in a decrease in GHb.[26]

3.2.2 Sample Size Consideration

Sample size was calculated with a power of 0.8 and α=0.05 with a two sided t-test to detect a mean absolute difference of two percentage points (e.g. a change from 0.11 to 0.13 in GHb) between GHb change scores in the intervention and control group. A standardized effect size of 0.8 was estimated using the standard deviation of the change score (25.6) from the GHb assessment in Jaber.[13] Based on these calculations, 27 participants per group were required. Assuming a 25 % dropout rate, the number of participants was increased to 35 per group or 70 participants in total. Because the sample size calculations were based on one outcome measure, a post-hoc power analysis on other measures was planned.

3.2.3 Recruitment

Potential study subjects were recruited from physicians' offices, seniors groups, the local chapter of the Canadian Diabetes Association, local newspapers, and posters in the community. Interested individuals were asked to contact the research office to obtain further information. Study inclusion criteria were:

1) diagnosis of type 2 diabetes for a minimum of one year,
2) non-institutionalized,
3) able to communicate in written and spoken English,
4) live in the Edmonton area, and
5) able to give consent.

Participants with type 2 diabetes were recruited because they have a higher prevalence in the population (90 % of people with diabetes) [1] and because they have been reported to have lower rates of education than type 1 diabetes.[21] Non-institutionalization

was an inclusion criterion so that participants were likely to be in charge of their own self-care. The last three inclusion criteria ensured that participants were able to fill out questionnaires, meet with the study pharmacists, and fulfill ethics requirements.

Exclusion criteria included:

1) legal blindness,
2) severe stroke,
3) kidney dialysis, and
4) participants under the age of 18.

These exclusion criteria were chosen to ensure full participation in all components of the study.

3.2.4 Participant Enrolment

After interested individuals contacted the research office, they were presented with two options for enrolment. First, if they verbally consented to participate in the study, an appointment was arranged at their convenience. In this meeting, the researcher reviewed the study information sheet (Appendix A), obtained written consent (Appendix A), randomly assigned the individuals to a study group, and had participants complete baseline questionnaires (Appendix B). The second enrolment option was to mail the consent package out to interested individuals. People who returned their consent form were randomized, and had baseline questionnaires mailed back to them. These participants were asked to mail the completed questionnaires back to the research office in an envelope provided. All participants were randomized using a table of random numbers.

All participants were supplied with a blood glucose meter and 200 testing strips, to help overcome financial barriers to participating in this study. Participants selected a meter from seven possible models. If they required help deciding on a meter, they were asked to consult their pharmacist. Participants in the intervention group received their testing supplies from the intervention pharmacy, and participants in the control group had supplies delivered to them.

3.2.5 Intervention Pharmacy

At the intervention pharmacy, participants received diabetes care from one of two pharmacists with a CDE designation. At the initial visit, pharmacists reviewed participant's concerns, identified drug-related problems, measured blood sugars, and recognized education deficits with the Diabetes Day Patient Questionnaire®, patient medical/medication history form, and goals setting form (Appendix C). Subsequent participant education included a minimum of the following topics: diabetes and its complications, hypo- and hyper-glycemia, medication use, the role of diet and exercise, and self-monitoring of blood glucose. Participants were contacted at least once a month for one-on-one educational sessions, follow-up on drug-related problems, review of self-care activities, and to address participants' concerns.

Follow-up sessions were documented on a separate form (Appendix D). A letter introducing the study was sent to the participants' primary physician (Appendix E), in addition to follow-up letters, as required for a participant's care. Pharmacists also referred participants to a dietitian or diabetes education program as required.

3.2.6 Control Pharmacy

Participants in the control group were contacted at the beginning and end of the study for completion of outcome measures. Participants in the control group were asked to name the primary pharmacy they would use for duration of the study; this pharmacy served as their control pharmacy. One pharmacist at each control pharmacy was asked to describe the structure of the pharmacy including prescription volume, the education of the pharmacy staff, and stock of diabetes supplies in addition to diabetes services provided to people with diabetes such as diabetes days, disease monitoring, and teaching on the use of blood glucose meters (Appendix F).

The pharmacist and manager at each control pharmacy were asked to review the study information sheet and had opportunity to ask questions about the study, before giving written consent for the interview. Standard care in the control pharmacy was presumed to consist of monitoring of the medication profile and potential side effects, contacting the physician with prescription concerns, and providing drug information. Given the low number of pharmacists in Alberta with a CDE designation,[122] it was highly unlikely that control pharmacies would have CDE pharmacists.

3.3.0 Measurement

The impact of CDE pharmacists' care was assessed using Donabedian's SPO framework,[62] whereby indicators of structure, processes, and outcomes are measured (Figure 3.2). Using the ECHO model, the clinical and humanistic outcomes of pharmacists' care for people with diabetes were assessed.[67] While the economic impact of care is an important part of ECHO, this study attempted to first determine the

effectiveness of pharmacists' care. If the effectiveness is established at one site, it would be more appropriate to look at its economic implications at multiple sites.

The following data were collected to characterize the sample: age, gender, education level, marital status, annual income, duration of diabetes, treatment of diabetes, attendance at a diabetes educational clinic, co-morbidites, and number of medications (prescription, over-the-counter, and herbal medications).

3.3.1 Structure Indicators

Information about structures was documented in both the intervention and control group. Data were collected on the extra training of pharmacists who were involved in patient care as well as the physical structures in each pharmacy (Figure 3.2).

3.3.2 Process Indicators

Process indicators are the care activities the pharmacists provide to the study participants. To assess the care provided, pharmacists in the intervention group documented care (Figure 3.2) on a follow up form (Appendix D).

Because complete information on processes of care in the control group were not available, control pharmacists were interviewed as described previously to collect information on process indicators for services that they provided to people with diabetes.

3.2 Study's Structure, Process, and Outcome Model

Resources in the pharmacy for patient care.

- Pharmacy type
- Pharmacist education
- Presence of counseling area
- Staffing ratios
- Stock of diabetes supplies

Activities of Care provided.

- Patients assessment
- Work-up of drug-related problems
- Follow-up
- Patient education/counseling
- Physician follow-up
- Recommendations to other health care professionals
- Diabetes screening days

Changes in patient's humanistic and clinical outcomes

- GHb
- Summary of Diabetes Self-Care Activities
- Diabetes Lifestyle Form
- Diabetes Attitude Scale
- Patient's Expectations and Satisfaction with Pharmacy Services
- SF-12

At the completion of the six month follow-up, a telephone interview was conducted with all study participants to inquire about 1) other activities they undertook to learn about diabetes and 2) the services their pharmacist provided. This interview (Appendix G) consisted of an open ended question asking what people had done to learn about diabetes during the follow-up period, followed by twelve yes/no questions. The first six questions asked if participants had visited a metabolic centre, family doctor, diabetes specialist, or dietitian, contacted the Canadian Diabetes Association, or accessed the Internet to learn about diabetes. The number of "yes" responses was summed to create an 'educational intensity' variable.

The second six questions asked if their pharmacist provided any of the following services: reviewed blood sugar levels, talked about blood sugar reactions, talked about how to use blood glucose monitors, asked about learning needs, measured blood pressure, or monitored medications. The number of "yes" responses was summed to form a

'pharmacists' care intensity' variable. The open-ended question was intended to identify confounding factors that were not anticipated in the survey design. For example, participants may have received diabetes education from magazines or support groups that were not listed in the six closed end-questions. While factors can not be controlled for in the analysis, the open ended-questions would allow these possible confounding factors to be identified and discussed.

For patients in the intervention group, the results of the pharmacist's care intensity variable in the telephone survey were compared with pharmacist's documentation to validate the telephone interview. For example, if a participant reported that their pharmacist measured their blood pressure, the documentation was checked for a blood pressure measurement. For each participant, the number of verified questions was divided by the total number of questions to construct an estimate of the validity of the telephone interview. This validation check was intended to increase confidence in the results of the telephone interview in both the intervention and control groups.

3.3.3 Outcome Measures

Clinical and humanistic outcomes were measured at baseline and endpoint. The clinical indicator for glycemic control was GHb, as it reflects change in blood glucose over the previous few months and is not subject to rapid fluctuations. GHb results may vary between laboratories, as not all instruments are calibrated to the same standard.[143] To avoid inter-site variation, all GHbs were analyzed at Dynacare Kasper Medical Laboratories.[144] Samples were frozen, stored, and analyzed in one batch at the study endpoint to further reduce variability.

The following humanistic outcomes were evaluated: participants' beliefs, attitudes, and confidence in managing diabetes, self-care activities, and participants' expectations and satisfaction with pharmacy services. Participants completed the baseline and endpoint questionnaires, placed them in unmarked sealed envelopes, and mailed them to the research office. Questionnaires were coded with a subject identification number known only by the research office. In this way, participants were assured that researchers, not their pharmacist, reviewed questionnaire responses, and that responses were confidential. This was intended to increase the truthfulness of participant's responses and reduce social desirability bias.

Diabetes Attitude Scale

The Diabetes Attitude Scale (DAS) (Appendix B) was first developed to measure the attitudes of health care professionals towards people with diabetes.[145] However, it has been revised for use in both patients and health care professionals.[70] The revised DAS measures seven attitude factors: 1) need for special training in order to provide diabetes care, 2) patient compliance, 3) seriousness of type 2 diabetes, 4) the relationship between blood glucose levels and complications, 5) the impact of diabetes on the patient's life, 6) patient autonomy, and 7) team care.[145] All items were scored on a five-point Likert scale (1 = strongly disagree to 5 = strongly agree). Higher scores represent more positive attitudes toward each factor. In the DAS, scores were calculated by averaging all items in each of the seven factors.

Evidence is available to support the reliability and validity of the DAS. All scales have been shown to have good internal consistency with Cronbach's alpha greater than 0.60.[145] A panel of diabetes experts developed the questionnaire and thus has been reviewed for face validity.[145] Evidence for concurrent validity was established by

comparing the ranking of health care professionals on scales of the revised DAS to a previous version of the DAS.[70] For example, if on a given scale dietitians had the highest score on the original DAS, they also had the highest score on the revised DAS for patients.

Diabetes Lifestyle Form

The Diabetes Lifestyle Form (DLF) is a 20-item questionnaire that measures attitudes and beliefs toward diabetes and confidence in managing diabetes (Appendix B).[7] Items are rated on a four-point Likert scale with higher scores representing more positive attitudes and beliefs, or more confidence in managing diabetes. For this study, the scale was converted to a five-point Likert scale to be consistent with other instruments being used. The test-retest reliability of the four-point scale instrument is 0.82.[7] No further evidence for reliability or validity of the DLF was available. To score this instrument, items were averaged in each factor in addition to averaging all items for an overall scale score. The developer also recommends that individual items of the DLF be examined.[7]

Summary of Diabetes Self-Care Activities

The Summary of Diabetes Self-Care Activities (SDSCA) is a 12-item measure of compliance with diet, exercise, blood glucose testing, and diabetes medication activities (Appendix B). It is a brief and practical instrument that is both validated and has adequate internal reliability (with the exception of the diet scale).[146] Participants rate either the number of days or percentage of time that they performed each self-care activity. Higher scores indicate that participants were performing more self-care activities. For the SDSCA, raw scores for each measure were converted to standard scores with a mean of zero and standard deviation of one in order to weight all items equally. Standardized item scores were averaged for the four areas of diabetes self-care.

Patients' Expectations of Pharmacy Services

Patients' expectations were measured using a modified version of the instrument developed by Brown and Green (Appendix B).[111] The original instrument had 4 factors: documentation, patient assessment, monitoring plans, and patient advising and counseling. Factors with more than one item had good internal consistency (Cronbach's alpha between 0.76 and 0.81). No evidence for validity was presented. The instrument was modified to simplify the terminology and to add one question inquiring if participants expected their pharmacists to communicate with their physicians. Pharmacy practice faculty members at the University of Alberta and a small convenience sample of people with type 2 diabetes reviewed the modified instrument for face validity. Patient expectation scores were averaged in the each of the four factors and all items were averaged for an overall score.

Patients' Satisfaction with Pharmacy Services

Satisfaction with pharmacy services has previously been measured with a multidimensional 33 to 45-item scale.[108,110,147] Johnson et al. demonstrated that a four-item measure of general satisfaction would provide adequate assessment of overall patient satisfaction.[148] Thus, the four-item measure of general satisfaction was used to assess overall patient satisfaction with pharmacy services (Appendix B).[109] This general satisfaction measure was found to have good internal consistency with Cronbach's alpha of 0.67 to 0.76 in two samples of patients from community pharmacies in Alberta.[107] Previous work, showing a positive correlation between general satisfaction and other measures of satisfaction supports the construct validity of this measure.[109] Satisfaction with pharmacy services is high when expectations are being met.[101] CDE pharmacists will most likely have met new expectations that they create, and therefore, satisfaction

was not expected to vary. As previously published, patient satisfaction scores were converted to a one to 100 scale and then all four items were averaged to form a single domain called general satisfaction.[107,109,149]

Health-Related Quality of Life

Participants also completed the SF-12 (Appendix B). The SF-12 was not considered an outcome measure itself, but was used to adjust for differences in health-related quality of life in patient satisfaction results and other outcome measures. Satisfaction with pharmacy services has been shown to vary with HRQL,[148] and it might also be hypothesised that other subjective assessments, like attitudes and beliefs about diabetes might be modified by people's HRQL. The SF-12 [150]is an abbreviated version of the SF-36, one of the most commonly used health status profile measures.[151] Like the SF-36, summary scores for physical and mental health status can be derived from the SF-12 and are referred to as the Physical Component Summary (PCS12) and the Mental Component Summary (MCS12), respectively. Scoring for the PCS12 and MCS12 of the SF12 was performed using the SAS scoring program from the New England Medical Center. [150]

The summary scores of the SF-12 have also been shown to closely represent the summary scores of the SF-36.[152] The PCS12 and MCS12 scores have also been found to be virtually identical to the SF-36 summary scores in indicating the level of health and sensitivity to change in studies of patient study groups with various conditions.[153,154] There is an abundance of evidence that the PCS12 and MCS12 provide valid and reliable measurement of HRQL in a variety of settings.

3.4.0 Data Analysis

Complete data were entered into Microsoft Access by two separate people and imported into SAS statistical analysis package (Copyright 1996 by SAS Institute Inc., Cary, NC, USA). The two unique data sets were compared for accuracy using PROC COMPARE (SAS 1996). Any discrepancies were corrected against the original data.

Data was analyzed using SAS statistical analysis package v7 (SAS 1996). A two-sided a priori α=0.05 was used for all hypotheses tested. Although multiple tests were used, the alpha value was not adjusted. This increases the probability of committing a type 1 error, where the null is rejected when it was true. Conversely, this decreases the probability of committing a type 2 error, where the null hypothesis is not rejected when it is false or in other words, saying there is no difference when there is one. This research was exploratory in nature and thus it was important to identify differences that may exist, while accepting an increased risk of finding false differences.

3.4.1 Descriptive Statistics

Variables used to characterize the sample included age, gender, education level, marital status, annual income, duration of diabetes, treatment of diabetes, attendance at a diabetes educational clinic, co-morbidites, and number of medications (prescription, over-the-counter, and herbal medications). Using data from the exit telephone interview, an educational intensity, and a pharmacists' care intensity variable were calculated for both study groups, as described previously. The baseline characteristics of the two study groups were compared with a t-test or chi-square test depending on the level of the data.

To assess normality, independent variables were examined using the PROC UNIVARIATE function (SAS 1996). This function plots the shape of the data and

conducts the Shapiro-Wilk test for normality.[155] Because this test is sensitive to small deviations from normality, if the plot of the data appeared normal, the variable was considered normal.

The structure and process indicators of the study pharmacies were primarily descriptive in nature. The activities of the CDE pharmacists were collected from their documentation forms. To ensure completeness, information from the documentation forms was verified with files kept by the CDE pharmacists. Data from the control pharmacists was summarized from interviews and presented in aggregate.

3.4.2 Data Preparation

For each questionnaire, items reflecting negative attributes were re-coded with the appropriate scale conversions. Questionnaires were then scored based on developer's guidelines, as described. When items were missing from a scale, the mean of the available items was inserted for the missing data.[156] However, if more than half of the items in a scale were missing for a participant, that scale score was treated as missing data in the analysis.

3.4.3 Bivariate Analysis

It was hypothesized that there would be differences in the endpoint scores of the outcome measures between the intervention and control group after controlling for the baseline scores (Table 3.1). This was assessed using a one factor analysis of covariance (ANCOVA) (SAS 1996). ANCOVA controls for differences in the covariates thus "reducing the effects of chance differences between the two groups."[157]

Table 3.1 Hypothesis in the Bivariate Analysis

H_0	Null Hypothesis:	There is no difference between endpoint *DV* in the intervention & control group while controlling for *DV* at baseline.
H_A	Alternate Hypothesis:	There is a difference between endpoint *DV* in the intervention & control group while controlling for *DV* at baseline.

Where: *DV (dependent variable)=GHb, DAS, DLF, SDSCA, Patient Satisfaction, Patient Expectations*

Measuring change in outcomes over time has been favoured because "instruments which are responsive to changes in health status are more sensitive measures of the effects of clinical interventions than those which simply assess health status after an intervention."[158] However, this study's randomized pretest-posttest design could have been analyzed using a less complex between group t-test on the change scores in each outcome. Change scores (otherwise called gain scores) can be calculated by subtracting the pre-test scores from the post-test scores. The t-test is equivalent to using an ANCOVA model where the single regression coefficient for the group assignment is constrained to one.[157] The farther that the regression coefficient differs from 1.0 the greater the power advantage of ANCOVA over a t-test.[157] Others reasons for choosing the ANCOVA model over t-test on change scores are that t-tests can be limited by the ceiling effect, regression towards the mean, assumption of equal intervals in the scale, different types of changes (i.e., different participants may improve in different areas and a change from an average score to a higher score may imply less change than a change from a low score to an average score), and low reliability of the measurements. [157,159] [157] However, the ANCOVA model may also be limited by measurement error such as the type of change a participants makes and low reliability.

While the ANCOVA model has increased efficiency, it is at the cost of increased complexity and assumptions. ANCOVA shares the following assumptions of general linear models: independence, normality of error, and homogeneity of variance between groups. In the general linear model, the normality assumptions are robust except when samples are quite small or the departures from normality are marked.[157] Furthermore, the ANCOVA model is unlikely to be severely biased by violations of normality and homogeneity of variance if there are equal numbers of participants in each groups and the covariate itself is approximately normally distributed.[157] To ensure the assumption of normality was met, the regression residuals were plotted against the predicted values and the Shapiro-Wilks test for normality of the distribution of residuals was examined. If a variable's distribution is not found to be normal, a Kruskal Wallis (KW) test for non-parametric distribution was used. Homogeneity of variance was assessed using Levenes test which is considered the gold standard test of homogeneity.[160]

There are four additional assumptions for the ANCOVA model.[157] The model assumes that the dependent variable and the covariate are measured independently and have a linear relationship. The third assumption is homogeneity of the regression lines. The final assumption is that the covariate is fixed and contains no measurement error. These assumptions were substantiated in several ways. The study design ensured that independent measurement of the covariate. The linearity was checked by plotting a scatter diagram. The assumption of homogeneity of slopes was verified by creating a third interaction term in the model consisting of the dependent variable and covariate. If this interaction term was not significant, there was no difference between the slopes of the study groups and the assumption of homogeneity has been met.[161] The final

assumption that the covariate is measured without error was not assessed because it can be violated without serious consequences when the participants have been randomly assigned to treatment groups.[157]

If the ANCOVA model violated the assumptions of linearity or homogeneity of the regression lines for any variable, the change between groups for that variable was examined with a t-test for the change scores. While this test is not as powerful as the ANCOVA, it does require the same assumptions.

The small sample size may limit the power of statistical analysis to detect change after pharmacists' intervention. However, a power analysis was conducted to assess the power of each statistical test performed. For statistical tests that were greatly under powered (power less than 50%), the effect size was examined to discern if there were important differences between study groups.[162]

3.4.4 Multivariate Analysis

It is known that demographic, clinical, and quality of life factors affect the outcomes of people with diabetes. To account for the effect of these variables, a multivariate model was used to assess the differences between the intervention and control group (Table 3.2 & 3.3).

This multivariate model was reviewed to ensure that it met the same assumptions as the bivariate model with the exception of homogeneity of regression slopes. Because of the small study sample, the study was not powered to assess multiple interaction terms. However, violation of parallel slopes has not been found to be a serious limitation in the ANCOVA model.[163]

This model was large for the study's sample size. By convention, approximately 15-30 subjects are required in a model per covariate and therefore a sample size of 60 could have four covariates.[159] To reduce the size of the proposed model, a correlation matrix consisting of the independent variables was examined. It was expected that related factors would be revealed and eliminated from the analysis. For example, number of co-morbidities and number of total medications were expected to be collinear, meaning that they both are strongly correlated.[159] A collinear variable accounts for little variance in the ANCOVA model and may not be significant. Thus it would be eliminated from the ANCOVA model. Finally, the size of the final model was reduced by only including variables that significantly contributed to the model.

3.5 Quality Control

This study had several quality controls to ensure consistency of the data. The research proposal detailed recruitment techniques, consent procedures, randomization procedures, and outcome measurement. The researcher contacted the intervention pharmacy weekly to assess pharmacist documentation and discuss data management issues.

Table 3.2 Hypothesis in the Multivariate Analysis

H_0-2	Null Hypothesis:	There is no difference between endpoint *DV* in the intervention & control group while controlling for *DV* at baseline, demographic, clinical, and quality of life.
H_A-2	Alternate Hypothesis:	There is a difference between endpoint *DV* in the intervention & control group while controlling for *DV* at baseline, demographic, clinical, and quality of life.

Where: *DV=GHb, DAS, DLF, SDSCA, Patient Satisfaction, Patient Expectation*

Table 3.3 Proposed ANCOVA Model

$$\{DV\}_{post} = \beta + \{DV\}_{pre} + \{group\} + \{demo\} + \{clinical\} + \{HRQL\} + \varepsilon$$

Where:

Demo	**= Demographics** ▪ Age (years) ▪ Gender (0=male; 1=female) ▪ Education level (0=high school or less; 1=college/university) ▪ Income (spilt on distribution ex: 0=< $40 000; 1=≥ $40 000) ▪ Marital status (0=married 1=not married)
Clinical	**= Clinical Factors** ▪ Number of co-morbidities, ▪ Number of medications (total) ▪ Method of treating diabetes (0=diet/pills; 1=insulin) ▪ Educational Intensity (0-6) ▪ Treatment Intensity (0-6) ▪ Duration of Diabetes (years)
HRQL	**= Health Related Quality of Life** ▪ MCS12 ▪ PCS12
ε	**= error** ▪ Variance not accounted for in the model

Data were collected on standardized forms, checked for omissions, and then entered into a Microsoft ACCESS database. All data was entered by two separate individuals and checked for accuracy. Standard forms were developed for participant consent, demographics, process documentation, and outcome measures. Triplicate documentation forms were used so that both CDE pharmacists and the research office maintained copies. All files were backed up and will be stored in a locked cabinet for seven years.

3.6 Ethical Considerations

The Health Research Ethics Review Board at the University of Alberta approved this study. Every effort was made to ensure that participants were informed about the study, selection of the participants was equitable, and participant confidentiality was protected. Upon entry into the study, participants received a Study Information Sheet outlining the nature, procedures, risks, and benefits of receiving care from either the intervention or control pharmacy. Participants were informed that incentives (use of a blood glucose meter and a six-month supply of testing strips) were given equally to the intervention and control group. Participants were given the opportunity to ask questions about any area of the study. Finally, written consent was obtained from each participant.

Although the study status of the participants could not be blinded to the participants or the pharmacists, participant confidentiality was maintained by assigning numbers to each participant's outcome data. The researcher was the only individual able to decode these numbers. Any document identifying the participants are stored in a locked cabinet. Signed consent forms and all raw data will be stored for seven years following the completion of the study. The outcome results were presented in an anonymous aggregate form.

Chapter 4

Results

This chapter will present the results of a randomized controlled trial to assess the outcomes of people with type 2 diabetes after receiving care from a CDE pharmacist. Initially, participant demographics will be used to characterize the study sample. Other study results are organised in the structure, process, and outcomes model. Structure and process indicators for the pharmacies are described. Finally, baseline outcome variables and results of hypothesis tests are presented.

4.1.0 Study Sample

4.1.1 Sample Recruitment

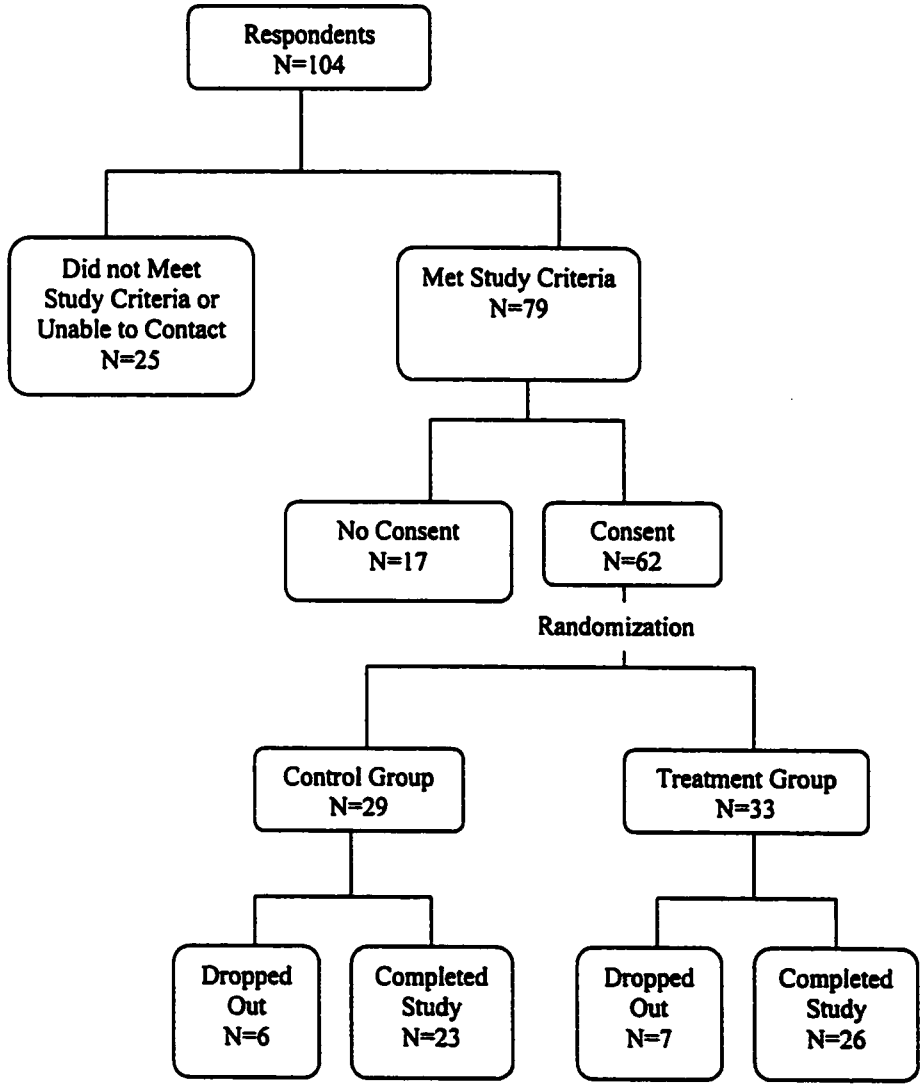
Advertisements in the Edmonton area generated one hundred and four respondents (Figure 4.1). Seventy-nine respondents met study criteria, of which 62 consented to participate in the study. Over the course of the study 13 (21 %) participants dropped out. Similar numbers dropped out of the intervention (n=7) and control (n=6) groups. The final study sample consisted of 49 participants.

Participants dropped out of the study for various reasons. In the intervention group, one participant dropped out because of the location of the intervention pharmacy, another felt he could receive similar services in his community, and one participant dropped out due to mental health reasons. The final four participants who dropped out of

the intervention group were unable to regularly met with the CDE pharmacists and three of these people did not complete baseline data collection.

In the control group, one person did not complete baseline data collection, one dropped out for health reasons, and four were unable to be contacted for the endpoint data collection. Of those four, two left the province to be with relatives.

Figure 4.1 Participant Recruitment



4.1.2 Demographics

The intervention and control groups had similar demographic characteristics with the exception of the method of diabetes treatment (Table 4.1). Overall, study participants were 59.3 (± 11.3) years old. The majority were married (69 %) and had an income less than $40 000 (74 %). Participants had been diagnosed with diabetes for 6.9 (±6.6) years.

Participants in the control group were more likely to use medications to treat diabetes. Eighty four percent of participants had attended a diabetes education clinic, but this occurred on average 3.9 (±4.2) years ago. Study participants had approximately 1.5 concurrent medical conditions and used a mean of four prescription or non-prescription medications on a daily basis. One participant reported taking 24 separate vitamins a daily. This was reported as a single non-prescription medication (i.e. a multivitamin), so that the variable's distribution was not skewed.

4.2.0 Structure Indicators

4.2.1 Intervention Pharmacy

The intervention site was Kingsway Shoppers Drug Mart (SDM). This chain pharmacy had a recognized diabetes program and stocked a wide variety of diabetes supplies. The Kingsway store has a private counseling area, blood pressure machine, and patient diabetes literature section.

Most pertinent to this study, the two pharmacists at Kingsway SDM (AB and PD) are Certified Diabetes Educators (CDEs) and were meeting with patients to help them manage their diabetes. AB had her certificate for 3 years and PD for 4 years. These

pharmacists approached the Faculty of Pharmacy and Pharmaceutical Sciences for help in evaluating their practice and this project was initiated.

Table 4.1 Demographics

	Intervention	Control
Number	26	23
Age	57.1 ± 12.4	61.9 ± 9.4
Gender (% Male)	13 (50 %)	13 (57 %)
Education		
High school	15 (58 %)	12 (52 %)
Some University/College	11 (42 %)	11 (47 %)
Marital Status		
Married	16 (62 %)	18 (78 %)
Single/Divorced/Widowed	10 (38 %)	5 (22 %)
Income*		
< $40, 000	19 (79 %)	15 (68 %)
≥ $40, 000	5 (21 %)	7 (32 %)
Duration of Diabetes	7.4 ± 7.3	6.3 ± 5.8
Method of Treating Diabetes**		
Diet Alone	8 (31 %)	2 (9 %)
Pills	14 (54 %)	19 (83 %)
Insulin	4 (15 %)	2 (9 %)
Insulin and Pills	0	0
Attended Diabetes Education Centre? (%Yes)	21 (81 %)	20 (87 %)
Years since last visit? n=21,20	4.1 ± 4.5	3.7 ± 4.0
Number of Concurrent Medical Conditions***	1.6 ± 1.3	1.2 ± 1.0
Number of Concurrent:		
Prescription Medications***	2.3 ±1.7	2.9 ± 1.7
Non-Prescription Medications***	1.3 ± 1.8	1.5 ± 1.7
Total Medications***	3.6 ± 2.4	4.4 ± 2.9

*Three participants did not report income (2 intervention and 1 control group)
**Mantel-Haenszel chi-square p=0.03
***n=48 (one participant in the intervention group did not complete the second page on demographics)

The two CDE pharmacists were funded for one day a week in this study. This time was used to set up appointments, follow-up with study participants, document care, and follow-up with other health care providers without typical responsibilities of the pharmacy dispensary. Previously, these CDE pharmacists directly billed their patients for diabetes care services. The pharmacy where the CDE pharmacists worked had a large variety of blood glucose meters, a blood glucose meter loan program, and a private consultation area.

4.2.2 Control Pharmacies

There were 23 participants in the control group. Each participant named one pharmacy, which they frequented for their diabetes needs. Several participants named the same pharmacy, thus 21 different stores were named in the control group. Of the 21 pharmacies, 18 were interviewed (Table 4.2). Pharmacy managers gave consent to participate in the interviews. In 16 of 18 pharmacies, the managers were interviewed. In two cases, a staff pharmacist was interviewed, thus consent was also obtained from that individual. One pharmacy refused to participate because of store policy, and scheduling difficulties precluded interviews at two other stores. The one that refused an interview was a high volume grocery store pharmacy .

The control pharmacies were divided among grocery, independent, and chain stores. Grocery refers to pharmacies that are located in grocery stories (i.e., Safeway or Real Canadian SuperStore). Chain pharmacies are clearly associated with other stores of the same name and may or may not be owned by a parent company.[164] Examples include London Drugs and SDM. Independent pharmacies are not affiliated with other stores and frequently are owned and operated by a pharmacist.

Table 4.2 Characteristic of Control Pharmacies

Characteristic	n=18
Type of Pharmacy (%)	
Chain	4 (22 %)
Grocery	7 (39 %)
Independent	7 (39 %)
Prescription Volume (%)	
<100 prescriptions per day	5 (28 %)
100-149 prescriptions per day	2 (11 %)
150-199 prescriptions per day	7 (39 %)
>200 prescriptions per day	4 (22 %)
Counseling Area	12 (67 %)
Pharmacist Full Time Equivalents*	1.3 (±0.3)
Technician Full Time Equivalents**	0.7 (±0.4)

* Calculated by dividing the number of pharmacist hours in one week by the store hours in one week
**Calculated by dividing the number of technician hours in one week by the store hours in one week

The majority of control pharmacies filled over 150 prescriptions per day and had one pharmacist on shift with about 30 % overlap (Table 4.2). Interestingly, half the pharmacies filled ≥ 150 prescriptions per day, but control pharmacies reported less than one full time technician worked at each pharmacy.

All of the pharmacies stocked blood glucose meters, injectable supplies, and sugar substitutes. Pharmacies carried an average of 6.5 (± 3.4) different blood glucose meters models. Most of the pharmacists in the control pharmacies had some form of blood glucose meter training (Table 4.3). Fewer had "other" training such as in-store courses or continuing education courses. One control pharmacy reported that one pharmacist was a CDE. This was one of the intervention pharmacists, AB who worked on a casual basis, so it was unlikely that she influenced care in the control group.

Table 4.3 Training of Pharmacists in the Control Group Pharmacies

Type of Training	n=18
CDE	1 (6 %)
Number of pharmacists per store	1*
Other Diabetes Training**	10 (56 %)
Number of pharmacists per store	3.2 (±0.79)
Meter Training	16 (89 %)
Number of pharmacists per store	2.9 (±1.4)

* One pharmacist; AB worked casually at a control pharmacy
** This includes in-store training and other courses in diabetes management such as ones hosted by local metabolic centres.

4.3.0 Process Indicators

4.3.1 Intervention Pharmacy

At the intervention pharmacy, the CDE pharmacists followed study participants for approximately six months. One pharmacist, AB, followed 18 participants while PD followed eight participants.

The pharmacists met with each participant for an average of 6.9 (± 1.0) visits with two visits in the first month and then approximately one visit a month for the remainder of the six-month study period. There were no differences in the number of visits per participant between CDE pharmacists. The majority (95 %) of visits were face-to-face in the pharmacy. However, PD regularly met face-to-face with one study participant in the participant's home. The remaining visits were conducted over the telephone.

The teaching topics and services provided at the initial visits are listed in Figure 4.2 and 4.3. These services were summarized from the visit documentation forms. Examples of completed documentation forms are provided in Appendix H. At the initial visit, the CDE pharmacist taught participants about blood glucose meters and evaluated

participant's teaching needs in over 95 % of cases. They also measured blood glucose levels, reviewed medication profiles, measured blood pressures, and contacted participants' physicians to introduce the study in over 85 % of visits.

At the follow-up visits, CDE pharmacists provided teaching on medication use, diet/nutrition, and hypoglycemic reactions at 40 to 50 % of visits (Figure 4.2). Other topics such as diabetes and its complications, how to monitor blood glucose levels, exercise, insulin use, and foot care were discussed less frequently. Two services were conducted in 50 % of visits: contacted the physician and measured blood pressure. Addressing participant concerns, measuring blood glucose levels, and reviewing the medication profile were documented in approximately 40 % of follow-up visits. All other services were documented in less than 25 % of visits. One service listed on the documentation form (pre-filling of insulin syringes) was not provided to any participants.

Figure 4.2 Patient Teaching Provided by CDE Pharmacists by Time of Visit

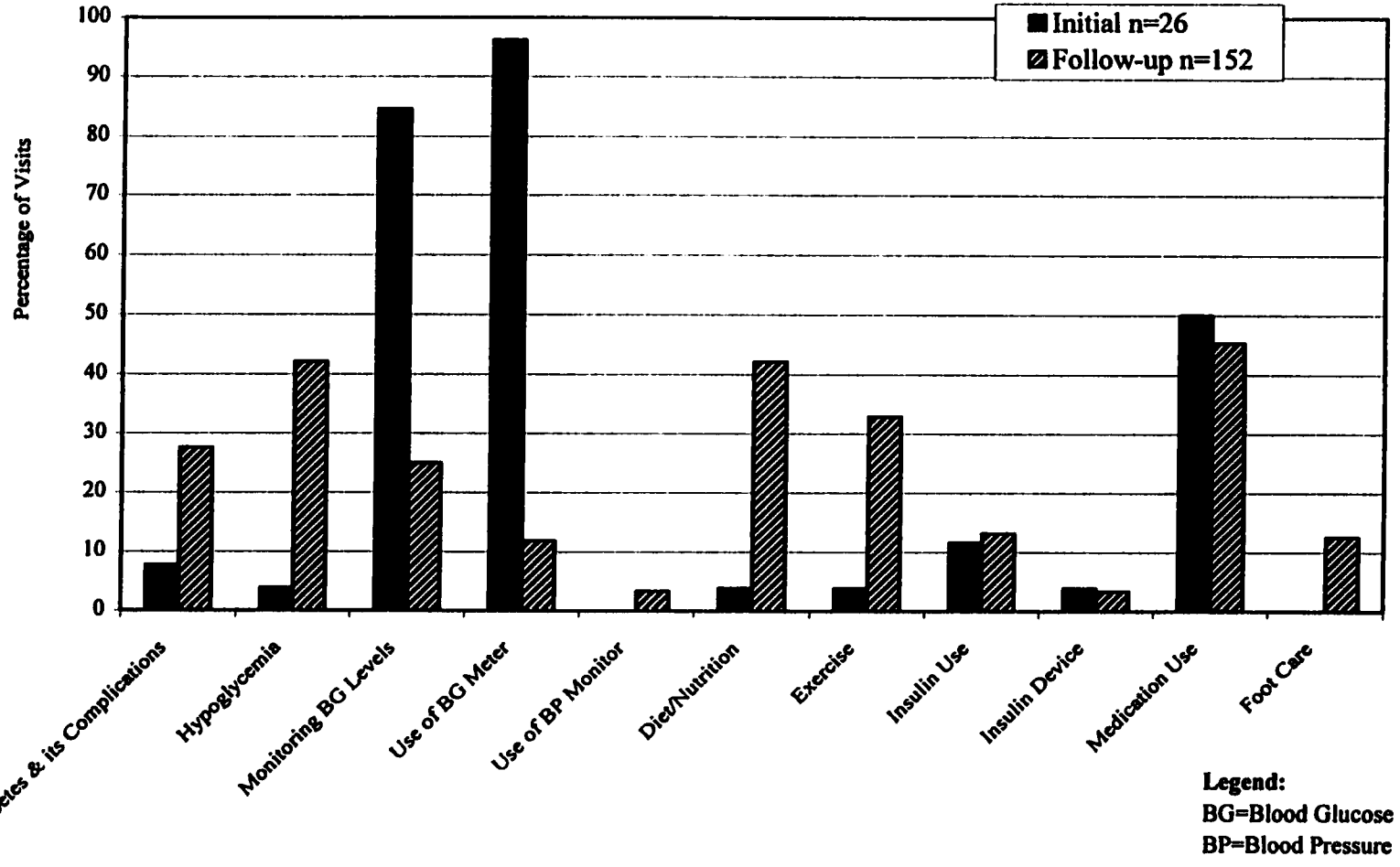
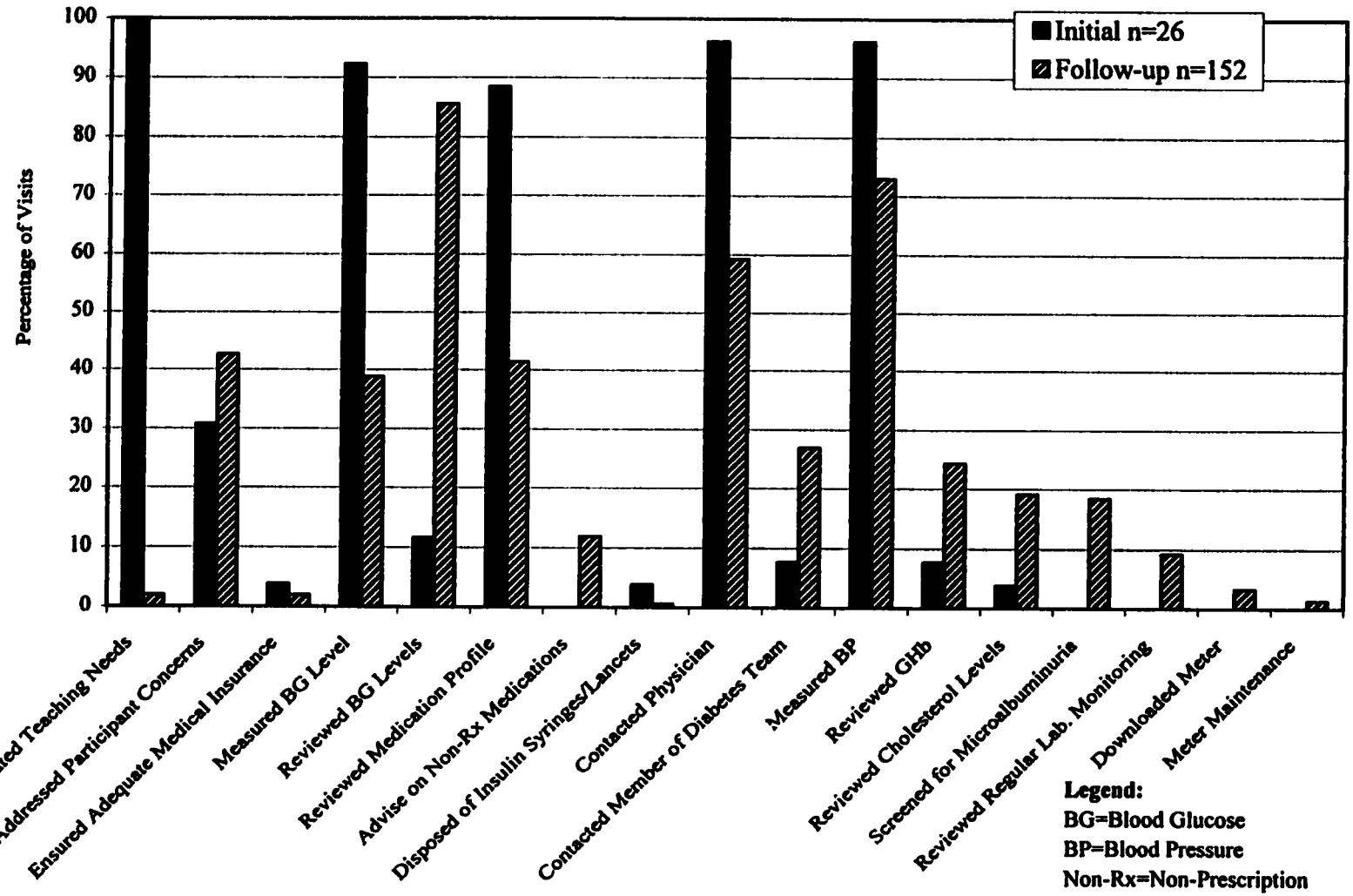


Figure 4.3 Services Provided by CDE Pharmacists by Time of Visit



The pharmacists' interventions were also analysed by the percentage of participants that received teaching or a service during the study (Figure 4.4 and 4.5). All participants received teaching on monitoring blood glucose levels and the use of a blood glucose monitor. Over 80 % of participants received teaching on diabetes and complications, hypoglycemic reactions, diet/nutrition, exercise, and medication use. Teaching on the use of blood pressure monitors, insulin use, and insulin devices were provided less frequently.

Most services were provided to over half the study participants (Figure 4.5). CDE pharmacists evaluated teaching needs, reviewed blood glucose levels, contacted the physician, and measured blood pressure for everyone in the intervention group. For over 80 % of participants, the pharmacists addressed participants' concerns, measured blood glucose levels, and reviewed medication profile. Other frequent services included advising on over-the-counter medication use, contacting members of the diabetes team, reviewing GHb, reviewing cholesterol levels, screening for microalbuminuria, and reviewing a booklet from the Canadian Diabetes Association. This booklet defines common laboratory values and contains recommendations on how often they should be performed for people with diabetes.

The CDE pharmacists identified a total of 70 drug-related problems (DRPs) in the intervention group, for an average of 2.9 (±2.4) DRPs per participant. DRPs can be categorized as potential or actual.[66] It is not specified whether DRPs had, in fact, occurred or if they were potential DRPs that may have been previously addressed by other

Figure 4.4 Percentage of Participants Receiving Patient Teaching Provided by CDE Pharmacists n=26

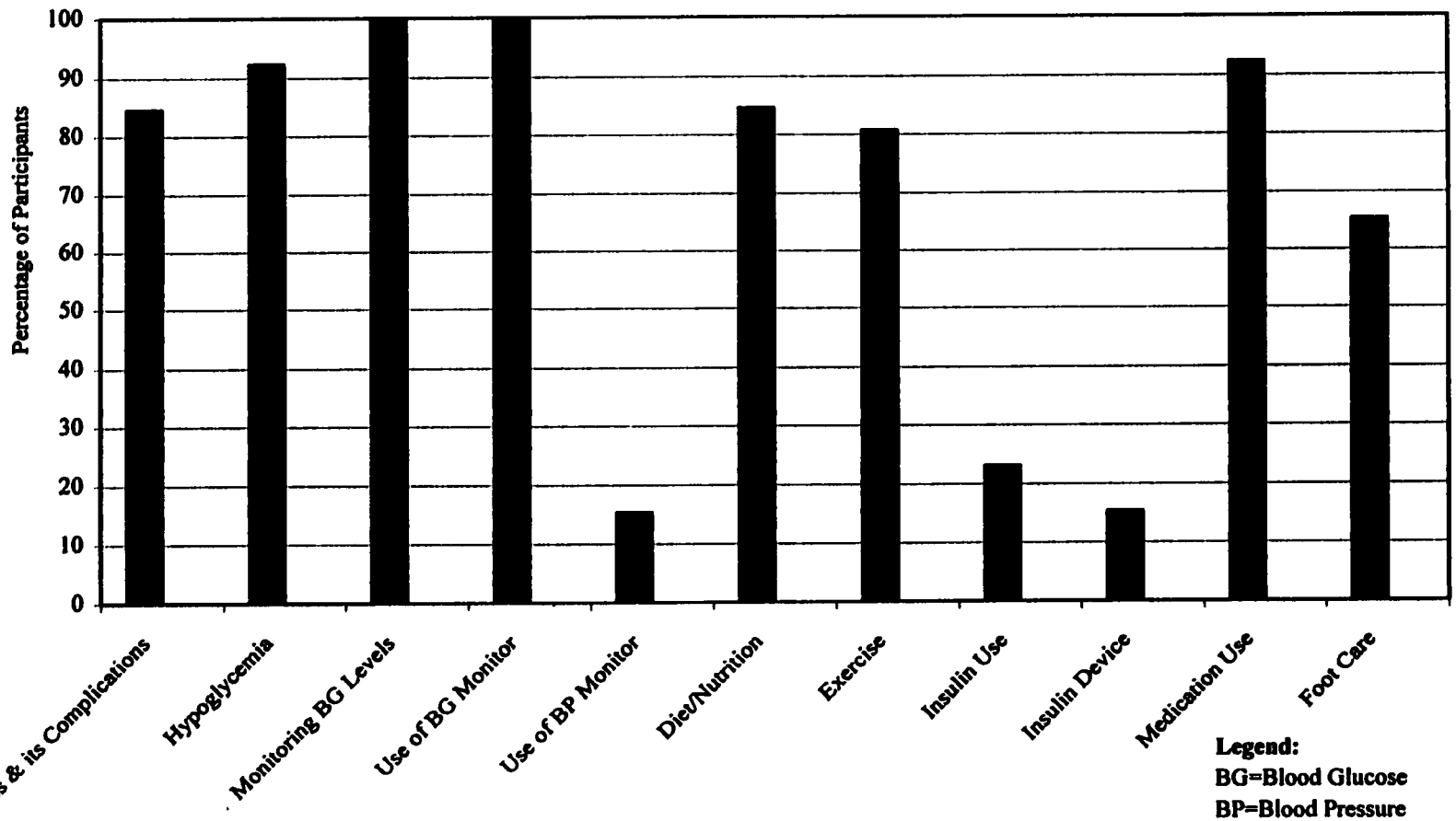
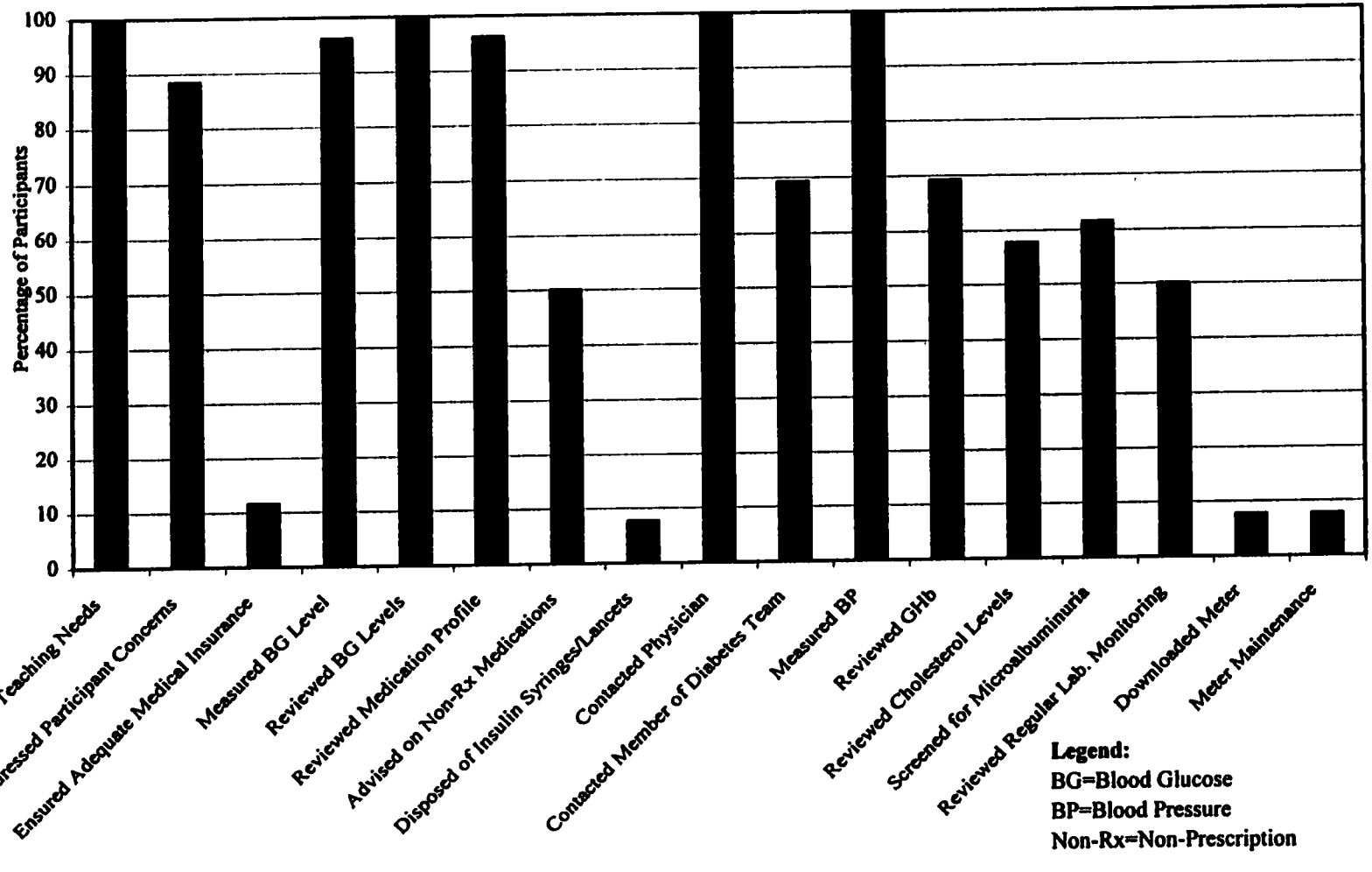


Figure 4.5 Percentage of Participants Receiving Services Provided by CDE Pharmacists n=26



hypoglycemic or insulin therapy (Figure 4.6). Data on physician acceptance of recommendations regarding DRPs was not collected.

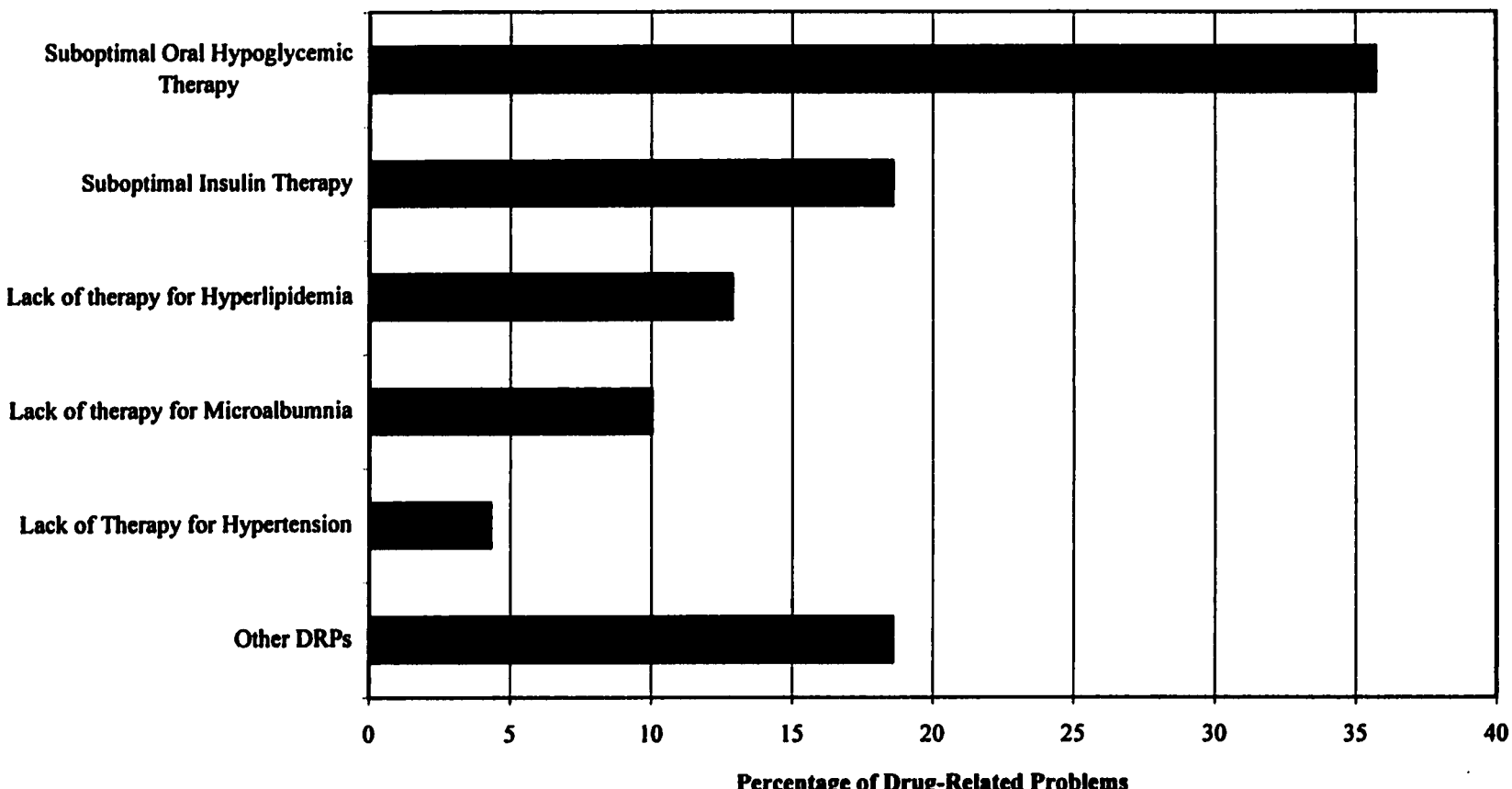
4.3.2 Control Pharmacy Processes

Due to the design of the study, documentation was not available about the specific services provided to individuals in the control group. Instead, the control pharmacies were asked in a structured interview about the general services they customarily provide to patient with diabetes. This level of care may or may not have been provided to the control study participants.

Ninety-four percent of pharmacies indicated that they hosted diabetes days. When asked to briefly describe the program, 67 % described a screening program where a nurse either demonstrated a new meter or device, answered patients questions, or screened for diabetes. Only two pharmacies indicated that a pharmacist provided care or advice directly to patients at diabetes days. The 22 % of remaining stores hosted in-store meter training sessions, but did not specify who provided the teaching. Finally, in addition to in-store diabetes days, three stores indicated that their chain or franchise hosted group educational seminars on diabetes, which were available to all customers.

Eleven percent of pharmacies stated that they regularly reviewed patients' diabetes control through meter logs or lab values, 39 % reported that they regularly discuss hypoglycemic reactions with their patients, and 100 % of pharmacies reported that they provide training when they sell a blood glucose meter. All pharmacies indicated that they had demonstration meters and one pharmacy indicated that it had a program established to lend meters to patients before they purchased their own.

Figure 4.6 Types of Drug Related Problems n=70



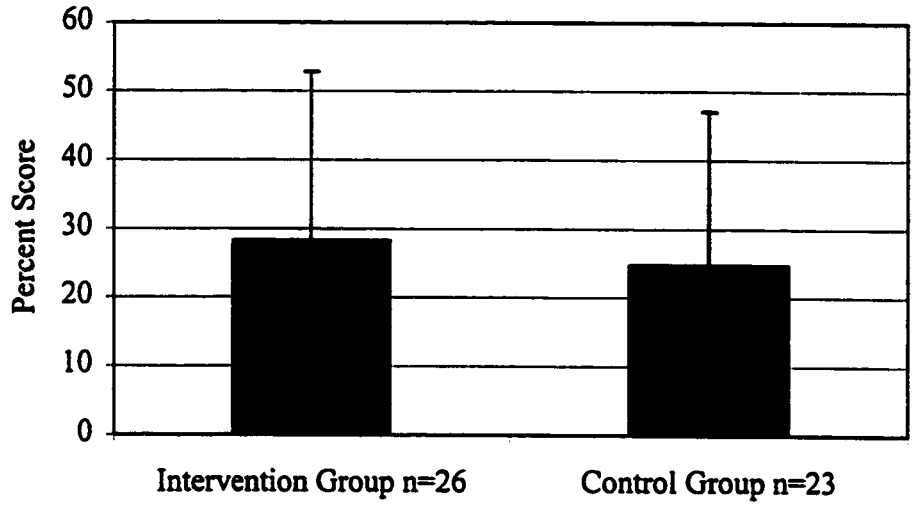
Legend:

Other DRPs included side effect of medications, lack of therapy for osteoporosis, suboptimal compliance, financial constraints, and drug disease interactions.

4.3.3 Exit Telephone Interview

All study participants completed the exit telephone interview. On the external education intensity variable, there were no differences between the intervention and control group ($p>0.05$) (Figure 4.7). This variable assessed what proportion of participants visited a metabolic centre, family doctor, diabetes specialist, or dietician, contacted the Canadian Diabetes Association, or surfed the Internet to learn about diabetes.

Figure 4.7 Education Intensity



The intervention and control group sought care from different sources (Table 4.4). The intervention group made more visits to a metabolic centre, but fewer visits to their family physician or contacts with the CDA, and "surfed" the internet less often. In addition, participants were asked an open-ended question about other activities they undertook to learn about diabetes. They indicated the following: attended seminars, read pamphlets from physician's offices or pharmacies, read books on diabetes, followed news

items in the newspaper or on television, reviewed food packaging, and learned from friends and family.

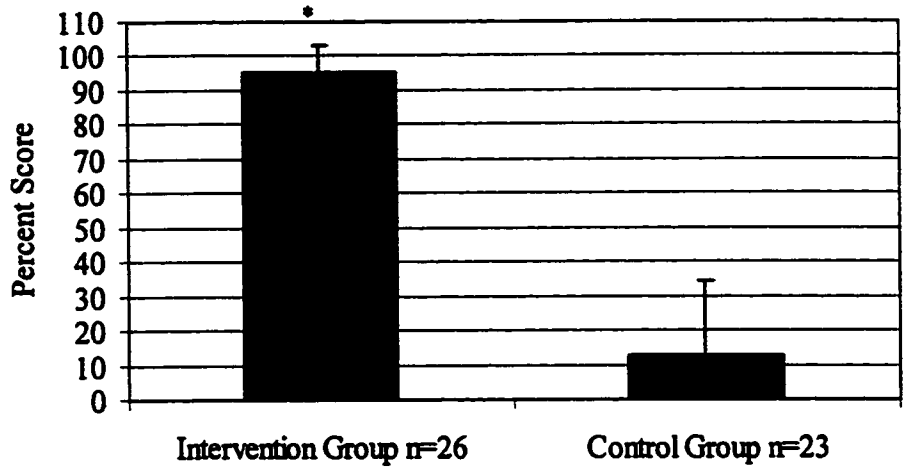
Table 4.4 Items in External Education Intensity Variable by Study Group

In the past six months while in the study have you:	Intervention Group n=26	Control Group n=23
Visited a metabolic centre?	29 %	12 %
Visited your family doctor with diabetes concerns?	58 %	73 %
Visited diabetes specialist doctor?	25 %	23 %
Visited a dietician?	25 %	31 %
Contacted the Canadian Diabetes Association?	0	19 %
Surfed the internet?	4 %	12 %
Total External Education Score	28 %	25 %

The second set of questions in the telephone interviewed assessed the intensity of the pharmacists' care. The intervention group scored significantly higher on the Pharmacists' Care Intensity variable than the control group ($p<0.001$) (Figure 4.8). Thus, participants in the intervention group were more likely to report having a pharmacist review their blood sugar levels, speak to them about blood sugar reactions and how to use their blood glucose monitor, assess their learning needs, measure their blood pressure, or monitor their medications.

For patients in the intervention group, the results of the Pharmacists' Care Intensity variable were compared with pharmacists' documentation to estimate the validity of the telephone interview. Ninety-five percent of the responses in the telephone interview were confirmed with the pharmacists' documentation. All of the discrepancies occurred on one question which asked participants if their pharmacist talked to them about hypoglycemic reactions. The discrepancies were divided between the participant

Figure 4.8 Pharmacists' Care Intensity



* $p < 0.05$ with a T-Test for Independent Means with Unequal Variance

reporting that their pharmacist reviewed reactions and the pharmacists did not document this (n=2) and vice versa where the participant did not report the pharmacists reviewing reactions and the documentation showed that the pharmacists had (n=3).

4.4.0 Outcome Measures

4.4.1 Descriptive Baseline Statistics

4.4.1.1 Distributions

All variables, except patient satisfaction with pharmacy services and one subscale of the SDSCA, diabetes medications, were approximately normally distributed. Thus, hypotheses about patient satisfaction with pharmacy services and diabetes medication outcomes were confirmed with the Kruskal-Wallis (KW) test. This rank-order test does require assumptions about normality of the distribution.[157]

4.4.1.2 Descriptions of Clinical Outcomes

The primary study outcome was GHb. At baseline, mean GHb were 7.9 % (± 2.2) and 7.9 % (± 1.3) in the intervention (n=24) and control (n=23) group, respectively.

4.4.1.3 Descriptions of Humanistic Outcomes

Diabetes Attitude Scale

The DAS for patients measured participants' attitudes toward diabetes (Figure 4.9). This instrument has seven factors, which were totalled to form one total DAS score. Higher DAS scores are associated with more positive attitudes toward diabetes. Overall study participants were positive toward diabetes. Participants' mean attitude scores were positive to strongly positive for *special training* and *control complications* factors. Attitudes toward *patient compliance, seriousness of type 2 diabetes,* and *impact on patient lives* factors were neutral to positive. The intervention group appeared to have more positive attitudes on *seriousness of type 2 diabetes,* and *impact on patient* factors and less positive attitudes toward *patient compliance* factor when compared with the control group. Nevertheless, the baseline total DAS scores were not statistically significantly different between the intervention and control group (p=0.12).

Diabetes Lifestyle Form

On the second outcome measure, the DLF, participants' mean scores were 'neutral' to 'agree' with factors referring to diabetes attitudes, beliefs, and self-efficacy (Figure 4.10). Higher DLF scores are associated with more positive attitudes and beliefs toward diabetes and increased self-efficacy. The control group had more positive scores on the total DLF at baseline when compared to the intervention group (p=0.0126).

Figure 4.9 Baseline Diabetes Attitude Scale

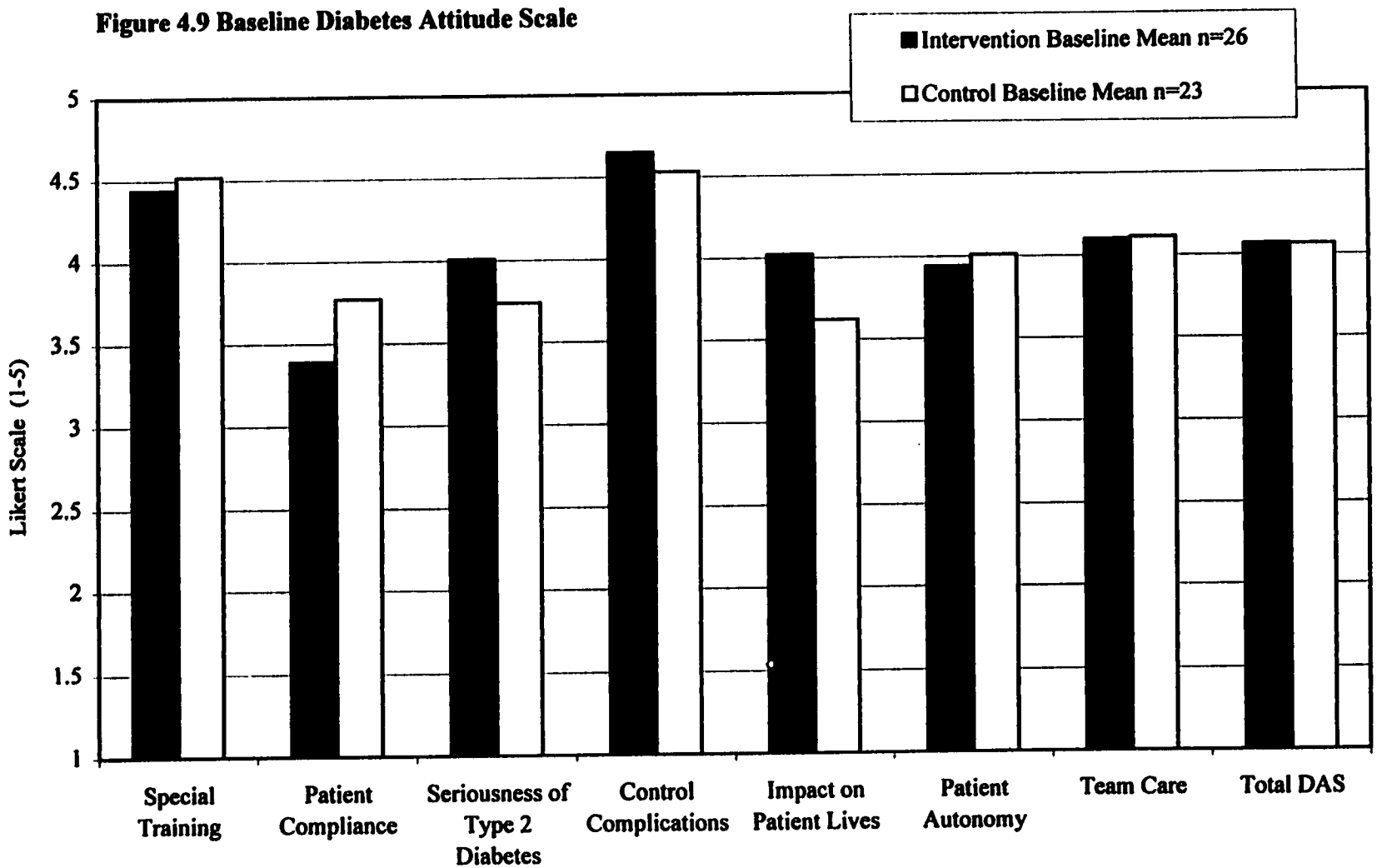
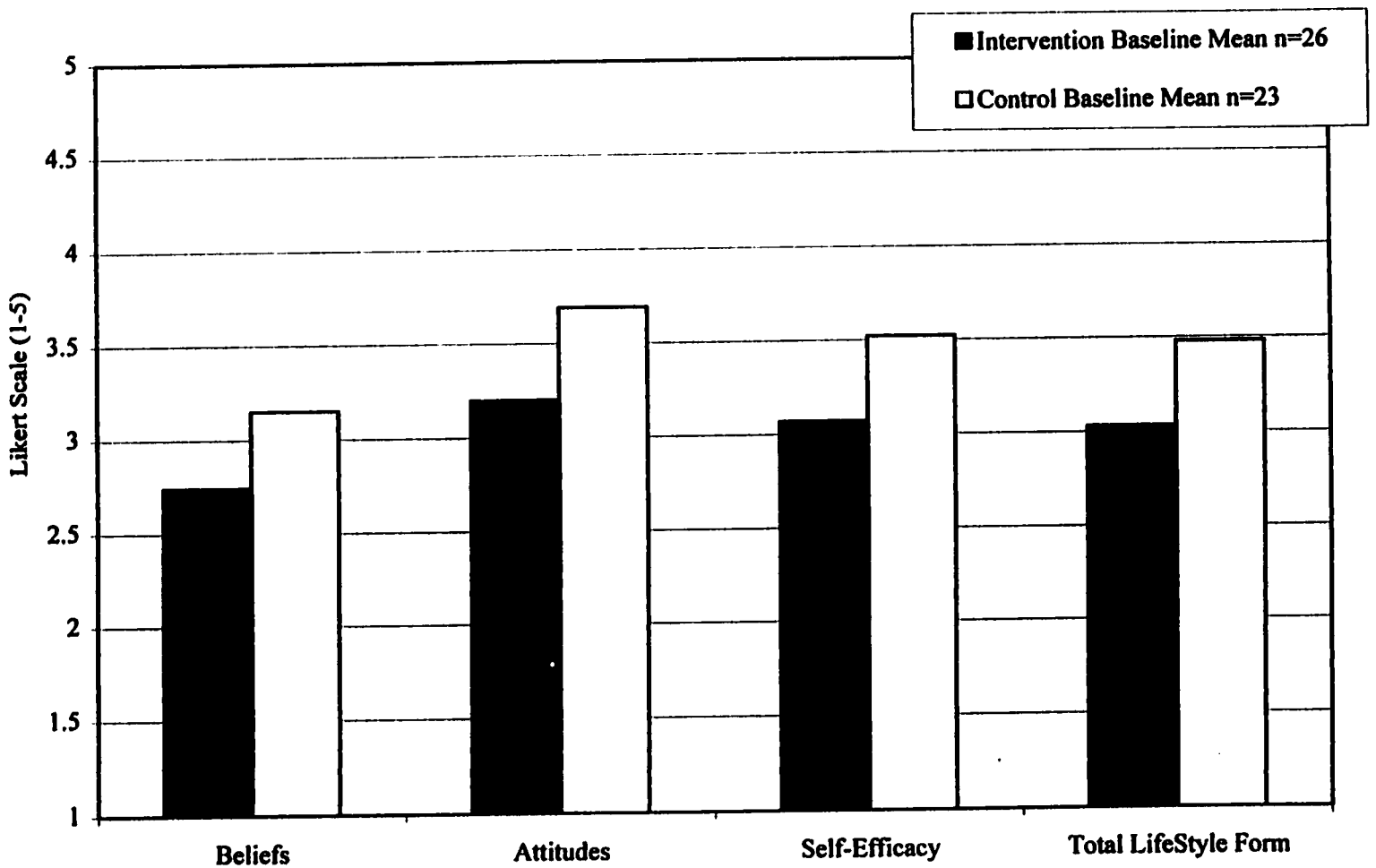


Figure 4.10 Baseline Diabetes LifeStyle Form



Summary of Diabetes Self-Care Activities

The SDSCA assessed participants' level of self-care activities. The statistical analysis was performed on scores that were standardized to a mean of zero and standard deviation of one. To better understand participants' baseline level of self-care, the raw item scores were presented (Table 4.5). Items were scored as either a number of days, percentage of time, or on a (one to five) Likert scale.

Participants reported that they followed their diet as recommended about 50 % of the time. On most days of the week, participants reported exercising at least 20 minutes. Participants also reported that they tested their blood glucose 60 % as often as their physician recommended, or on about 2 days a week. Finally, those participants on insulin reported perfect compliance with their injections and those on medications reported near perfect compliance with diabetes medications. At baseline, both groups appeared relatively similar. The intervention group reported that they had a lower percentage of meals, which included sweets and participated in slightly less exercise. However, there were no statistically significant differences between study groups on the any of the baseline SDSCA factor scores.

Table 4.5 Raw Item Scores for Summary of Diabetes Self-Care Activities

	Intervention Baseline Mean	Control Baseline Mean
*1. How often did you follow your recommended diet over the last 7 days?	2.32 (±0.9) n=25	2.34 (±0.8) n=23
2. What percentage of the time did you successfully limit your calories as recommended in healthy eating for diabetes control?	47.9 (±23.2) n=24	56.5 (±26.3) n=23
3. During the past week what percentage of your meals included high fiber foods?	68.3 (±26.0) n=26	71.7 (±29.5) n=23
4. During the past week, what percentage of your meals included high fat foods?	29.8 (±17.3) n=26	28.3 (±20.4) n=23
5. During the past week what percentage of your meals included sweets and desserts?	15 (±16.1) n=25	22.8 (±12.7) n=23
6. On how many of the last 7 days did you participate in at least 20 minutes of physical exercise?	3.85 (±2.1) n=26	4.1 (±2.0) n=23
7. What percentage of the time did you exercise the amount suggested by your doctor?**	48.1 (±40.7) n=21	52.3 (±28.8) n=22
8. On how many of the last 7 days did you participate in a specific exercise session other than what you do around the house or as part of your work?	2.5 (±2.4) n=26	2.9 (±2.0) n=23
9. On how many of the last 7 days (that you were not sick) did you test your glucose level?	2.11(±1.2) n=26	2.34 (±1.2) n=23
10. Over the last 7 days (that you were not sick) what percentage of the glucose tests recommended by your doctor did you actually perform?	63(±38.3) n=23	58.0 (±45.24) n=23
11. How many of your recommended insulin injections did you take in the last 7 days that you were supposed to?***	1(±0.0) n=4†	1 (±0.0) n=2
12. How many of your recommended number of pills to control diabetes did you take that you were supposed to?*	1.3 (±0.8) n=15‡	1.2 (0.7) n=19

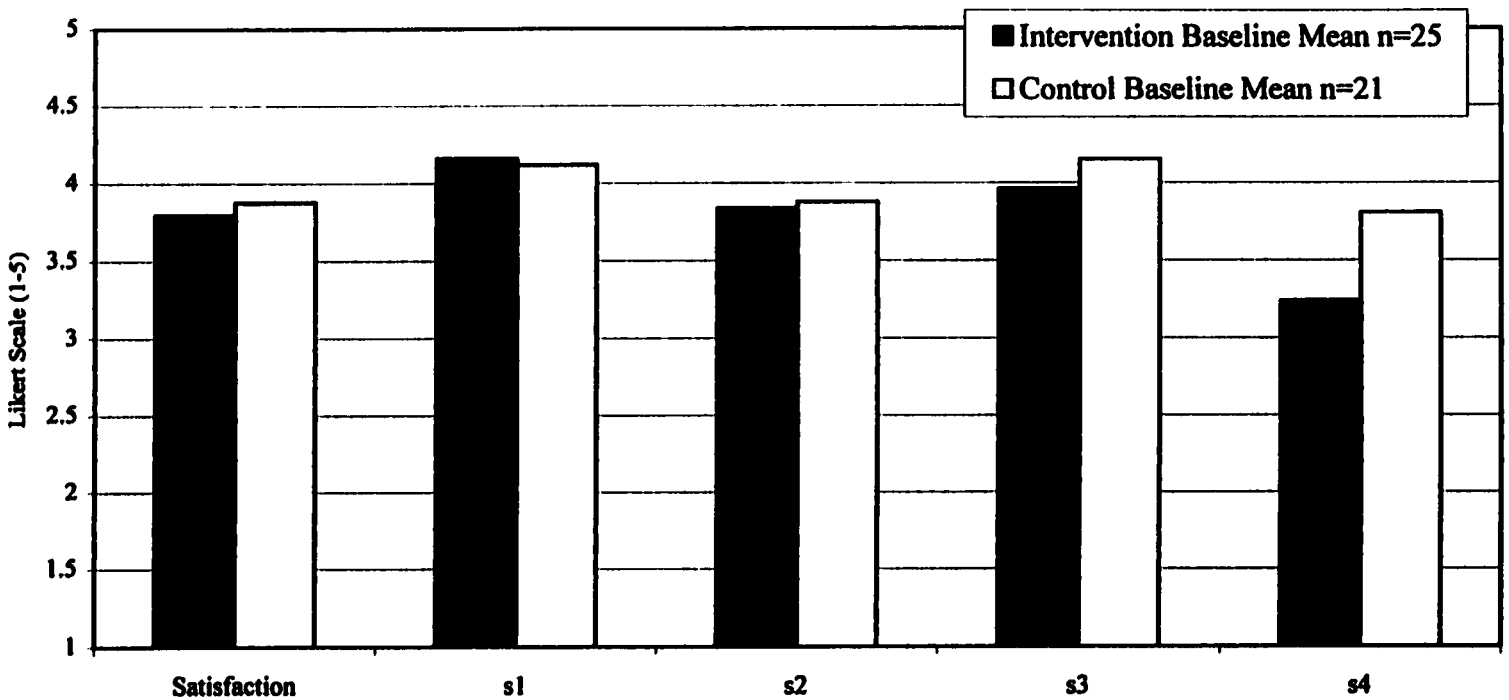
*Questions were abbreviated in chart, ** non-respondents indicated that their physician did not recommend physical activity, *** 1-4 Likert Scale (1=all of them, 2=most of them, 3=some of them, 4=none of them), † non-respondents did not use insulin, ‡ non-respondents did not use pills

Patient Satisfaction and Expectations of Pharmacy Services

Overall, patient satisfaction and expectations of pharmacy services were high (Figure 4.11 and 4.12). Participants agreed that they were satisfied with their pharmacies' services. The mean score on the item asking if their pharmacy services could be better was near neutral and the intervention group appeared to have lower scores at baseline, although this difference was not statistically significant (p=0.32).

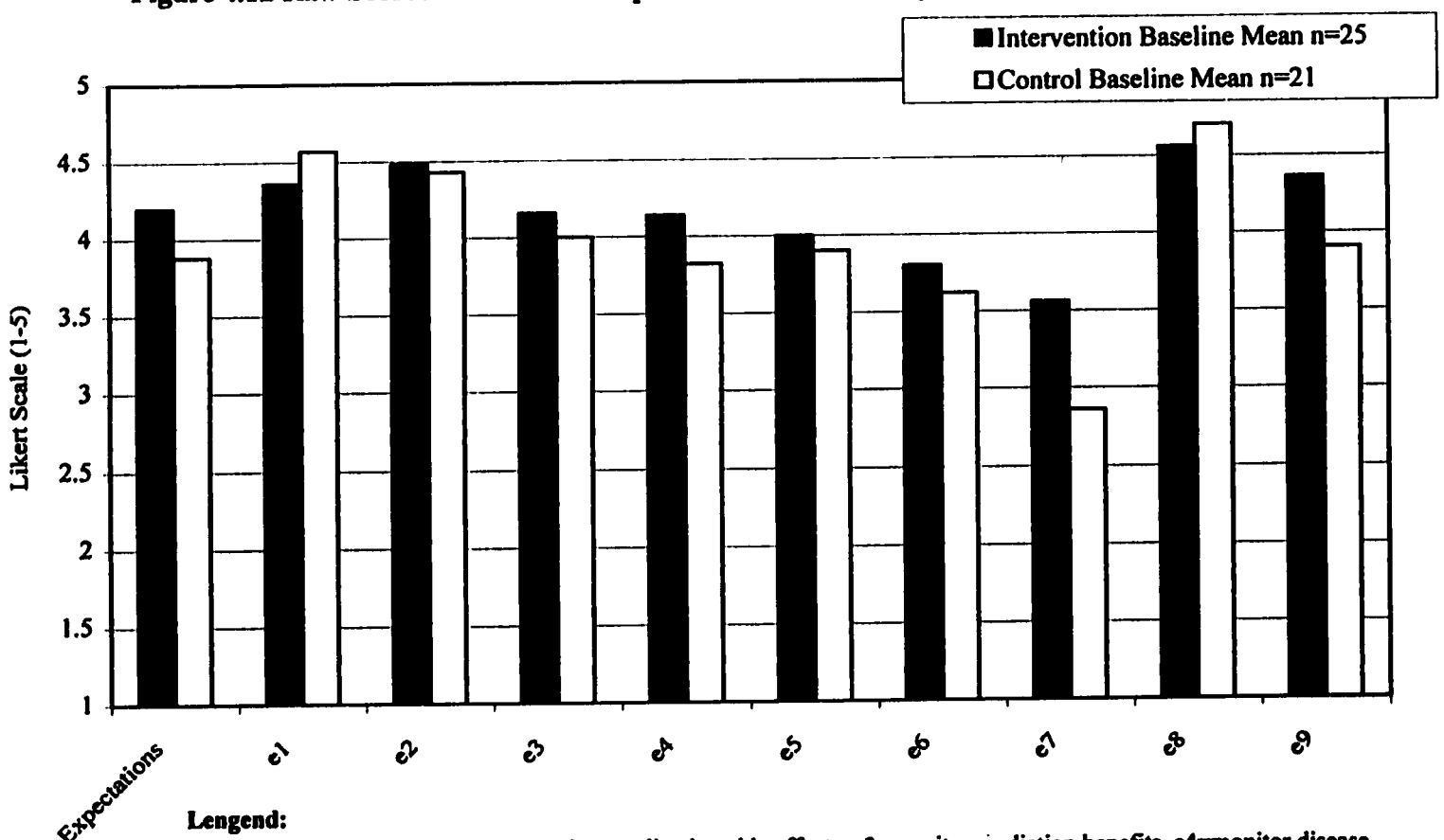
There was more variability in response to the expectation questions. Participants agreed that pharmacists should document their disease and medication information and should explain medications to them. Participants had close to neutral responses on items that asked if their pharmacist should offer appointments to discuss diabetes and phone participants to monitor medications. The intervention group appeared to have higher expectation scores for questions asking if they expected a phone follow-up or the pharmacists to contact the physician. There were no differences in total expectations scores at baseline (p=0.56).

Figure 4.11 Raw Scores for Baseline Satisfaction with Pharmacy Service



Legend:
s1=I'm very satisfied with the pharmacy services that I receive.
s2=The pharmacy services that I've received are just about perfect.
s3=I have some complaints about the pharmacy services that I receive.*
s4=There are things about my pharmacy services that I receive that could be better.*
*=items were reverse scored

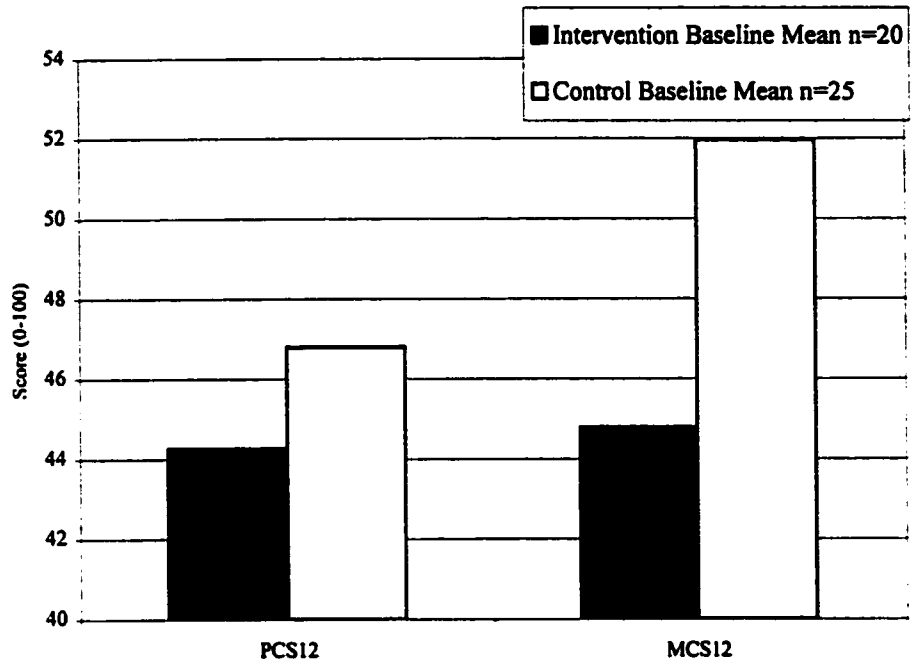
Figure 4.12 Raw Scores for Baseline Expectations of Pharmacy Services



Lengend:
e1=document pt information, e2=monitor medication side effects, e3=monitor mediation benefits, e4=monitor disease, e5=monitor between refills, e6=offer appointments, e7=phone follow-up e8=explain medications, & e9 =contact physician

Lastly, participants' quality of life was assessed to control for error in the analysis model. PCS12 scores were similar, but the MCS12 scores were statistically different at baseline different in each group (p=0.035) (Figure 4.13)

Figure 4.13 Baseline Health-Related Quality of Life



4.4.2 Bivariate Models

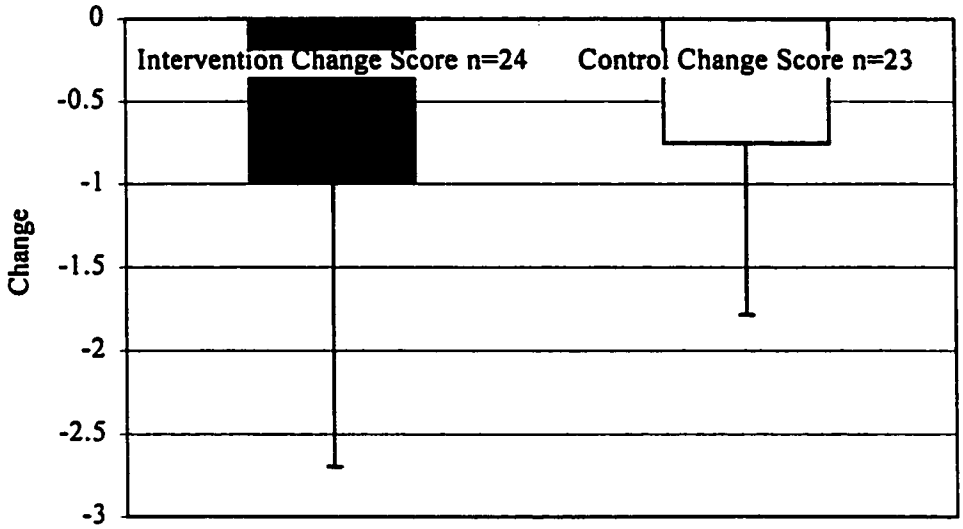
4.4.2.1 Clinical Outcomes

The primary study hypothesis (i.e. change in GHb) was intended to be tested with the ANCOVA model. However, the ANCOVA model did not meet the assumption of parallel regression lines, thus it could not be interpreted. Accordingly, a t-test on the change scores was used to test the hypothesis in Table 4.6. However, the change was not significant from the control (change score t-test, p=0.57) (Figure 4.14).

Table 4.6 Clinical Bivariate Hypothesis

H_0	Null Hypothesis:	There is no difference between *GHb change score* in the intervention & control group.
H_A	Alternate Hypothesis:	There is a difference between *GHb change score* in the intervention & control group.

Figure 4.14 Change in GHb



In order to better understand the results, the differences in GHb were examined within the study groups with a paired t-test. Overall, the both study groups and the total sample, improved significantly over baseline (Table 4.7).

Table 4.7 GHb Baseline/Endpoint

	Intervention n=24	Control n=23	Total n=45
Baseline	7.9	7.9	7.9
Endpoint	6.9	7.1	7.0
Significance	p=0.0095	p=0.0021	p<0.001

4.4.2.2 Humanistic Outcomes

While the overall models were significant, the p values for the group effects were greater than p=0.05. Thus, for each dependent variable, the null hypothesis was not rejected (Table 4.8).

Table 4.8 Humanistic Bivariate Hypothesis Tests

H_0	Null Hypothesis:	There is no difference between endpoint *DV* in the intervention & control group while controlling for *DV* at baseline.
H_A	Alternate Hypothesis:	There is a difference between endpoint *DV* in the intervention & control group while controlling for *DV* at baseline.

Where: *DV (dependent variable)*=

	n	Model	Group
DAS	49	p>0.0001	p=0.10
DLF	49	p>0.0001	p=0.16
SDSCA Diet	49	p=0.016	p=0.78
SDSCA Exercise	49	p=0.011	p=0.73
SDSCA Glucose Testing	49	p=0.030	p=0.14
SDSCA Diabetes Medication	39	N/A	N/A
Patient Expectations	46	p>0.0001	p=0.19
Patient Satisfaction	46	N/A	N/A

The humanistic bivariate model met the ANCOVA assumptions for the following dependent variables: DAS, DLF, SDSCA (diet, exercise, glucose testing factors), and patient expectations. The distributions of the patient satisfaction and the diabetes medication factor of the SDSCA were highly skewed. Furthermore, the diabetes medication factor also had heterogeneous regression lines. Thus, the analysis of these two factors was conducted with the KW non-parametric tests. This tests the null hypothesis that there is no difference between change score in the intervention and control groups. The null hypothesis was not rejected in the case of the diabetes

medication scale (n=39, p=0.59) and patient satisfaction with pharmacy services (n=46, p=0.40).

In summary, there were no statistically significant differences in the amount of change between the intervention and control group on the DAS, DLF, SDSCA (Diet, Exercise, Glucose Testing factors, and Diabetes Medication), patient expectations, and satisfaction with pharmacy services questionnaires (Figures 4.15, 4.16, and 4.17).

Figure 4.15 Change in Diabetes Attitude Scale & Diabetes Lifestyle Form

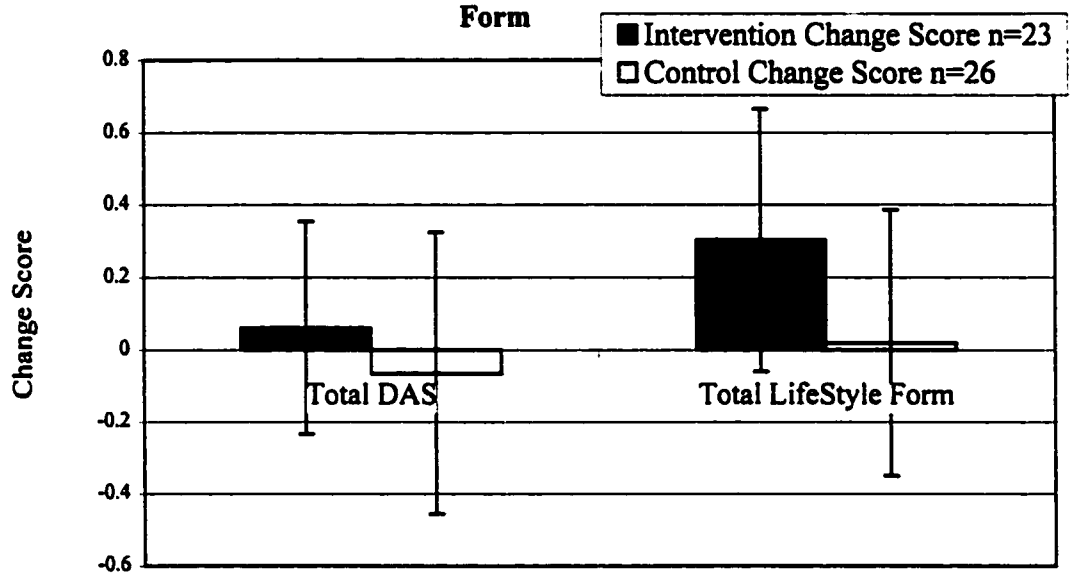


Figure 4.16 Change in Summary of Diabetes Self-Care Activities

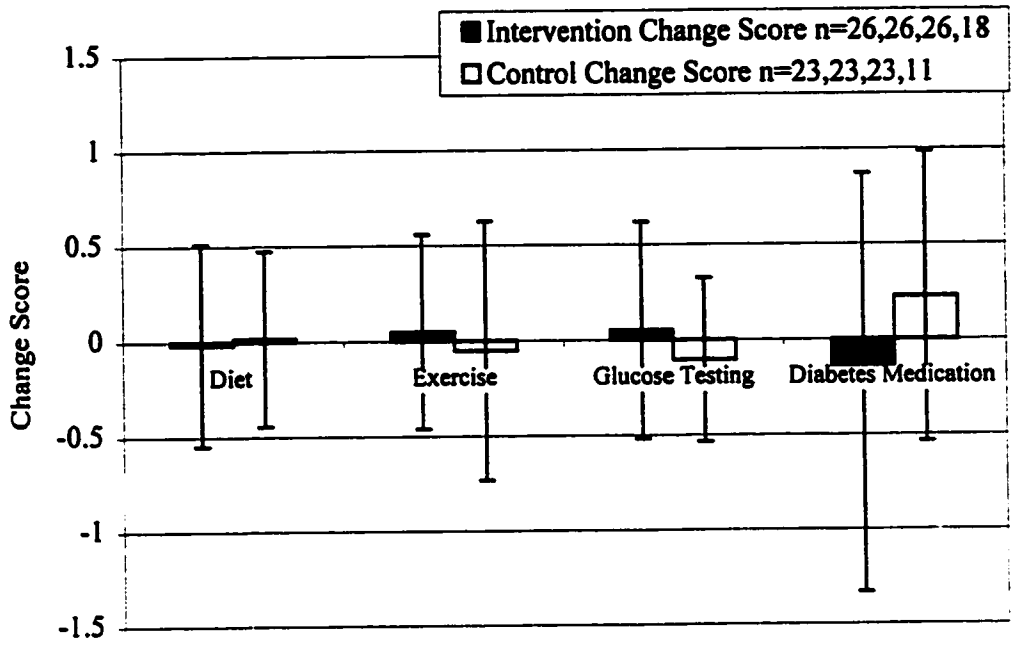
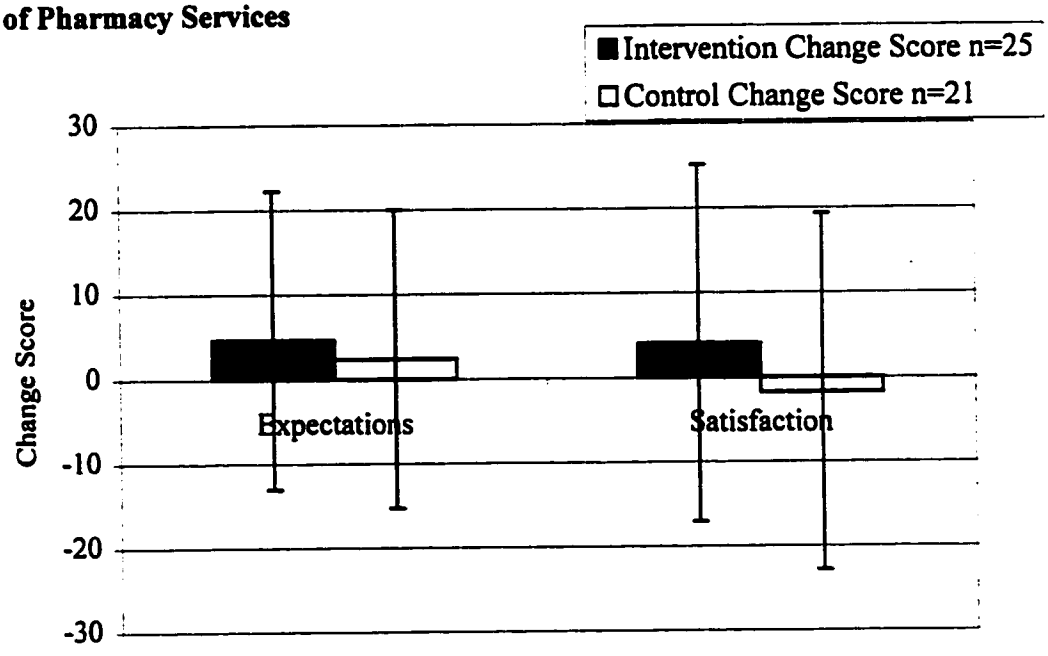


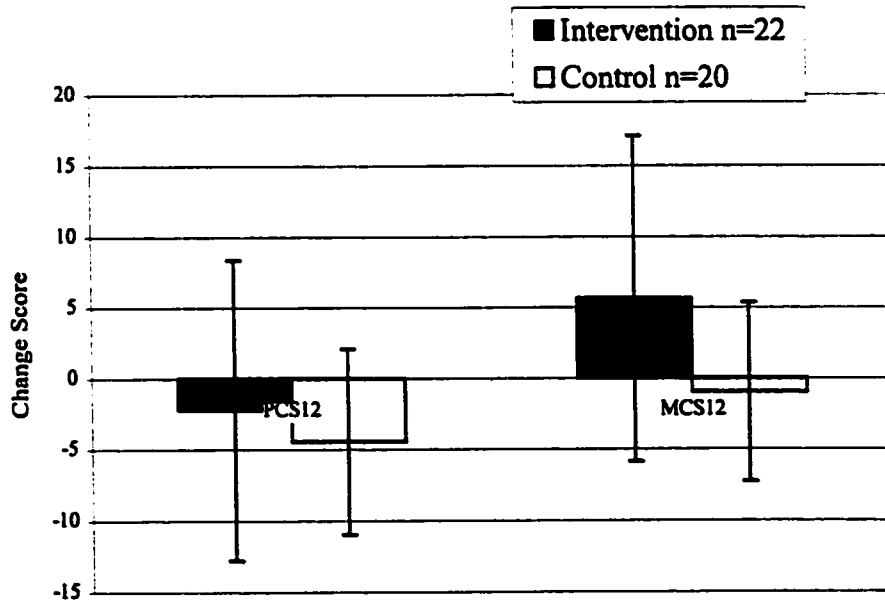
Figure 4.17 Change in Patient Satisfaction with and Expectations of Pharmacy Services



4.4.2.3 Health-Related Quality of Life

Change in HRQL was not a primary study hypothesis, however change in HRQL was assessed using the ANCOVA model in Table 4.8 to better understand what was happening in the study sample (Figure 4.18). The PCS12 model was significant, but the group term was not significant, indicating that there were no differences between the change in PCS12 between study groups. When testing the MCS12, there was significant interaction term, thus the ANCOVA model could not be interpreted. A t-test was performed on the change scores between the study groups and a significant effect was found (p=0.026). These results should be interpreted with caution, as they are not a primary study hypotheses and increasing the number of tests may also increase the type 1 error or chance of finding a difference that does not exist in the population.

Figure 4.18 Change in Health-Related Quality of Life



4.4.2.4 Power Analysis

This final study sample (n=49), did not meet the intended sample size of 60. Therefore, the power and effect of each statistical test was examined (Table 4.9). Power ranged from 6 % to 37 % and the effect size ranged from small to moderately large.

Table 4.9 Power of Bivariate Analysis

Outcome	Observed Power in ANCOVA*	Eta *	Effect Size***
GHb	N/A	N/A	0.18
DAS	37 %	0.49	0.35
DLF	29 %	0.45	0.47
SDSCA -Diet	6 %	0.05	-0.08
SDSCA -Exercise	6 %	0.22	0.13
SDSCA -Glucose Testing	32 %	0.47	0.37
SDSCA -Diabetes Medication	N/A	N/A	0.51
Patient Expectations	9 %	0.32	0.14
Patient Satisfaction	N/A	N/A	0.21

* Calculated by SPSS, * Eta refers to the strength of the relationship or square root of the amount of variance in the dependent variable that is associated with the independent variable.[165] It is analogous to "r" in regression.
**(Change Score $_{intervention}$-Change Score $_{Control}$)/ Standard Deviation of Baseline Questionnaire in Control Group[166]

4.4.3 Multivariate Models

A correlation matrix was examined to eliminate collinear variables (Table 4.10). Because of the small sample size of the study, the ANCOVA model was restricted to four covariates. The covariates included pretest, PCS12, MCS12, and duration of diabetes. Other factors were eliminated for the following reasons: age and gender were correlated with each other and age was correlated with MCS12. Therefore age and gender were removed assuming that MCS12 would account for variance in both. Income was correlated with the PCS12 and MCS12, education level, and gender, and consequently

was eliminated. The PCS12 was correlated with medical conditions and income that were subsequently removed from the model while MCS12 was correlated with the marital status, thus marital status was dropped. The number of medical conditions was removed from the model because of its correlation with the MSC-12. Number of medications and method of treating diabetes were both removed from the model, because they were related to the duration of diabetes. Participants diagnosed with diabetes for a longer duration were more likely to be on insulin and a greater number of medications. Finally, education was removed in favour of the retaining the HRQL scores.

Table 4.10 Correlation Matrix

	Age	Gen	Inc	Med Cond	# Meds	MS	Tx	Educa	PCS12	MCS12	EEI
Gend	-0.38*										
Inc	0.00	-0.35*									
Med Cond	0.16	0.00	-0.19								
# Meds	0.21	-0.15	0.18	0.25							
MS	-0.22	0.26	-0.26	0.00	-0.13						
Tx	0.00	0.27	-0.21	0.08	-0.15	0.43*					
Educ	-0.13	0.05	0.38*	0.15	0.01	0.02	-0.09				
PCS12	-0.25	0.05	0.33*	-0.65*	0.08	-0.07	-0.15	-0.05			
MCS12	0.32*	-0.05	0.39*	-0.07	-0.05	-0.43*	-0.26	0.10	0.02		
EEI	-0.01	0.11	0.08	-0.23	0.00	-0.03	0.12	0.19	0.00	-0.01	
DD	0.28	0.09	-0.14	0.14	0.39*	0.16	0.31*	-0.15	-0.07	0.05	0.03

* $p<0.05$

Legend:
Age (years)
Gender (0=male; 1=female)
Inc= Income (spilt on distribution ex: 0=< $40 000; 1=≥ $40 000)
Med Cond= Number of co-morbidities
#Meds= Number of medications (total)
MS= Marital status (0=married 1=not married)
Tx= Method of treating diabetes (0=diet/pills; 1=insulin)
Educ= Education level (0=high school or less; 1=college/university)
EEI= Educational Intensity (0-6)
DD= Duration of Diabetes (years)

4.4.3.1 Clinical Outcomes

The revised multivariate model (Table 4.11) was used to test the following hypothesis regarding the primary outcome, GHb (Table 4.12).

Table 4.11 Revised ANCOVA Model

$\{DV\}_{post} = \beta + \{DV\}_{pre} + \{group\} + \{clinical\} + \{HRQL\} + \varepsilon$

Where:

DV	**= Dependent Variable**
Clinical	**= Clinical Factors** ▪ Duration of Diabetes
HRQL	**= Health Related Quality of Life** ▪ MCS12 ▪ PCS12
ε	**= error** ▪ Variance not accounted for in the model

For the primary outcome, the model was found to be significant ($p<0.001$), but the group effect was not significant ($p=0.21$). Thus, there was no statistically significant difference in GHb between the treatment and control group after controlling for GHb at baseline, duration of diabetes, and baseline HRQL. Because there was missing data in the HRQL instruments, the multivariate analysis used a sample size of only 41.

Table 4.12 Hypothesis in the Multivariate Analysis

H_0	Null Hypothesis:	There is a no difference between endpoint *GHb* in the intervention & control group while controlling for *GHb* at baseline, clinical, and HRQL.
H_A	Alternate Hypothesis:	There is a difference between endpoint *GHb* in the intervention & control group while controlling for *GHb* at baseline, clinical, and HRQL.

4.4.3.2 Humanistic Outcomes

Differences in humanistic outcomes between study groups were also examined with multivariate ANCOVA models (Table 4.13). The null hypotheses were not rejected for any of the dependent variables, thus there were no differences detected between endpoint scores of DAS, DLF, SDSCA, or patient expectations in the intervention and control group while controlling for questionnaires at baseline, clinical variables, and HRQL. In the case of the glucose testing scale of the SDSCA, the model was not significant, therefore individual effects were not interpretable.

Table 4.13 Hypothesis in the Multivariate Analysis

H_0	Null Hypothesis:	There is no difference between endpoint *DV* in the intervention & control group while controlling for *DV* at baseline, clinical, and HRQL.
H_A	Alternate Hypothesis:	There is a difference between endpoint *DV* in the intervention & control group while controlling for *DV* at baseline, clinical, and HRQL.

Where: *DV (dependent variable)* =

	n	Model	Group
DAS	44	p<0.001	p=0.23
DLF	44	p<0.001	p=0.22
SDSCA -Diet	45	p=0.04	p=0.54
SDSCA -Exercise	44	p<0.001	p=0.81
SDSCA -Glucose Testing	21	p<0.53	N/A
SDSCA -Diabetes Medication		N/A	N/A
Patient Expectations	42	p=0.001	p=0.73
Patient Satisfaction		N/A	N/A

4.4.3.3 Power Analysis

As with the bivariate analysis, there were concerns that the study was under powered to detect any difference between the intervention and control groups. Thus the

power and eta of multivariate models were examined (Table 4.14). Power ranged from 6 % to 25 % and the strength of the relationship estimates (eta) were generally small.

4.14 Power and Strength the Relationship in the Multivariate Model

Outcome	Observed Power in ANCOVA*	Eta **
GHb	24 %	0.21
DAS	22 %	0.19
DLF	23 %	0.19
SDSCA -Diet	11 %	0.51
SDSCA -Exercise	6 %	0.10
SDSCA -Glucose Testing	18 %	0.31
SDSCA -Diabetes Medication	N/A	N/A
Patient Expectations	6 %	0.054
Patient Satisfaction	N/A	N/A

*Calculated by SPSS

** Eta refers to the strength of the relationship or square root of the amount of variance in the dependent variable that is associated with the independent variable[165] It is analogous to "r" in regression.

4.4.4 Summary of Bivariate and Multivariate Analysis

There were no statistically significant differences between the intervention and control groups on clinical or humanistic outcomes. Small but positive differences were observed for most outcome measures, with small to moderate effect size estimates and eta values.

There was no significant difference between study groups on the PCS12, but there was a difference between groups on the MCS12. Participants who received care from CDE pharmacists had greater improvements in MCS12 scores.

Chapter 5

Discussion and Implications

This randomized controlled trial assessed the impact of CDE pharmacists in a community pharmacy caring for people with type 2 diabetes in the community. Results demonstrated that there were structural differences in the pharmacists' education and time to provide care in addition to process differences in the level of care provided between the intervention and control group. The intervention resulted in positive small to moderate effect sizes (ES) in clinical and humanistic outcomes, however this study did not have sufficient power to conclude that these changes were statistically significant.

This chapter will review the findings of this pilot study using the *structure, process* and *outcomes* model.[62] Findings will also be compared to other evaluations of pharmacists' care for people with diabetes. Study limitations will be discussed in terms of threats to internal and external validity of the results. Finally, implications for practice and future research will be discussed.

5.1.0 Summary and Discussion of Results

Donabedian's *structure, processes,* and *outcomes (SPO)* framework was used to evaluate the quality of pharmacists' care.[62] This framework assesses *structures* which support the *processes* or the actions of care, which are intended to influence patient *outcomes* (Figure 5.1). All three elements of the SPO model were measured during the study. This framework helped to link pharmacist's care to any changes in study participants' outcomes that may have occurred.

Figure 5.1 Summary of Study Results

Pharmacy resources for care.

Activities of care provided.

Participants' outcomes

Intervention pharmacy:
- pharmacists were CDE
- pharmacists provided care outside of dispensary time
- had private counseling area

Control Pharmacy:
- pharmacists not certified as diabetes educators
- 1.3 pharmacists FTE
- 0.7 technician FTE
- had counseling areas

Intervention Pharmacy:
- 6.9 visits per participant
- teaching focused on BG monitors, diabetes complications, BG reactions, diet/nutrition, exercise and medication use
- services: evaluated learning needs, reviewed BG control, reviewed med. profile, addressed participant concerns, contacted physician, and measured blood pressure
- identified 2.9 DRPs per participant

Control Pharmacy:
- general description
- 94 % hosted diabetes days
- 11 % regularly reviewed diabetes control
- 40 % discussed hypoglycemia
- 100 % provided meter training

There were no statistically significant differences between the control and intervention group on the following outcome measures. Small differences were observed, with small to moderate effect size estimates for most outcome measures:

- GHb (ES=0.18)
- DAS (ES=0.35)
- DLF (ES=0.47)
- SDSCA (ES=0.08-0.51)
- Patients' Expectations (ES=0.14) and Satisfaction (ES=0.21) with Pharmacy Services

Legend:
BG = Blood Glucose;
ES = Effect size

5.1.1 Structure Indicators

The first element of the *SPO* model, *structure,* refers to the resources in the intervention and control pharmacies required to provide care to patients. Structures are vital to support a high level of care in a community pharmacy. Yet, in a recent review of the PC research literature, only two of eleven studies described structural indicators.[167]

Traditionally, pharmacists have focused on the product (i.e., prescription) and the structural similarities between the control and intervention pharmacies in this study reflected this. All pharmacies carried a variety of diabetes supplies including meters, injectable supplies, and sugar substitutes. However, study participants were provided with blood glucose testing supplies as part of the study protocol, thus the stock in a pharmacy may not have impacted care.

Pharmacists frequently cite space to provide care as a barrier to PC.[168] Pharmacists may require a private area for discussions with patients about confidential topics and to take patient histories. In five studies evaluating pharmacists' care for people with diabetes in the community, presence of a counseling area was not addressed,[18,134,135-137] although one may assume such as area was available to deliver the care described. The intervention pharmacy in this study had a private counseling area, while 67 % of the control pharmacies had counseling areas. A third of control pharmacies did not have a dedicated area to assess or counsel people with diabetes.

The pharmacists' education is another structure indicator that may impact the level of diabetes care. Kennie et al. recommended that pharmacists' qualification should be addressed when assessing PC.[167] In the 12 published studies evaluating the role of the pharmacist in diabetes, six indicated that pharmacists received diabetes education prior to

the study either self-directed or in a workshop.[15,18,134,135-138] In one of those studies, three CDE pharmacists attended further diabetes education, and in another, CDE pharmacists led an education session for other pharmacists. However, in both cases, CDE pharmacists' care was not differentiated from the care provided by other pharmacists. In this study, both pharmacists in the intervention pharmacy are CDEs, whereas control pharmacies reported one CDE pharmacist. In fact, this was the same pharmacist from the intervention group. AB worked at the control pharmacy casually, so it was unlikely that she encountered participants from the control group. Half of the control pharmacies reported that their staff had other training in diabetes and 90 % indicated that pharmacists had meter training. While diabetes training may increase pharmacists' knowledge, it is unlikely that it is equivalent to CDE training. Certification not only requires the pharmacists to demonstrate their knowledge on a written exam, but also requires the pharmacist to care for people with diabetes the equivalent of one day a week for two years. These requirements differentiate certification from other types of diabetes training.[59]

While pharmacists have been encouraged to become diabetes educators, [12,57] the impact of a CDE designation on patient care not been evaluated. In general, CDEs have reported that certification increased their confidence.[61] It has been reported that CDEs pharmacists provide more nutritional education[124] and have significantly more positive attitudes toward the need for specialized training and team care than non-CDE pharmacists.[122] These attributes may positively affect the outcomes of people with diabetes.

Time to devote to patient care is another essential structure indicator that pharmacists have listed as an obstacle to the provision of PC.[169] Staffing equivalents may be used to estimate the number of pharmacists available to provide care in the pharmacy. The control pharmacies reported a mean of 1.3 full time pharmacist equivalents and 0.7 full time technician equivalents. A staffing equivalent of 1.3 may not permit enough staffing for pharmacists to spend time counseling people with diabetes or monitoring their disease while working in the dispensary.

At the intervention pharmacy, CDE pharmacists were paid a flat rate per participant for meeting with study participants, documenting their care, and contacting other members of the diabetes team. Before the study, CDE pharmacists directly billed their patients for diabetes care services. This arrangement allowed CDE pharmacists to provide diabetes care outside of their time in the dispensary. In this environment, factors such as prescription volume and pharmacist to technician ratios should not affect patient care. Similarly, in previous studies evaluating the role of the pharmacist in diabetes care,[13,14,15-19,134-137] it appeared that pharmacists provided care outside of time in the dispensary.[13,137,138]

The pharmacist and technician staffing of a pharmacy currently are a function of its prescription volume.[63] Understaffing a high prescription volume pharmacy may lead to dispensing errors and discourage pharmacist counseling.[170] Furthermore, Sisson and Israel found that community pharmacists who filled over 150 prescriptions per day scored lower on the community-based pharmaceutical care index.[171] This index assessed the extent to which pharmacists documented care, developed patient-physician relationships, and counseled their patients.

Over 50 % of control pharmacies in this study filled more that 150 prescriptions per day and the pharmacists staffing increased only slightly as the prescription volume increased (Table 5.1). Technician staffing did not increase as the prescription volume increased (Table 5.1). Thus, it is unlikely that control pharmacists were able to accommodate this heavy workload and provide a high level of care to people with diabetes. However, a lower prescription volume does not ensure a higher level of care. Lower volume pharmacies tended to have fewer technicians, and as a result pharmacists may spend more time on non-clinical functions such as ordering stock and preparing prescriptions.

Table 5.1 Full Time Equivalents (FTE) of Control Pharmacy Staff by Rx Volume

Prescription Volume	No of Pharmacies	Pharmacist FTE	Technician FTE
<99	5	1.1 (±0.2)	0.4 (±0.6)
100-149	2	1.1 (±0.1)	1.1 (±0.4)
150-199	7	1.3 (±0.2)	0.8 (±0.3)
>200	4	1.5 (±0.4)	0.9 (±0.1)

In summary, while the intervention and control pharmacies had counseling areas and a similar stock of diabetes supplies, the intervention pharmacy had pharmacists with advanced training and certification (i.e. CDE) who were supported to provide care outside of their typical pharmacy responsibilities. This support allowed them time to provide care to people with diabetes. These structure indicators were similar to two other studies which demonstrated the benefits of the pharmacist. .[13,18]

18

5.1.2 Process Indicators

Processes are the actual activities of care that pharmacists provided to study participants. Kennie et al. found that clear descriptions of pharmacists' care were lacking in the PC literature.[167] In previous studies examining the role of the pharmacists in diabetes care, processes were addressed in 10 of 11 studies. However, the pharmacists' processes were described in the introduction or methods section without discussing how the details of pharmacists' interventions were gathered[13-16,18-19,134-137] Encouragingly, three papers did report the amount of time pharmacists spent with patients.[14,18,134] In the intervention pharmacy in this study, documentation on each visit was collected and summarized to describe the pharmacists' care. This ensured that the description of care reflects the level of care CDE pharmacists provided. CDE pharmacists spent, on average, one hour with each participant at the initial visit, and half an hour for each follow-up visits.

The goal of PC is to identify, resolve and prevent drug-related problems.[66] The recent Canadian Pharmacist Intervention Study (CPhIS) found that community pharmacists intervened on 1.4 prescriptions per 100 filled and 2.3 prescriptions per 100 new prescriptions.[172] In CPhIS, pharmacists documented interventions that resulted in checks or changes in drug therapy during the screening, dispensing and monitoring process. In three papers evaluating the role of pharmacists in diabetes, pharmacists detected 0.4, 1.1, 3.9, and 2.2 DRPs per patient, respectively.[13,15,137,138] The study that identified 3.9 DRPs per patient defined DRPs to include prescription clarification and patient focused problems whereas other studies only included patient focused problems.[13,15,137,138] The CDE pharmacists in this study identified 2.9 DRPs per

participant. This high rate could be due to the intensity of the intervention, the pharmacists' focus in one therapeutic area, or the time taken to develop relationships with study participants.

A principal difference in the care provided by the intervention and control pharmacies was diabetes monitoring. Monitoring of laboratory values, particularly GHb, has been underused in assessing glycemic control.[173] The current Canadian Clinical Practice Guidelines recommend that GHb be measured every three to four months for people on insulin and every six months for people on diet or oral hypoglycemic therapy.[4] Ten percent of control pharmacies indicated that they regularly reviewed laboratory values or log books to assess patients' glucose control, whereas CDE pharmacists reviewed participants blood glucose level at over 80 % of visits and for all participants in the intervention group. Furthermore, CDE pharmacists reviewed GHb for 70 % of participants during the six months of follow-up. Still, 30 % of participants in the intervention group did not have a GHb reviewed during the study. It is possible that another health care provider monitored participants' GHb outside of the study. Since community pharmacists cannot order laboratory tests and they can only recommend that a GHb be performed, the CDE pharmacists were not the sole influence on whether a GHb was available.

Diabetes education is recognized as a factor that contributes to improved self-care, and thus improved control in diabetes.[51] Pharmacists can help to educate people with diabetes about their disease and medications. Approximately 40 % of control pharmacies reported regularly discussing hypoglycemic reactions with their patients. In 40 % of follow-up visits the CDE pharmacists discussed hypoglycemic reactions,

however, it was documented that they discussed these reactions with 92 % of participants. In addition, CDE pharmacists educated participants on diabetes complications, diet, nutrition, exercise, and medication use.

CDE pharmacists evaluated the learning needs for all participants at the initial visit, but did not document that they evaluated participants learning needs in subsequent visits. A formal process was in place to evaluate participants learning need at the beginning of the study with the Diabetes Days Questionniare®, however a process was not in place for other time periods. It appeared that CDE pharmacists did not re-evaluate participant's learning needs as the study progress, however it may also be possible that this evaluation occurred informally and was not documented.

Diabetes education days are a tool to provide diabetes education to pharmacy patrons. Ninety four percent of control pharmacies reported hosting diabetes days for their customers. Yet, pharmacists provided direct care in only 11 % of these diabetes days. Nurse educators provided the majority of care. So while diabetes days do increase care to patients in the pharmacy setting, one should not assume that a pharmacist provides this care.

The current Canadian Practice Guidelines recommend that all people with diabetes should be educated on blood glucose meter use.[4] A CDE pharmacist recently described training on blood glucose monitoring as one of CDE pharmacists' primary roles.[123] Seven studies which have described pharmacists educating patients on meter use have also demonstrated some improvement in diabetes control.[13,16,18-19136-137]

It is encouraging that all study pharmacies reported that they provide training on how to use blood glucose meters. This may have been anticipated because a meter is a

product and pharmacists working in a traditional pharmacy practice style of may be more comfortable counseling on products such as meters and less comfortable with PC such as regularly monitoring lab values. CDE pharmacists educated study participants on blood glucose meter use, but they also provided patient-focused services such as teaching about diabetes, evaluating patients' learning needs, monitoring clinical laboratory values, and contacting other members of the diabetes team.

Not only did pharmacists report differences between the intervention and control group in interviews and documentation, study participants also reported that the intervention group provided more care. In the exit interview, participants in the intervention group noted higher scores on the pharmacists' care intensity variable than participants in the control groups. This may help to support the fact that differences did exist between the study groups, if one assumes that study participants are not motivated to overestimate the intervention. Participants in the intervention group may have formed a relationship with AB and PD, thus may have been motivated to overestimate the intervention.

Interestingly, the CDE pharmacists' interventions appeared to change over time. As the study progressed, CDE pharmacists made more interventions and identified more drug-related problems. This finding may be due to increased self-efficacy with PC over the study period. Additionally, there were subtle differences between the care provided by each CDE pharmacist. One pharmacist tended to provide more documentation and intervened on a greater number of drug-related problems. However, this pharmacist saw the majority of the study participants, and thus she may have developed more confidence

in her practice. Another explanation may be that she became more proficient at documenting her interventions.

Processes of care were difficult to compare between the previous literature evaluating the role of the pharmacists and the research in this thesis because a considerable amount of the previous literature did not describe how information about pharmacists' care was collected. In this study, data on process indicators was collected after they occurred so they may represent care and education provided, instead of care that was intended to be provided.

In much of the literature evaluating the role of the pharmacist, interventions focused on providing education.[14-16,18-19,134-137] Both this research study and four other studies[15,18-19,135,137] described a combination of disease education and monitoring by the pharmacists. In this project, it may be difficult to discern what effects are due to education and which are due to disease monitoring.

In summary, there were clear differences in the processes of care provided by the intervention and control groups. CDE pharmacists were more likely to monitor glucose control and educate participants on hypoglycemia. Moreover, CDE pharmacists provided teaching in a variety of areas and identified DRPs for study participants.

5.1.3 Outcomes Measurement

In this section, the elements of statistical analysis, namely power and its components will be reviewed followed by discussions on specific clinical and humanistic outcomes.

5.1.3.1 Statistical Analysis

Overall, there were no statistically significant differences between the study groups in the primary clinical or humanistic outcomes. Differences were observed with small to moderate ES for most outcome measures. The study's sample size was small and the statistical analyses were under-powered, consequently it was difficult to draw clear conclusions. However, the power of a statistical analysis is not only determined by sample size, it also may be influenced by the *a priori* alpha value, the statistical test selected, and ES. Each of these factors and their impact on study results will be discussed.

The alpha value represents the probability that a researcher is willing to accept of committing a type 1 error, that is, finding a difference when there is not a difference. The alpha value does not change in the course of a study and is traditionally set at 0.05 or a 5 % risk, as was done in this study.

The choice of statistical test affects power in three ways. First, choice of a non-parametric over a parametric test can decrease the power of the analysis when the data is normally distributed. In this study, parametric tests were used whenever possible. Secondly, the directionality of a test can affect its the power. A one-tailed test has greater power than a two-tailed test. A two-tailed test was chosen in this study because the direction of the effect of this study was unknown. Third, the ability of the test to control for error affects its power. Methods such as stratifying the sample or ANCOVA can increase the power of a test by accounting for otherwise unrecognized variance. This study intended to use ANCOVA to increase its power, however, in the end, the sample was too small to fully support this analytic method.

ES is a measure of the clinically relevant difference between the intervention and control groups. The ES is the difference between the two group means divided by the standard deviation of the control group.[174] Degradation of treatment, inconsistency of the intervention, sample heterogeneity, and extraneous sources of variance can diminish ES.[174] Degradation of treatment refers to the decreased impact of an intervention under study conditions. If degradation of treatment occurred in this project, the effect of participating in a research study may have decreased the "dose" of CDE pharmacists' intervention relative to usual care. However, as described in process indicators section, the CDE pharmacists appeared to recognize an increased number of DRPs as the study progressed, so it might be more plausible to assume that the study initially increased pharmacists' interventions.

Toward the end of the study, the consistency of the intervention may have decreased, which in turn may have reduced the ES. Due to personal reasons, CDE pharmacists left longer intervals between visits with participants at the end of the study. Inconsistency of the follow-up may also be reflected in the change in GHb between participants who finished the study early and those who finished the study later in its course. Of the 24 intervention participants, the first 12 to complete the study had a mean change in GHb of 1.55 % (± 3.61) and the last 12 participants had a mean change of 0.43 % (± 1.80). However, it is also possible that study participants from the latter part of the study were from a different population. The mean GHb in the first half of the intervention group was 8.3 %, compared with 7.4 % in the later half. It could also be hypothesized that a combination of a decrease in the intensity of the intervention and study participants' baseline GHb impacted on the amount they changed.

Heterogeneity of the sample may have also impacted the ES estimates by increasing the ES denominator. Hetrogeneity is an issue when dependent variables and sample characteristics interact (e.g. satisfaction with pharmacy services and HRQL). The sample was similar on most baseline characteristics except method of treating diabetes and MCS12, and appeared homogeneous. Differences in the method of treating diabetes and MCS12 were controlled for in the statistical analysis.

Extraneous sources of variance, such as care or education about diabetes received from other health care professionals, media, or literature, may also decrease ES by decreasing the numerator. Because extra care is beneficial to the patient, it was not restricted in this study. However, it was anticipated and therefore assessed in the external education intensity variable, which was not significantly different between the study groups.

Cohen has suggested that, across a large range of research studies, an ES of 0.3 should be considered small, 0.5 considered moderate, and 0.8 considered large.[162] The ES of common outcomes from this study and a recent meta-analysis of the diabetes education literature are presented in Table 5.2. The meta-analysis included studies from 1961 to 1989 if the study had an adult sample and was conducted in one location with either a single group pretest posttest or intervention and control group design. [5]

Notably, in both the meta-analysis and this study, ES were small to moderate (Table 5.2). Lipsy makes the argument that small to moderate ES are meaningful improvements for research in the social sciences.[174] First of all, the majority of research in the social sciences produces small to moderate ES and it is difficult to assume that most research does not have an effect. Secondly, a small effect in an area such as health

care can provide a clinically meaningful effect especially for highly prevalent diseases. For example, an ES=0.2 which decreased death rate from 55 per 100 to 45 per 100 has saved 10 lives. In the case of diabetes education, a small change GHb can be considered meaningful (e.g. the ES=0.23 observed in this study resulted from an average reduction in GHb of 1.1 %). Evidence from the recent clinical trials indicates that any relative reduction in GHb offers some benefits to people with diabetes.[2,89]

Table 5.2 Meta-Analysis on Educational Interventions ES and Study ES[5]

Meta-Analysis		Current Study on CDE Pharmacists	
Variables	ES* (SD)	Variables	ES **
GHb	0.41 (0.05)	GHb	0.23
Dietary	0.57 (0.7)	SDSCA –Diet	0.070
Psychological	0.27 (0.08)	DLF	0.35
		DAS	0.77

*WeightedES corrected for study sample size and precision.
** Raw ES

Another way to look at the strength of a relationship between the independent and dependent variables is Eta values. Eta is not as frequently applied as ES and is not directly comparable to the ES because they are calculated differently. Eta is the square root of the proportion of variability in the dependent variable that is associated with the independent variable.[165] Eta values can range from 0-1 and is analogous to the "R" in linear regression analysis. The R represents the strength of the relationship and can range from 0 to 1, whereas the R^2 relates to the proportion of variance in the dependent variable accounted for by independent variable(s) in the regression/ANCOVA models.[175] The benefit of Eta is that it can be used to estimate the strength of the relationship from the

ANCOVA model. In the literature, Eta values have been characterized as weak (Eta <0.3), moderate (Eta between 0.3-0.5), and strong (Eta > 0.5).[165]

In the bivariate ANCOVA models, small to moderate Eta values were observed. In the multivariate models, small effects were primarily observed with one moderate (glucose testing compliance scale of SDSCA) and one large effect (medication compliance scale of SDSCA). This study was intended to influence the behavior of people with diabetes and such behavior is impacted by a multitude of variables,[165] thus a small effect can be considered a reasonable intervention effect.

Finally, sample size is well recognized in affecting the power of a statistical analysis.[174] Smaller samples have large sampling error, thus the precision of the point estimates (e.g., means) may differ from the true population. This discrepancy introduces error into the statistical analysis. Reviews of the literature have observed that many studies have small sample sizes and moderate effects, thus have a low power and high rate of type 2 errors. [174,176]

Nine of the previous studies in pharmacy-based diabetes education literature had sample sizes between 23 and 60 participants.[13,14-16,18,134-136,138] The sample size of this study (total n=49) was similar in size to those studies. However, the participants were randomly assigned into two study groups, whereas many of the previous studies had single group designs.

Together, the choice of alpha, test selected, ES, and sample size decreased the power of this study. While this study is under-powered, the ES estimates indicated that CDE pharmacists might have impacted the health of people with diabetes.

5.1.3.2 Clinical Outcomes

The mean GHb, the primary clinical outcome improved in both study groups during the study period. Nevertheless, there was no statistically significant difference in the change in the GHb between intervention and control groups. Previous pharmacy-based studies have shown a benefit in glycemic control,[13,15,16,138] with the exception of two studies.[17,134] The most recent studies demonstrated that pharmacist management improved participants' glycemic control over baseline, however these studies lacked control groups.[16,18,135-138] Thus, it is hard to determine if improvements in glycemic control were due to the pharmacist interventions, the blood glucose monitors provided to all patients, or other influences in the communities. While this research was underpowered to show differences between the study groups, the design did include a control group to address these issues. The ES of GHb change was small, thus an adequately powered study may have demonstrated a difference.

Because of the small sample size, the ES is greatly affected by outliers or extreme cases. In the intervention group, two participants had GHb that deteriorated substantially during the study. If these people were eliminated from the sample, the ES is increased to 0.37. One of these participants experienced a death in the family and commented to the research office that the GHb may have worsened. If just this person was eliminated from the sample, the ES would increase to 0.37. While the primary analysis includes these participants, the impact of outliers should be recognized.

5.1.3.3 Humanistic Outcomes

Again, there were no significant differences in the secondary humanistic outcomes assessed in this study. However, positive ES estimates of change scores were

small to moderate and similar to the effects in the most recent meta-analysis on the studies of educational interventions and outcomes in diabetic adults.[5] This supports the position that there were differences between study groups; however, the study was not adequately powered to detect them.

There were differences between groups at baseline that may have been due to the timing of data collection in intervention group. Intervention participants scored statistically significantly lower on DLF and appeared to have higher expectations of pharmacy services. These differences may be due to the fact that participants in the intervention group completed their surveys after their first visit with the CDE pharmacists. At this visit, CDE pharmacists reviewed participants' diabetes history, assessed their learning needs, and helped them to set goals. Participants may have become more aware of shortcomings in their management of diabetes and therefore scored lower on the DLF. This questionnaire asked if participants agree or disagree with statements about their beliefs, attitudes, and self-efficacy in diabetes management.

Secondly, participants may have scored higher on the expectation of pharmacy services instrument as they had already received services from CDE pharmacists. The largest differences in expectations occurred on items that asked if participants expected the pharmacist to follow-up up with them on the phone and to contact their physician. These expectations may have increased for three reasons. At the initial interview, CDE pharmacists collected personal and physician contact information from participants for follow-up, thus participants would expect the pharmacist to contact them. At study enrollment, participants were asked to review the consent form (Appendix A) that explained how pharmacists would regularly meet with participants in intervention group.

This may have increased expectations for follow-up. Finally, participants' expectations also may have increased by simply taking part in the study.

The role of the pharmacist in the provision of health care may have impacted the amount of change observed on the humanistic outcomes. Pharmacists are one part of the health care team and the health care team is one part of diabetes management. As such, the pharmacist may contribute a small, but meaningful, role in changing the health of people with diabetes. The pharmacists' role focuses on optimizing medication use, but may also include 1) training and on-going assessment of blood glucose monitoring, 2) supplying diabetes care products and literature, 3) advising on acute complications, 4) advising third-party coverage set-up, 5) identifying learning needs and 6) making referrals to the diabetes care team, and 7) providing support and encouragement.[123] Thus, it is not surprising ES estimates were moderate in the diabetes medication factor of the SDSCA (ES=0.60) and very small on the diet (ES=0.070) and exercise (ES=0.15) factors where pharmacists have less focus. CDE pharmacists provided teaching on blood glucose meters and monitoring of blood glucose levels to every participant in the intervention group. Consequently, the small ES for glucose testing factor (ES=0.36) was disappointing.

A comparison of HRQL between study groups was not originally planned. Because baseline and endpoint data was collected to adjust comparisons between other humanistic outcomes, it was analyzed to understand the impact of pharmacists' care. There was no significant difference between the mean PCS12 change scores between study groups. However, participants who received care from CDE pharmacists had greater improvement in mental health than those who did not. Items in the MCS12 asked

if participants felt 1) blue or peaceful, 2) they had a lot of energy, 3) their emotional health interfered with their social activities, and 4) their emotional problems resulted in them accomplishing less, or work less carefully. It is possible that the social support provided by regularly visiting a pharmacist may have contributed to participants' improved scores on those items, leading to the significant difference in change observed in the composite scores.

This project was not powered to demonstrate differences in primary humanistic outcomes, yet other researchers have shown that pharmacists can improve patients' attitudes[14], satisfaction with pharmacy services, [18,18,135] and diabetes management skills.[137] These studies did not employ standardized instruments, a control group, or a complete sample, thus further study is warranted in these areas. Though HRQL was not a primary outcome, subjects receiving care from CDE pharmacists in this research project had improved mental health. Similar results were reported for three other studies,[18,135,137] while one study showed no effect. These results suggest that pharmacists can improve the HRQL of people with diabetes.

5.2.0 Limitations

5.2.1 Internal Validity

Internal validity refers to the control of extraneous variables by a researcher so that observed effects in a study can be attributed to the study's intervention. Threats to internal validity include: history, maturation, testing, instrumentation, statistical regression, differential selection, experimental mortality, treatment diffusion, compensatory equalization of treatments, and response of the control group.[159] The

Hawthorne effect and pretest sensitization, though sometimes classified as external validity, may also have impacted the internal validity of this study. By selecting a true experimental design, such as a pretest-posttest control group design, the majority of these factors were minimized.[177]

History, which refers to events that happened during a study and maturation, or natural improvement over time, should not have impacted the findings since study groups were exposed to the same environment outside of the pharmacy and were followed for a similar duration of time. The next threat to internal validity, testing, is the effect of the pretest on the posttest. The questionnaires were administered six months apart, thus recall from pretest to posttest scores may have been limited. The effect of instrumentation was limited by using previously developed and tested questionnaires whenever possible, the same measures at baseline and endpoint data collection, and administering the questionnaires in the same fashion.

Statistical regression is the tendency for participants who have extreme scores at baseline to score nearer to the mean at endpoint measurements.[178] In the present study, this effect was minimal because groups were not selected based on extreme scores and because a control group was used.

Differential selection is another threat to internal validity.[179] The study was designed to control for this by asking participants to give consent to participate before they were randomized. However, study groups were different on three baseline characteristics: the method of treating diabetes (intervention group was more likely to use diet alone to manage diabetes), MCS12 score (intervention group had a higher mental

component scores), and DLF scores (intervention group had significantly lower scores). ANCOVA techniques were used in the analysis to limit these threats to internal validity.

Experimental mortality or attrition may have weakened this study. This study had a 21 % attrition rate. However, it was similar in both the treatment and control group, thus it is less likely that it was a direct result of the intervention and less likely to impact this study's internal validity. A review of diabetes education/self-management literature published in *Diabetes Care* and *The Diabetes Educator* between 1990-1995 (n=44) reported a mean attrition rate of 12 %, which is lower than this study's attrition rate.[179] This study's rate was higher than the 13 % dropout rate reported by a similar six-month pharmacist intervention study[13] and similar to the 24 % attrition rate at six months and 35 % attrition rate at 12 months in a single group study of pharmacists' intervention in a community pharmacy.[138]

Thus, the attrition rate in this study is generally greater than that in the diabetes education literature. This will limit this study, as those who dropout may be different than those who completed the study. Data was not available from all participants that did not complete the study to see if difference existed. However, studies that reach as larger sample of participants, including those less motivated, may have greater attrition rates.[181] It is possible that this study was able, through advertisements on TV or in bingo halls, to reach some people with lower motivations who were less likely to complete the study. This may account for the higher attrition rate when compared to studies that are based out of medical centres or pre-existing clinics. Thus, the high attrition rate may be indicative of a "real world" study sample.

Experimental treatment diffusion occurs when the control group receives the intervention. This can obscure any differences between study groups, and reduce the ES estimates for the intervention. Separate study sites were selected to avoid contamination of the control group; while one of the CDE pharmacists worked casually at a control pharmacy, it is unlikely that contamination occurred. Another possible research design could involve randomizing participants within the intervention pharmacy to either receiving care from a CDE or another pharmacist. In this scenario, participants in the control group would have been able to approach the CDE pharmacist for help with diabetes management and the CDE pharmacists may have felt compelled to provide enhanced care for people in the control group. Furthermore, by using separate study sites, it was possible to compare the structures and processes between the intervention and control pharmacies to better characterize all elements of care.

Compensatory equalization of treatments refers to compensating the control group because the intervention group is receiving a desirable service. This may have occurred in the control group. Both participants in the intervention and control group were provided with blood glucose meters to overcome barriers to study participation and to act as an incentive. By testing alone, study participants may have become more aware of their blood sugars and made adjustments to improve their glucose control. The GHb improvements in the control group may have been caused by the provision of the meter as an incentive. This "meter" effect may not have occurred if the control group had not received the study incentive. However, without a third study group that received neither the intervention or incentive, improvements in the control group cannot be solely attributed to the incentive.

Two threats to interval validity are compensatory rivalry by the control group know as the John Henry effect[159] and resentful demoralization of the control group. The mean GHb in the control group improved 7.9 % to 7.1 %. However, it is unlikely that this was rivalry and more likely that was due to equalization of study incentives as discussed above. As the group tended to improve it was unlikely that demoralization was occurring.

Finally, pretest sensitization and the Hawthorne effect may have reduced the difference in change between the study groups and obscured the pharmacists' impact. In this study, participants may have became aware of negative attitudes from the DAS, roles that their pharmacists could play from the pharmacy expectation questionnaire, or perhaps their negative beliefs or low self-efficacy from the DLF. Perhaps it was sensitization to the pre-test that affected change in individual participants' scores. Furthermore, sensitization is more likely to occur on a self-report attitude or personality measure.[159] While sensitization may have occurred, the importance of collecting baseline and endpoint data to assess change between groups outweighed that risk.

Administering the pretest questionnaire to the intervention group after the first visit with the CDE pharmacists may have generated the baseline differences that were apparent on the DLF and patient's expectations with pharmacy services. Baseline measurement was designed this way to allow participants to complete baseline data without the pharmacist present, so that the pharmacists' presence did not influence participants' answers.

Similar to sensitization, the Hawthorne effect occurs when study participants improve because of the mere fact that they are participating in research. In this study,

participants read a study information sheet, signed a consent form, and completed baseline data collection. This may have made participants more aware of their diabetes. This was minimized by administering the questionnaires only twice, mailing questionnaires to participants' homes in the control group to lessen contact with researchers, and designing the trial such that control participants continued to use their regular pharmacy. However, it is impossible to completely eliminate the Hawthorne effect. Thus, the act of being studied may have encouraged participants to more aggressively manage their diabetes and this effect may have overshadowed the intervention.

5.2.2 External Validity

External validity refers "to the extent to which the findings of an experiment can be applied to individuals and settings beyond those that were studied."[178] Threats to external validity include: representativeness of participants, study setting, and the intervention by CDE pharmacists, timeframe, pretest sensitization, and the Hawthorne effect.

Glasgow identified representativeness of participants in outpatient diabetes education programs as a limitation of previous studies.[179,180] In this research, study participants appeared to be representative of people with type 2 diabetes. No Canadian data is available on which to base comparisons, however, people with type 2 diabetes are expected to be older adults, have comorbities such as hypertension or cardiac disease, and take multiple medications.

This sample's representativeness was established by comparing its characteristics to the characteristics of participants in two published trials. In the Sixty Something Trial,

people with type 2 diabetes over the age of sixty were recruited for diabetes education.[55] While participants in the Sixty Something Trial were about seven years older and had diabetes about 3 years longer than participants in this study, the majority of participants in both studies used oral hypoglycemics.

The UKPDS was a large multicentre trial in the United Kingdom that examined the benefits of glycemic control in people with type 2 diabetes. In the UKPDS, participants were recruited at diagnosis of type 2 diabetes and were 54 years of age at study initiation.[2] Participants in this study were older (60 years) than the UKPDS sample. However, the participants had diabetes for approximately 6.9 years, thus they would have been diagnosed around 53 years of age, similar to the UKPDS. After 10 years of follow-up in the UKPDS, 80 % of people who started on diet therapy required medication. Again, this is similar to the sample in this study, where the majority of participants used drug therapy at the age of 60.

Approximately 80 % of the study participants previously visited a diabetes education centre. Yet, the Canadian Diabetes Association (CDA) estimates that only 30 % of people with type 2 diabetes have received education.[21] This may be due to a response bias. People who volunteer for research studies tend to be more educated than non-volunteers.[159] In addition, those who were willing to attend a diabetes education centre may also have been willing to receive further education. Finally, the CDA estimate was based on a chart review in eastern Canada and the results may not be generalizable to this study sample.

Study recruitment may have also selected participants who were not representative of all persons with type 2 diabetes, because they were ready to change.

The study advertisements encouraged people who were interested in learning more about diabetes from a pharmacist to contact the University of Alberta for further information. According to the Transtheorectical Model (TTM), people go through five stages of change including: precontemplation, contemplation, preparation, action, and maintenance.[81] The act of participating in the study may have indicated that participants were in the action phase.

If control participants were ready to change and did not receive the support they required, they might have sought help elsewhere. This was anticipated, thus in an exit interview, participants were asked what other activities they undertook to learn about diabetes. This was reported as external educational intensity variable and there were no significant differences in the total scores between groups. In the breakdown of the items in the external education intensity variable, the intervention group made more visits to a diabetes education centre, but fewer visits to their family physician, contacts to the CDA, and "surfed" the internet less often. Part of the CDE pharmacists' intervention was to refer participants to a diabetes education centre or dietitian, thus, it is not surprising that more intervention participants used these services. However, while control group participants sought information at the same intensity, they sought it from different sources. Because there were no differences between total external education sought by each study group, and the intervention group was encouraged to seek external education, it could be hypothesized that the control group independently sought out more education than the treatment group. Thus, this sample may not be representative of the all people with type 2 diabetes, but may represent a population that was more ready for change.

A lack of CDE pharmacists also limits the external generalizability of the study. The majority of Canadian pharmacists practice in the community setting and research in this setting is most relevant to them. Previous pharmacy practice-based research was set in the US and the majority of pharmacists practiced in hospital-affiliated clinics.[13-17] Moreover, in two studies, pharmacists had prescribing authorization which limits the generalizablity of these results to community pharmacists.[13,17] This study is the first to describe the care provided by CDE pharmacists in community pharmacies. While two other studies used CDE pharmacists, their care was not distinguished from care provided by others.[137,138]

In Alberta, only four percent of pharmacists are CDEs.[122] However, pharmacists have expressed an interest in pursuing certification in diabetes.[122] Certification in an area such as diabetes has allowed for some pharmacists to be reimbursed for their care[125] and such news might help encourage more pharmacists to seek certification.

The small number of pharmacies in the study also limits the generalizability of its results. This study was intended as a pilot to assess the feasibility of measuring change in beliefs, attitudes, confidence, self-care activities, and patient expectations and satisfaction after a CDE pharmacist's intervention. The DAS and DLF have not been previously used to evaluate pharmacists' intervention, and thus it was appropriate to pilot this study before extending it to multiple sites.

Another limitation was this study's short time frame. This prevented the researchers from determining if the impact of pharmacist's care increases or can be maintained over time, and consequently whether it affects long term diabetic complications. However, evidence from the DCCT and UKPDS would suggest that

improvements in GHb can decrease microvascular complications, and thus improve study participants' long term health.[2]

The impact of pretest sensitization and the Hawthorne effect in this study were discussed in the internal validity section, but they also influence external validity. Exposure to the pretest may have sensitized participants to some areas that required improvement and thus results may not be generalized to participants who have not taken a pretest. If participants improve because of the fact they are being studied, research findings are then not generalizable to participants who are not being studied.[159]

5.2.3 Measurement Limitations

The use of self-report tools and the "ceiling" or "floor" effect may have limited the measurement of structure and process indicators and clinical and humanistic outcomes.

Structure and process data for the control pharmacies was obtained from structured interviews and in the intervention pharmacy from documentation, self-report, and limited observation. Malone et al. found that self-reported structures and processes did not correlate with the observed practices in outpatient pharmacies.[181] In the invention group of this study, documentation was compared with data from the exit telephone interview which asked participants if their pharmacists provided the following services and was found to be similar in 94 % of cases. This provides some evidence for the validity of the exit telephone interview. In the control group, there were a large number of pharmacies, thus the trade off of over- or under- reporting diabetes care was balanced against the practicality of telephone interviews.

Documentation of pharmacists' processes of care may also have limited the comparison of study groups. Previous work has shown that pharmacists do not consistently document patient care.[168] As the study progressed, pharmacists' activities were summarized from their documentation. The CDE pharmacists were asked to review these summaries and ascertain if they reflected their actual activities. This process is a form of "member checking" or quality assurance and helped to ensure the documentation tool was being used consistently and was characterizing the pharmacists' interventions. While member checking was intended to improve documentation, it may also have influenced the level of care pharmacists delivered.

This study relied on self-administered measures to collect humanistic outcome data. Such tools may be susceptible to recall and social desirability bias.[159] Instructing the study participants to complete the questionnaires after visiting the pharmacists and mailing questionnaires to the research office may have minimized social desirability bias. Furthermore, whenever possible, previously developed instruments were chosen, with some evidence of reliability and validity so that social desirability bias may factor less into the results. Finally, with randomization, the bias should have been equally distributed amoung study groups and should not have effected the amount of change between groups.

Another possible measurement limitation is the "ceiling" or "floor" effect, whereby the range is restricted and participants scored at the maximum or minimum, respectively.[159] Participants generally agreed to strongly agreed with items in the DAS, satisfaction, and expectations with pharmacy services. Because participants began with high scores at baseline, it was difficult to improve on these scores (i.e., a ceiling effect).

Conversely, mean GHb change may have been influenced by a floor effect. Participants in this study started with reasonable control, thus it may have been more difficult to lower these levels. The 1998 Clinical Practice Guidelines classify GHb into optimal (< 7 %), suboptimal, (7 % to 8.4 %) and inadequate (> 8.4 %).[4] Study participants' mean baseline GHb (7.9 %) was classified as suboptimal. Thus, participants were near optimal control and could only improve by about 1 % (i.e. from 7.9 % to 6.9 %) to achieve good control. In future, limiting recruitment to people with inadequate glucose control could minimize this.

5.2.4 Summary of Limitations

There are potential limitations to this study. The use of a randomized pretest posttest control group design controlled for many of the internal validity limitations. The external validity may be limited by the participants selected, study setting, the intervention chosen, and its timeframe. Measurement error from the use of self-report measures was limited by using previously validated instruments whenever possible. Despite these measures, pretest exposure, timing of baseline questionnaires, ceiling or floor effect, and "meter" effect may have threatened the internal validity and accounted for the lack of statistically significant differences between the study groups. [32,32,156]

5.3.0 Study Implications

5.3.1 Implications for Future Research

"Low statistical power can easily produce a majority of null results in research areas where, in fact, the treatments are universally effective."[174] In this study, the null

hypothesis was not rejected. The ES estimates suggest that this is a failure of the statistical analysis to detect a difference, rather than the inability of the intervention to produce an effect. Future research may include expanding this study to include more participants and thereby increasing the statistical power. Based on sample size calculations for GHb with 80 % power and alpha=0.05, a sample of at least 600 participants would be required to detect the absolute difference of 0.25 % in GHb that was found between study groups. However, if the treatment effect was increased to an absolute difference in GHb of 0.5 %, a sample of 140 would be required to detect a statistically significant difference.

The ES could be increased by recruiting study participants with inadequate glucose control to eliminate the "floor" effect or by increasing the "dose" of the CDE pharmacists. This might be accomplished by working more closely with other members of the diabetes team, or by maintaining the intensity of the study intervention toward the end of the study. As noted earlier, study participants in the early phase of the intervention group had a mean GHb of 8.3 % that decreased by 1.55 % whereas the last 12 participants had a mean GHb of 7.4 % and lesser change of 0.43 %. It appeared that participants with higher baseline GHb, and who were enrolled earlier in the study had greater improvements.

Modifying the timing of the questionnaire and eliminating the study incentive could also increase ES. Pretest questionnaires should be given before study participants are exposed to the intervention. This would ensure that baseline questionnaires were not influenced by the pharmacists' intervention. Eliminating the use of blood glucose meters as study incentives may decrease the improvement in the control group and increase the

difference in the amount of change between the two groups. This would also eliminate concerns that GHb improvements were due to the "meter" effect rather than the effect of CDE pharmacists.

Another strategy to assess the impact of pharmacists would be to perform a meta-analysis combining the results of this study with others to find the "true" intervention effect of the pharmacist.[174] This could increase the power and the generalizablity of the study results, in addition to summarizing the current literature evaluating the role of the pharmacist, although heterogeneity of in study design might preclude this.

This study again underscores the importance of measuring all three factors in the SPO model. While the intervention group had differing structures and processes from the control group, these did not translate into statistically significant differences in clinical or humanistic outcomes. The lack of significant change may be a factor of a lack of power, not a lack of pharmacist's effect. However, a simple assessment of processes such as the number of DRPs detected or educational topics covered would not have provided the full picture.

An interesting aside for the implications of this study is the telephone exit interview. The telephone interview was verified with the pharmacists' documentation and found to be the same 94 % of time. It is much easier to conduct a telephone interview than collect and summarize documentation from pharmacists, because pharmacists do not regularly document their activities. Thus, telephone interviews with patients may serve to provide similar information in a more efficient fashion.

A sound documentation system was developed for this study (Appendix D). A triplicate form was developed with one copy for the pharmacists' records, one for the

research office, and one copy for the either the physician or patient. This system facilitated data collection and quality assurance, and may be considered for other projects.

Finally, this study described structures in place and the care provided by CDE pharmacists. This will provide a description on which to base further research investigations. The CDE pharmacists focused their teaching on blood glucose testing and medication use and their services on monitoring diabetes (e.g., GHb and blood pressure), reviewing participants' medications, and contacting other members of the diabetes team. These services capitalize on the pharmacists' training in medication monitoring, strengths in teaching on blood glucose meters, and availability as a liaison to other members of the diabetes team. However, this intervention may not have been applied uniformly. In the future, steps might be taken to standardize the intervention by designing a specific care protocol.

5.3.2 Implications for Practice

One interpretation of this study may be that simply providing blood glucose meters can improve the health of people with type 2 diabetes. It is possible that awareness of hyperglycemia and appropriate adjusting could lead to improvements in participants' glycemic control. The current Canadian Clinical Practice Guidelines recommend that self-monitoring of blood glucose levels should be an integral part of managing type 2 diabetes.[4] The cost of testing supplies is significant, thus free supplies may have allowed some study participants to test more regularly. This suggests that pharmacists should encourage people with diabetes to test their blood sugars, assist in accessing coverage for people with diabetes, and perhaps lobby for blood glucose meter

coverage for people with diabetes. However, this would require further research to substantiate it before becoming a policy.

A further implication for practice could be the use of questionnaires to sensitize participants to areas of diabetes that may need improving. In this study it was possible that the pretest questionnaire may have made participants more aware of their diabetes and more motivated to manage this disease. This unintended study effect may be useful to practitioners as a simple and inexpensive intervention, however future research would be necessary to assess its effect independent of other interventions.

Pharmacists who want to help people with diabetes may consider becoming CDE. In this study, CDE pharmacists provided a high level of care to people with diabetes as demonstrated by their documentation. CDE certification may increase confidence in providing care and recognition for that care. Furthermore, the ES suggest that CDE pharmacists may have improved the health of study participants and participants who met with CDE pharmacists had statistically significant improved mental health.

In addition, to providing quality assurance for research purposes, the documentation system developed for this study could also be applied as part of pharmacists' practice. In completing the documentation and follow-up forms, the pharmacists may have been reminded of important aspects of care. Further, it appeared that the CDE pharmacists practice did change over the course of the study, which may have been supported by the documentation of their activities and practice patterns.

5.4.0 Conclusions

Results of this study demonstrated that there were structural differences in the education of the pharmacists and time to provide care, in addition to differences in the

level of care provided between the intervention and control group. Glycemic control (i.e., GHb) in the intervention group significantly improved from 7.8 % to 7.0 % ($p<0.001$). However, this improvement was not significantly different from the change in the control group. Small but positive differences were observed for most outcome measures, with small to moderate ES estimates. Limitations in this pilot study included the small sample size, the "meter effect" observed in the control group, and the ceiling or floor effect of study measures. Important information on the structure and processes of care were documented, but further study is required to determine the full impact of CDE pharmacists on outcomes of care for people with type 2 diabetes.

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Appendix A

Study Information Sheet and Consent Form

UNIVERSITY OF ALBERTA

Impact of Community Pharmacists' Care on Self-Management in Type 2 Diabetes

Researchers	Affiliation	Phone Number
Lisa Schapansky	Faculty of Pharmacy & Pharmaceutical Sciences	492-0092
Jeffrey Johnson	Faculty of Pharmacy & Pharmaceutical Sciences	492-9266
Karen Farris	Faculty of Pharmacy & Pharmaceutical Sciences	492-2020
Ellen Toth	Faculty of Medicine, Endocrinology	492-6223
Ross Tsuyuki	Faculty of Medicine, Cardiology	492-8772

Purpose

You are being asked to take part in a study. It will compare the care people receive from pharmacists to the care that people's receive from pharmacists with extra diabetes training. We are doing this study to see if people with diabetes, who are looked after by pharmacists with extra diabetes training, have improved health. This information will help us to help people with diabetes.

Procedures

You would be asked to take part in the study for 6 months. You will have an equal chance of having care from your regular pharmacist or a pharmacist with extra diabetes training. Extra care may include meetings or phone calls from the pharmacist each month, and a letter sent to your doctor about the care you may get in the study. At the end of the study, everyone will have the chance to see the pharmacist with extra diabetes training.

People in this study will:

a. complete a 20-minute survey at the start of the study and end of the study.
b. have your blood sugar control taken at the start and end of the study. This will be done at a central lab or clinic.
c. give permission to use the records your pharmacist keeps about the care you receive at the pharmacy.

Risks and Benefits

By taking part in this study, you will have the chance to learn more about your diabetes. Another benefit is that you will be helpful in measuring how a pharmacist can help patients with diabetes. There are no known risks for taking part in this study. You may become more aware of how you take care of your diabetes.
All people in the study will be given blood sugar testing supplies while they are in the study.

Confidentiality

Personal records relating to the study will be kept confidential. Your pharmacist or physician will not see any surveys you complete. Any report about this study will not identify you by name. The study data will be kept for seven years following the end of the study in a secure place accessible by only the research team.

Freedom to Withdraw

We would truly value your participation in this study. However, you are free to refuse to take part in the study. You are also free to refuse to answer any questions. If, for any reason you want to stop being in this study, you are free to withdraw at any time. In any case, you current level of pharmacy care will not change in any way.

Contacts

If you have any questions or concerns about this study please, contact Lisa Schapansky at the University of Alberta at 492-0092.

You may also contact the Associate Dean of Research, Len Wiebe at 492-5905, if you have concerns about any part of this study.

Thank you very much for your interest in this study.

_____ _____

Initials of the Research Participant Initials of the Researcher

UNIVERSITY OF ALBERTA

Impact of Community Pharmacists' Care on Self-Management in Type 2 Diabetes

Lisa Schapansky BSc. Pharm, Jeffrey A. Johnson Ph.D., Karen Farris Ph.D., Ellen Toth M.D., & Ross Tsuyuki Pharm.D.

Please fill in the following form.

Do you understand that you have been asked to be in a research study?	Yes	No
Have you read and received a copy of the attached Information Sheet?	Yes	No
Do you understand the benefits and risks involved in taking part in this research study?	Yes	No
Have you had an opportunity to ask questions and discuss this study?	Yes	No
Do you understand that you are free to refuse to participate or withdraw from the study at any time?	Yes	No
Has the issue of confidentiality been explained to you? Do you understand who will have access to your records?	Yes	No

This study was explained to me by: _____

I agree to take part in this study.

_____ _____ _____

Signature of Research Participant Date Witness

_____ _____

Printed Name Printed Name

I believe that the person signing this form understands what is involved in the study and voluntarily agrees to participate.

_____ _____

Signature of Investigator or Designee Date

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Appendix B

Questionnaires

UNIVERSITY OF ALBERTA

Thank-you for taking the time to fill in this questionnaire. Please answer the questions as honestly and accurately as you can. Your responses will be confidential. When you have finished completing the questionnaire, please seal it in the post paid envelope provided and mail it to the University of Alberta.

Questionnaire

Part 1 Background Information
Part 2 Diabetes Attitude Scale for Patients
Part 3 Diabetes Lifestyle Form
Part 4 Summary of Diabetes Self-Care Activities
Part 5 SF-12 Health Survey
Part 6 Expectations and Satisfaction with Pharmacy Services

Study Identification Number _____

Faculty of Pharmacy and Pharmaceutical Sciences

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PART 1

Please fill in the blanks or put a ✓ in the appropriate space.

Your Present Age: _____ years

Gender (check one):
___ Male
___ Female

Education Level (check one):
___ High School or Less
___ College/University

Marital Status (check one):
___ Married
___ Single
___ Divorced
___ Widowed

Annual Income (check one):
___ < $10 000
___ $10 000 to $24 999
___ $25 000 to $39 999
___ $40 000 to $54 999
___ >$55 000

How long have you had diabetes: _____years

How do you take care of your diabetes? (check one)

___ Diet Alone
___ Insulin
___ Pills
___ Insulin and Pills

Have you been to a diabetes education clinic? (check one)

___ Yes
___ No

If yes, how when did you last attend the clinic? _____ years ago

Do you have any of the following (check all that apply to you):

___ High Blood Pressure
___ Foot Ulcers
___ Loss of Feeling in Extremities
___ Heart Disease
___ Other Conditions_____

How many prescription medicines do you take every day?

_____Medicines

How many medicines available without prescription do you take every day?

_____Medicines

How many herbal medicines do you take every day?

_____Medicines

PART 2

Circle the number that best describes the opinion closest to your own. Number 1 means that you strongly disagree and number 5 means that you strongly Agree .

In general I believe that:		Strongly Disagree		Neutral		Strongly Agree
1.	...health care professionals who treat people with diabetes should be trained to communicate well with their patients.	1	2	3	4	5
2.	...it is important for pharmacists who teach people to care for their diabetes to learn counseling skills.	1	2	3	4	5
3.	...health care professionals should be required to continue to learn about diabetes because diabetes is changing fast.	1	2	3	4	5
4.	...health care professionals need to have special training to provide effective treatment of diabetes.	1	2	3	4	5
5.	...pharmacists who have special training in diabetes will give better care to patients.	1	2	3	4	5
6.	...diabetes education for health care professionals should cover diabetes in the elderly.	1	2	3	4	5
7.	...to do a good job, diabetes educators should learn a lot about being teachers.	1	2	3	4	5
8.	...people who do not follow their recommended diabetes treatment don't really care about controlling their diabetes.	1	2	3	4	5
9.	...controlling their diabetes should be the most important thing in the lives of people with diabetes.	1	2	3	4	5
10.	...the parents of diabetic teenagers should be in charge of how their children take care of their diabetes.	1	2	3	4	5
11.	...decisions about caring for diabetes should be made by the doctor.	1	2	3	4	5
12.	...telling patients about the complications of diabetes will scare them into following their recommended treatment.	1	2	3	4	5

In general I believe that:		Strongly Disagree		Neutral		Strongly Agree
13.	...if people with diabetes do not co-operate and follow their recommended treatment there is not much that health care professionals can do for them.	1	2	3	4	5
14.	...type 2 diabetes is a less serious disease than insulin-dependent diabetes.	1	2	3	4	5
15.	...people whose diabetes is treated by just a diet do not have to worry about getting many long term complication of diabetes.	1	2	3	4	5
16.	...diabetes that can be controlled by just being on a diet is a pretty mild disease.	1	2	3	4	5
17.	...good blood sugar control will reduce the long-term complications of diabetes.	1	2	3	4	5
18.	...people with diabetes who have poor blood sugar control are more likely to have diabetes complications than people who have good blood sugar control.	1	2	3	4	5
19.	...having high blood sugar over a long period of time is linked to getting long-term diabetes complications.	1	2	3	4	5
20.	...there is not much use in trying to have good blood sugar control because the complications of diabetes will happen anyway.	1	2	3	4	5
21.	...diabetes affects almost every part of a diabetic person's life.	1	2	3	4	5
22.	...the emotional effect of diabetes is pretty small.	1	2	3	4	5
23.	...having diabetes changes a person's outlook on life.	1	2	3	4	5
24.	...it is frustrating to treat diabetes.	1	2	3	4	5
25.	...diabetes is a very serious disease.	1	2	3	4	5

In general I believe that:		Strongly Disagree		Neutral		Strongly Agree
26.	...the most important decisions regarding daily diabetes care should be made by the person with diabetes.	1	2	3	4	5
27.	...people with diabetes should choose their own goals for diabetes treatment.	1	2	3	4	5
28.	...people with diabetes should learn a lot about the disease so they can be in charge of their own diabetes care.	1	2	3	4	5
29.	...people with diabetes should be taught how to choose their own self-care methods (e.g., type of diet, type of blood sugar monitoring, number of daily insulin injections).	1	2	3	4	5
30.	...people with diabetes have the right to decide how hard they will work to control their own blood sugar.	1	2	3	4	5
31.	...doctors do not need help from pharmacists to treat patients with diabetes.	1	2	3	4	5
32.	...to provide enough information about diabetes care to patients, physicians need the help of pharmacists.	1	2	3	4	5
33.	...doctors should send people with diabetes to a dietician to help them with their diet.	1	2	3	4	5
34.	...doctors should send people with diabetes to a pharmacist to help them learn about their diabetes.	1	2	3	4	5

PART 3

Circle one number that best describes the opinion closest to your own.

		Strongly Disagree		Neutral		Strongly Agree
1.	I think I am managing my diabetes okay.	1	2	3	4	5
2.	Talking to my doctor about my diabetes usually makes me feel better.	1	2	3	4	5
3.	I try to let people know that I have diabetes.	1	2	3	4	5
4.	I do not like testing my blood sugars away from home.	1	2	3	4	5
5.	I know as much about my diabetes as I need to know.	1	2	3	4	5
6.	My diabetes does not spoil my social life.	1	2	3	4	5
7.	I am afraid of low blood sugar reactions.	1	2	3	4	5
8.	I can talk to my doctor and ask for the things I need.	1	2	3	4	5
9.	Diabetes is not really a problem because it can be controlled.	1	2	3	4	5
10.	I do not mind being called a "Diabetic".	1	2	3	4	5
11.	I always wear a medical alert which says I have diabetes.	1	2	3	4	5
12.	I am able to control the amount of food I eat when I go out.	1	2	3	4	5
13.	I like being told if my diabetes control is good.	1	2	3	4	5
14.	I have adapted well to changes I had to make.	1	2	3	4	5
15.	There are too many rules about what I can eat.	1	2	3	4	5
16.	I am able to get out and do what I want to do.	1	2	3	4	5
17.	I feel I can ask for help when I need it.	1	2	3	4	5
18.	I feel I can travel and look after my diabetes.	1	2	3	4	5
19.	I often feel upset and cranky with my family and friends.	1	2	3	4	5
20.	The person who is the most responsible for my diabetes is myself.	1	2	3	4	5

PART 4

These questions below ask you about your diabetes self-care activities ***during the past 7 days.*** If you were sick during the past 7 days, please think back to the last 7 days that you were not sick.

DIET

1. How often did you follow your recommended diet over the last 7 days?
   __ 1. Always __ 2. Usually __ 3. Sometimes __ 4. Rarely __ 5. Never

2. What percentage of the time did you successfully limit your calories as recommended in healthy eating for diabetes control?

   __ 0% (none) __ 25% (1/4) __ 50% (1/2) __ 75% (3/4) __ 100% (all)

3. During the past week what percentage of your meals included high fibre foods, such as fresh fruits, fresh vegetables, whole grain breads, dried beans and peas, bran?

   __ 0% (none) __ 25% (1/4) __ 50% (1/2) __ 75% (3/4) __ 100% (all)

4. During the past week, what percentage of your meals included high fat foods such as butter, ice cream, oil, nuts and seeds, mayonnaise, avocado, deep-fried food, salad dressing, bacon, or other meat with fat or skin?

   __ 0% (none) __ 25% (1/4) __ 50% (1/2) __ 75% (3/4) __100% (all)

5. During the past week what percentage of your meals included sweets and desserts such as pie, cake, jelly, soft drinks, or (regular, not diet) cookies?

   __ 0% (none) __ 25% (1/4) __ 50% (1/2) __ 75% (3/4) __100% (all)

Exercise

6. On how many of the last 7 days did you participate in at least 20 minutes of physical exercise?
   0 1 2 3 4 5 6 7

7. What percentage of the time did you exercise the amount suggested by your doctor? (for example, if your doctor recommended 30 minutes of activity.)

__ 0% (none) __ 25% (1/4) __ 50% (1/2) __ 75% (3/4) __100% (all)

8. On how many of the last 7 days did you participate in a specific exercise session other than what you do around the house or as part of your work?

0 1 2 3 4 5 6 7

Glucose Testing

9. On how many of the last 7 days (that you were not sick) did you test your glucose (blood sugar) level?

__ 1. Every day __ 2. Most days __ 3. Some days __ 4. None of the days

10. Over the last 7 days (that you were not sick) what percentage of the glucose (blood sugar or urine) tests recommended by your doctor did you actually perform?

__ 0% (none) __ 25% (1/4) __ 50% (1/2) __ 75% (3/4) __100% (all)

Diabetes Medication

11. How many of your recommended insulin injections did you take in the last 7 days that you were supposed to?

__ 1. All of them __ 2. Most of them __ 3. Some of them __ 4. None of them
__ 8. I do not take insulin

12. How many of your recommended number of pills to control diabetes did you take that you were supposed to?

__ 1. All of them __ 2. Most of them __ 3. Some of them __ 4. None of them
__ 8. I do not pills to control my diabetes

PART 5

Please check the answer that best describes your opinion. If you are unsure about how to answer, please give the best answer you can.

1. In general, would you say your health is:

___ **Excellent** ___ **Very good** ___ **Good** ___ **Fair** ___ **Poor**

The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

	Yes, Limited A Lot	**Yes, Limited A Little**	**No, Not Limited At All**
2. **Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	___	___	___
3. Climbing **several** flights of stairs	___	___	___

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	Yes	**No**
4. **Accomplished less** than you would like	___	___
5. Were limited in the **kind** of work or other activities	___	___

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	Yes	**No**
6. **Accomplished less** than you would like	___	___
7. Didn't do work or other activities as **carefully** as usual	___	___

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

___ Not at all ___ A little bit ___ Moderately ___ Quite a bit ___ Extremely

These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks -

		All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
9.	Have you felt calm and peaceful?	___	___	___	___	___	___
10.	Did you have a lot of energy?	___	___	___	___	___	___
11.	Have you felt downhearted and blue?	___	___	___	___	___	___

12. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

___ All of the time ___ Most of the time ___ Some of the time ___ A little of the time ___ None of the time

PART 6

Circle the number that best describes the opinion closest to your own.

A pharmacist should:		Strongly Disagree		Neutral		Strongly Agree
1.	...write necessary information about my medication and my diabetes in my pharmacy file so that other pharmacists can know what is going on with my treatment.	1	2	3	4	5
2.	...ask if I am having any problems with my diabetic medications.	1	2	3	4	5
3.	... ask if I feel like my medication is helping my diabetes.	1	2	3	4	5
4.	... check if I am having any other problems related to my diabetes.	1	2	3	4	5
5.	... ask me how my medication is working between refills.	1	2	3	4	5
6.	... offer appointments to me for further discussion about my diabetes.	1	2	3	4	5
7.	... ask me about the effects of my medication on the phone.	1	2	3	4	5
8.	... explain my medications to me.	1	2	3	4	5
9.	... *never* communicate with my physician about my medication.	1	2	3	4	5
10.	I'm very satisfied with the pharmacy services that I receive.	1	2	3	4	5
12.	The pharmacy services that I've received are just about perfect.	1	2	3	4	5
13.	I have some complaints about the pharmacy services that I receive.	1	2	3	4	5
14.	There are things about my pharmacy services that I receive that could be better.	1	2	3	4	5

Appendix C

Pharmacist Documentation Tools for Initial Visit

Diabetes Day
Patient Questionnaire
FOR PHARMACIST USE ONLY.

pharma science

Store Number:_____ Pharmacist Name: _____

Introduce yourself as the pharmacist. Complete one of either Part A or Part B for each patient.
Part A: For those not diagnosed with diabetes you are assessing relative risk of developing diabetes through the use of the Canadian Diabetes Association "Are You At Risk" quiz.
Part B: For those diagnosed with diabetes you are developing a personalized Diabetes Plan and providing, as required, related information as well as the HEALTHWATCH Blood Glucose Logbook.
Please note: Documentation and follow-up will be performed for both Part A & B.

Part A *Patient Segments not known diabetic*

Risk Assessment Quiz:

Use the CDA "Are You At Risk" quiz for those with an appointment for risk assessment and fit "drop-ins" where possible. Document the final score in either the "4 or less" space, or the "5 or more" space, based on the individual scores; and deliver the appropriate intervention.

- Scoring 4 or less (lower risk)—Appropriate Intervention: Discuss & circle low risk scoring details. Address tips on healthy living;
- Scoring 5 or more (greater risk)—Appropriate Intervention: Discuss & circle greater risk scoring details; and then refer a doctor can diagnose diabetes. Address tips on healthy living.

Name:_____(first name only)

Age:____ Telephone Number (day):_____

Date is gathered for follow-up & statistical purposes only.

Part B. *Patient Segments Patients with any type of diabetes*

Use the Diabetes Plan to guide your discussions on the cornerstones of diabetes care:

Background Information:
Name:_____(first name only)

Age:_____Telephone Number (day):_____
Data is gathered for follow-up & statistical purposes only.

Q: What type of diabetes did your doctor say you have?
Type 1_____ Type 2_____ Gestational_____
All medications taken (list medication name only):

Diabetes Medications:
Using the above medication profile, complete relevant medication section(s) on Diabetes Plan.
Address diabetes medications only (unless time permits to discuss non-diabetes medications).
Your intervention should include:

- What each medication is intended to do;
- When to take the medication;
- Identification & management of side effects.

Q: What did your doctor tell you your medication would do?
___ Patient aware of intended purpose of medication.
___ Patient not aware of intended purpose of medication.
COUNSELLED patient on intended use of medication — check when done ☐

Q: How did your doctor tell you to take your medication?
___ Patient aware of correct regimen
___ Patient not aware of correct regimen
COUNSELLED on how to take medication — check when done: ☐

Q: Are you experiencing any side effects from your medications?
___ Yes ___ No
If yes, explain: _____
For patient on a sulfonylurea, acarbose or insulin, provide TREATING HYPOGLYCAEMIA tear-off
COUNSELLED on adverse effects — check when done ☐
PROVIDE TREATING HYPOGLYCAEMIA tear-off (if applicable) — check when done ☐

Turn over *Diabetes Plan*.

Healthy Eating:

- Explain that healthy eating works hand-in hand with medication to achieve treatment goals;
- Discuss the importance of seeing a dietitian to establish a plan of healthy eating;
- Provide a telephone number of the closest Diabetes Education Program. Encourage patient to make an appointment.

Q: Have you ever attended a Diabetes Education Program? Yes____ No____
Q: If yes, within past 5 years? Yes____ No____
[illegible] Yes/No/eating — Check when done ☐
[illegible] — Check when done ☐
[illegible] — Check when done ☐

Active Living:

- Explain that active living works hand-in hand with healthy eating & medication to achieve treatment goals;
- Identify current physical activity regime;
- Refer to a physician or Diabetes Education Centre to help patient identify activity goals.

Q: How often do you engage in physical activity?
3 or more times/week:_____; 1-2 times/week_____; minimal or no activity _____
[illegible]

Blood Glucose Monitoring:

- Inform patient that blood glucose monitoring helps determine how well medications, healthy eating & active living are balanced;
- Determine whether patient regularly tests blood glucose levels;
- Identify, or take steps to identify, target blood glucose ranges, frequency & appropriate timing;
- If necessary, identify the monitor best suited to the individual.

Q: Do you use a blood glucose monitor?
Yes_____ Which one?_____ No_____
If patient response is "yes," and
A. *Patient knows desired target range, testing frequency & timing.* Complete "When Should I Test" section on Diabetes Plan;
or
B. *Patient does not know desired target range, testing frequency & timing.* Direct patient to have physician complete "When Should I Test" section on Diabetes Plan;
and/or
C. *Patient does not currently use appropriate monitor.* Offer to assist patient, now or in the future, to select a monitor best suited to his/her needs.
Note: When working with patient, consider "patient characteristics" as per the "Monitor Selection & Assessment Tool."
If patient response is "no"
1. Communicate that all persons with diabetes benefit from self blood glucose monitoring;
2. Direct patient to have physician complete "When Should I Test" section on Diabetes Plan; and,
3. Offer to assist patient to select a monitor best suited to his/her needs.

At this stage, provide patient with two things:

- BLOOD GLUCOSE MONITORING. Inform patient that this tear-off will explain why blood glucose testing is important; what the numbers mean; how to check for monitor accuracy, etc.
- HEALTHWATCH BLOOD GLUCOSE LOGBOOK. Complete the "medications" section as per the medication profile offered by the patient. Inform patient that by documenting blood glucose levels and showing the physician, appropriate treatment decisions can be made. Offering the Blood Glucose Logbook is an essential step. Why? Because it is a HEALTHWATCH exclusive.

Q: Would you like to book a 30 minute member training session?
_____ _____ @ _____ a.m./p.m.
Day of Week — Month/Day/Year — Time
Pharmacist Note: To help the patient, jot down the agreed upon appointment time on the Diabetes Plan and offer to confirm, via telephone, the day before the appointment.

Check all that apply:	
INFORMED patient on importance of blood glucose monitoring	check when done ☐
OFFERED tear-off on BLOOD GLUCOSE MONITORING	check when done ☐
OFFERED BLOOD GLUCOSE LOGBOOK	check when done ☐
REVIEWED use of BLOOD GLUCOSE LOGBOOK	check when done ☐
IDENTIFIED appropriate monitor for patient	check when done ☐
BOOKED appointment for training on monitor	check when done ☐
INFORMED on importance of target bg ranges, frequency & appropriate timing	check when done ☐

Additional comments:

Patient Exit Interview:
How did you learn about this HEALTHWATCH Diabetes Day?
TV Commercial_____ Shoppers Drug Mart flyer_____
In-store poster_____ Bag-stuffer_____
Other_____
Do you normally get your prescriptions from Shoppers Drug Mart?
Yes____ No____ If no, where_____ Why?_____
A former Shoppers Drug Mart Rx customer? Yes_____ No_____ (optional)

Conclusion & Follow-up:

Conclusion: Thank patient. Provide patient with their completed Diabetes Plan. Does patient have any further questions? Advise patient that you will create a new Diabetes Plan should their medication profile change. Also advise that you are available for further information at any time if additional questions/concerns arise.

[illegible]

Pharmacist Documentation: Mark all that apply

Problems Identified	Recommendations/Interventions
Patient not taking medication appropriately ☐	Provided clarification on administration ☐
Patient experiencing side-effects ☐	Recommended side effect advice/management ☐
Patient not monitoring glucose levels ☐	Referred to dietitian ☐
Patient not aware of target blood glucose ranges ☐	Referred to Diabetes Education Centre ☐
Patient not aware of importance of diet ☐	Identified appropriate blood glucose monitor ☐
Patient not aware of importance of exercise ☐	Referred to physician ☐
	Recommended regular blood glucose monitoring ☐

Pharmacist Comments:

Patient Outcomes Assessing from above Interview 30 days after Diabetes Day:
(Note: Ask only pertinent questions based on problems identified)
MEDICATIONS:
Are you still experiencing any side effects from your medication(s)? Yes ___ No ___
Comments: _____
As a result of our visit have you changed how you take your medication(s)? Yes____ No ___
Comments: _____
BLOOD GLUCOSE MONITORING:
Have you started monitoring your blood glucose levels? Yes____ No ___
Have you discussed your target blood glucose ranges with your physician? Yes ___ No ___
REFERRALS:
As a result of Diabetes Day have you seen any of the following health professionals?
Physician _____ Diabetes Nurse Educator _____ Dietitian _____
HEALTHWATCH Pharmacist _____ Other _____

Pharmacist Documentation - Outcomes:
Patient initiated blood glucose monitoring _____
Patient experienced decrease in side effects _____
Increased compliance of medications _____
Booked appointment at a diabetes education centre _____
Changed eating habits _____
Initiated/changed activity regime _____
Other _____

Retain this copy for your pharmacy records.

Goals for*Health Improvement

Why Am I here?

- loose weight, blurry eyes
- improve health!

What is the benefit to you, from better managing your diabetes?

- diet -
- feel better - very exhausted
- vision -

How will I better manage my Diabetes?

1. diet
2. improve food choices

What will I do if I "Fall off the Wagon"?

keep trying!!!

Date _____

Signature: _____ Witness: _____

Appendix D

Follow-up Documentation Form

SHOPPERS DRUG MART
RICHARD B. HACKMAN DRUGS LTD. 6317
KINGSWAY GARDEN MALL
109TH ST. & PRINCESS ELIZABETH AVE. PHONE: (403) 479-6619
EDMONTON, ALBERTA T5G 3A6 FAX: (403) 479-6090

[redacted], C.D.E.

[redacted], C.D.E.

Date: _____

Name: _____

Blood Sugar Level: _____

Appointment:
- ☐ Initial Visit
- ☐ Follow-up
- ☐ Phone Follow-up

Diabetes Care Program

Pharmacist provided teaching on:

- ☐ Diabetes & Complications
- ☐ "Hypo" & "Hyper" Reactions
- ☐ Monitoring Glucose Levels
- ☐ Use of Blood Glucose Monitor
- ☐ Use of Blood Pressure Monitor
- ☐ Diet/ Nutrition/ Weight Management
- ☐ Exercise
- ☐ Insulin Use
- ☐ Insulin Devices
- ☐ Medication Use
- ☐ Foot Care
- ☐ Glycosylated Hb
- ☐ _____
- ☐ _____

Other pharmacist services:

- ☐ Evaluate Teaching Needs
- ☐ Address Participant Concerns
- ☐ Pre-fill Insulin Syringes/ Insulin Pens
- ☐ Ensure Adequate Coverage
- ☐ Measured Blood Sugar Level
- ☐ Review Blood Sugar Levels
- ☐ Review Medication Profile
- ☐ Advise on OTC Prescription Use
- ☐ Dispose Insulin Syringes/ Lancets
- ☐ Contact Physician: _____
- ☐ Contact Member of Diabetes Team: _____
- ☐ _____
- ☐ _____

Recommendations:

Next Follow-up Date: _____

Participant: _____ Pharmacist: _____

Appendix E

Letter to Physician

SHOPPERS DRUG MART
RICHARD B. HACKMAN DRUGS LTD. #317
KINGSWAY GARDEN MALL
109TH ST. & PRINCESS ELIZABETH AVE.
EDMONTON, ALBERTA T5G 3A6
PHONE: (403) 479-8619
FAX: (403) 479-8090

[redacted]
B.S.P. C.D.E.

[redacted]
B.Sc. Pharm., C.D.E.

April 6, 1999

Dear Dr. [redacted]

Your patient Mr. [redacted] has enrolled himself in a research project; Impact of Community Pharmacists' Care on Self-Management in Type 2 Diabetes.

This study is coordinated at the University of Alberta between the Faculty of Pharmacy and Pharmaceutical Sciences and Faculty of Medicine and Oral Health Sciences. Participants in this study will be randomized to either the treatment or control group. People in the intervention group will receive care from a pharmacist who is certified as a diabetes educator. People in the control group will receive usual pharmacy services at their regular pharmacy.

Mr. Kopiak has been randomized in to the intervention group. He will receive diabetes education which it tailored specifically to his needs and concerns, but will also cover important topics needed for Ken to better manage his diabetes.

If you have any concerns about the study, please do not hesitate to contact me at Kingsway Shoppers Drug Mart at [redacted] or our research coordinator, Lisa Schapansky at 492-0092.

Sincerely yours,

[redacted]
BSc. Pharm, C.D.E.

[redacted]
B.S.P. C.D.E.

Appendix F

Control Pharmacy Interview

Pharmacy Number: _____
Date:_____

I would like to ask a few questions about your pharmacy, resources available at your pharmacy, and the services your provide to people with diabetes. All of your responses will be confidential. To start, I would like to ask two questions about the pharmacy.

1. **How would you classify this pharmacy, as a chain, grocery, independent or other pharmacy?**

0 ☐ Chain
1 ☐ Grocery
2 ☐ Independent
3 ☐ Other

_____

2. **What position do you work in the pharmacy: as a staff pharmacist, a manager, an owner, or other?**

0 ☐ Staff Rx
1 ☐ Manager
2 ☐ Other

_____

Thank you, next are a few questions about the education of the staff at the pharmacy.

6. **Have any staff at the pharmacy been certified as diabetes educators (i.e., CDE)? (if so how many?)**

1 ☐ Yes_____ staff
0 ☐ No
99 ☐ Unsure/Unknown

7. **Do any of staff members have other training in diabetes such as in store training ? (if so how many?)**

1 ☐ Yes_____ staff
0 ☐ No
99 ☐ Unsure/Unknown

8. **Do any staff members have specific training on blood glucose meter use? (if so how many?)**

1 ☐ Yes_____ staff
0 ☐ No
99 ☐ Unsure/Unknown

Thanks. Because the care does require space and time...

9. **Does the pharmacy have a designated counseling area?**

1 ☐ Yes
0 ☐ No
99 ☐ Unsure/Unknown

10. **How many prescriptions do you fill in an average day, less than 100 Rx, 100-149, 150-200, over 200?**

0 ☐ Less than 100
1 ☐ 100-149
2 ☐ 150-200
3 ☐ 200 and over
99 ☐ Unsure/Unknown

This set of questions are about service that you provide to people with diabetes

11. **Do you stock the following diabetes supplies yes or no?**

11a. **Blood Glucose Meters** 1 ☐ Yes
0 ☐ No

11b. **Injectable Supplies (alcohol swabs, syringes etc?)** 1 ☐ Yes

0 ☐ No

11c. **Sugar Substitutes** 1 ☐ Yes
0 ☐ No

12. **On average, how many different meters do you stock?**

_____ meters
99 ☐ Unsure/Unknown

13. **Do you have demonstration meters?**

1 ☐ Yes
0 ☐ No
99 ☐ Unsure/Unknown

14. **Do you have a trial meter loan program?**

1 ☐ Yes
0 ☐ No
99 ☐ Unsure/Unknown

15a **Do you run any education programs for people with diabetes such as diabetes days?**

1 ☐ Yes
0 ☐ No
99 ☐ Unsure/Unknown

15b. **If yes, could you tell me about the program(s)?**

16. **For people with diabetes, do you regularly review their diabetes control through meter logs or lab values?**

1 ☐ Yes
0 ☐ No
99 ☐ Unsure/Unknown

17. **For people with diabetes do you regularly discuss hypo and hyper glycemic reactions?**

1 ☐ Yes
0 ☐ No
99 ☐ Unsure/Unknown

18. **When you sell a meter do you provide training?**

1 ☐ Yes
0 ☐ No
99 ☐ Unsure/Unknown

I would like to ask a few questions about the staffing ratios in the pharmacy. First of all, do you know the full time pharmacist full time equivalents for pharmacists and technicians? If yes, Pharmacist FTU _____ Technician FTU _____.

If no then can I ask you the following three questions to estimated the full time equivalents?

19. **How many hours during the week is the pharmacy open? (How many days a week is the pharmacy open and how many hours each day?)**

_____ hours

20. **How many pharmacist hours per week are scheduled? (for example if a pharmacy is open 40 hours a week with 2 pharmacist on at all time there are 80 pharmacist hours) (Would this be easier if it is broken up per day?)**

_____ hours

21. **How many technicians' hours per week are scheduled? (Would this be easier if it is broken up per day?)**

_____ hours

Thank-You Comments:

Appendix G

Telephone Exit Survey

Study ID _____ **Name:**_____

Phone Exit Questionnaire

Initial Open Ended Question

Other than participating in the study, what else have you done to learn about diabetes?

Followed by Closed Ended Questions

Have you:

1. Visited a Metabolic Clinic..... Yes ☐ 1 No ☐ 0

2. Visited your Family Doctor with diabetes concerns..... Yes ☐ 1 No ☐ 0

3. Visited a Diabetes Specialist..... Yes ☐ 1 No ☐ 0

4. Visited a Dietitian..... Yes ☐ 1 No ☐ 0

5. Contacted the Canadian Diabetes Association..... Yes ☐ 1 No ☐ 0

6. Surfed the net?..... Yes ☐ 1 No ☐ 0

Please think about the pharmacist you see most often to help with your diabetes.

In the last 6 months has your pharmacist....

1.	Reviewed your *Blood Sugar Levels*?	Yes ☐ 1 No ☐ 0
2.	Talked to you about *High* or *Low Blood Sugar Reactions*?.....	Yes ☐ 1 No ☐ 0
3.	Talked to you about how to use your blood sugar testing meter?....	Yes ☐ 1 No ☐ 0
4.	Asked you what you want to learn about diabetes?.....	Yes ☐ 1 No ☐ 0
5.	Asked you how your diabetes medicines are working for you?.....	Yes ☐ 1 No ☐ 0
6.	Measured your blood pressure?	Yes ☐ 1 No ☐ 0

Appendix H

Sample Documentation

SHOPPERS DRUG MART
RICHARD B. HACKMAN DRUGS LTD
KINGSWAY GARDEN MALL
109TH ST. & PRINCESS ELIZABETH AVE.
EDMONTON, ALBERTA T5G 3A6
PHONE: (403) 479-6819
FAX: (403) 479-6080
[redacted], B.S.P., C.D.E.
[redacted], B.Sc. Pharm., C.D.E.

Name: [redacted]

Blood Sugar Level: _____

Appointment: ☒ Initial Visit ☐ Follow-up ☐ Phone Follow-up

Fast Take meter.

Diabetes Care Program

Pharmacist provided teaching on:

- ☐ Diabetes & Complications
- ☐ "Hypo" & "Hyper" Reactions
- ☑ Monitoring Glucose Levels
- ☐ Use of Blood Glucose Monitor
- ☐ Use of Blood Pressure Monitor
- ☐ Diet/ Nutrition/ Weight Management
- ☐ Exercise
- ☐ Insulin Use
- ☐ Insulin Devices
- ☐ Medication Use
- ☐ Foot Care
- ☐ Glycosylated Hb
- ☐ _____
- ☐ _____

Other pharmacist services:

- ☑ Evaluate Teaching Needs
- ☑ Address Participant Concerns
- ☐ Pre-fill Insulin Syringes/ Insulin Pens
- ☐ Ensure Adequate Coverage
- ☐ Measured Blood Sugar Level
- ☐ Review Blood Sugar Levels
- ☐ Review Medication Profile
- ☐ Advise on OTC Prescription Use
- ☐ Dispose Insulin Syringes/ Lancets
- ☐ Contact Physician: _____
- ☐ Contact Member of Diabetes Team: _____
- ☐ _____
- ☐ _____

Recommendations:

Patient has a referral will help him better manage his diabetes.

Next Follow-up Date: Feb 3.

Participant: [redacted]

Pharmacist: [redacted]

Time: 1 hour.

[redacted] SHOPPERS DRUG MART [redacted] Date: mar 30/99

[redacted] RICHARD B. HACKMAN DRUGS LTD. [redacted] 6317

KINGSWAY GARDEN MALL
109TH ST. & PRINCESS ELIZABETH AVE.
EDMONTON, ALBERTA T5G 3A6
PHONE: (403) 479-6619
FAX: (403) 479-6090

[redacted] B.S.P., C.D.E.

[redacted] B.Sc. Pharm., C.D.E.

Name: [redacted]

Blood Sugar Level: 9.3

Appointment:
- ☐ Initial Visit
- ☑ Follow-up 30 mins
- ☐ Phone Follow-up

Diabetes Care Program

Pharmacist provided teaching on:

- ☑ Diabetes & Complications
- ☐ "Hypo" & "Hyper" Reactions
- ☑ Monitoring Glucose Levels
- ☐ Use of Blood Glucose Monitor
- ☐ Use of Blood Pressure Monitor
- ☐ Diet/ Nutrition/ Weight Management
- ☐ Exercise
- ☐ Insulin Use
- ☐ Insulin Devices
- ☐ Medication Use
- ☐ Foot Care
- ☐ Glycosylated Hb
- ☐ _____
- ☐ _____

Other pharmacist services:

- ☐ Evaluate Teaching Needs
- ☐ Address Participant Concerns
- ☐ Pre-fill Insulin Syringes/ Insulin Pens
- ☐ Ensure Adequate Coverage
- ☑ Measured Blood Sugar Level
- ☐ Review Blood Sugar Levels
- ☐ Review Medication Profile
- ☐ Advise on OTC Prescription Use
- ☐ Dispose Insulin Syringes/ Lancets
- ☑ Contact Physician: _____
- ☐ Contact Member of Diabetes Team: [redacted] - community dietician
- ☐ _____
- ☐ _____

Recommendations:

re [redacted]
Please find enclosed a summary of self-monitoring blood glucose results mrs. Gamache has done at home over the last 2 weeks.
She will be coming to see you to discuss the results, she will be seeing the dietician at her home as soon as she books the appointment.
If you are considering drug therapy at this point, please consider a low dose metformin ie 250mg bid to start.
Benefits to mrs. [redacted]
1. ↓ insulin resistance
2. No weight gain
3. Beneficial effects on HDL cholesterol.

Next Follow-up Date: Apr. 13/99

Participant: _____ Pharmacist: _____

SHOPPERS DRUG MART
RICHARD S. HACKMAN DRUGS LTD.
KINGSWAY GARDEN MALL
109TH ST. & PRINCESS ELIZABETH AVE.
EDMONTON, ALBERTA T5G 3A6
PHONE: (403) 479-6619
FAX: (403) 479-6090
[redacted] B.S.P., C.D.E.
[redacted] B.Sc. Pharm., C.D.E.

Name: [redacted]

Blood Sugar Level: _____ 133

Appointment: ☐ Initial Visit ☒ Follow-up ☐ Phone Follow-up

Diabetes Care Program

Pharmacist provided teaching on:

- ☐ Diabetes & Complications
- ☑ "Hypo" & "Hyper" Reactions
- ☐ Monitoring Glucose Levels
- ☐ Use of Blood Glucose Monitor
- ☐ Use of Blood Pressure Monitor
- ☐ Diet/ Nutrition/ Weight Management
- ☐ Exercise
- ☐ Insulin Use
- ☐ Insulin Devices
- ☐ Medication Use
- ☐ Foot Care
- ☐ Glycosylated Hb
- ☐ _____
- ☐ _____

Other pharmacist services:

- ☐ Evaluate Teaching Needs
- ☑ Address Participant Concerns
- ☐ Pre-fill Insulin Syringes/ Insulin Pens
- ☐ Ensure Adequate Coverage
- ☐ Measured Blood Sugar Level
- ☑ Review Blood Sugar Levels
- ☐ Review Medication Profile
- ☐ Advise on OTC Prescription Use
- ☐ Dispose Insulin Syringes/ Lancets
- ☑ Contact Physician: referral.
- ☐ Contact Member of Diabetes Team: _____
- ☐ _____
- ☐ _____

100

Recommendations::

Discussed today:
① possible low blood sugar in the afternoon - will test this when in - possible solution smaller lunch + have afternoon snack.
② Mood + memory - effect of high blood sugar + also mood effecting her motivation to control blood sugar
③ Interest in referral to U of A Metabolic Center Doris will discuss this with you at her next visit.
Have also enclosed most recent blood glucose readings.

Next Follow-up Date: July 17

Participant: _____ Pharmacist: [redacted]

SHOPPERS DRUG MART
RICHARD B. HACKMAN DRUGS LTD. #317
KINGSWAY GARDEN MALL
109TH ST. & PRINCESS ELIZABETH AVE. PHONE: (403) 479-8619
EDMONTON, ALBERTA T5G 3A6 FAX: (403) 479-8090

[redacted] B.S.P., C.D.E.
[redacted] B.Sc. Pharm., C.D.E.

Date: May 13, 99

Name: [redacted]

Blood Sugar Level: Not done

Appointment:
- ☐ Initial Visit
- ☑ Follow-up 30 min
- ☐ Phone Follow-up

Dr. [redacted]
Fax [redacted]

Diabetes Care Program

113

Pharmacist provided teaching on:

- ☐ Diabetes & Complications
- ☐ "Hypo" & "Hyper" Reactions
- ☐ Monitoring Glucose Levels
- ☐ Use of Blood Glucose Monitor
- ☐ Use of Blood Pressure Monitor
- ☑ Diet/Nutrition/ Weight Management
- ☑ Exercise
- ☐ Insulin Use
- ☐ Insulin Devices
- ☑ Medication Use
- ☐ Foot Care
- ☐ Glycosylated Hb
- ☑ kidney check results
- ☐ _____

Other pharmacist services:

- ☐ Evaluate Teaching Needs
- ☐ Address Participant Concerns
- ☐ Pre-fill Insulin Syringes/ Insulin Pens
- ☐ Ensure Adequate Coverage
- ☐ Measured Blood Sugar Level
- ☑ Review Blood Sugar Levels
- ☑ Review Medication Profile
- ☐ Advise on OTC Prescription Use
- ☐ Dispose Insulin Syringes/ Lancets
- ☑ Contact Physician: via fax.
- ☐ Contact Member of Diabetes Team: _____
- ☑ Blood pressure 136/93.
- ☐ _____

Recommendations:

(1) mr. [redacted] Fasting Blood sugars still appear elevated. If there are no contraindications, you may want to consider a low dose diamicron (ie 40mg at supper to start.)
-see blood sugars enclosed-

(2) I am also concerned about mr. [redacted] Lipid. It seems like Lipid was d/c'd upon his discharge from hospital in Jan. 99. Based on the fact the gentleman has established CHD, would he benefit from preventative use of a lipid lowering agent.
See enclosed - cholesterol guidelines
- Summary of all available agents and their specific effects on blood lipids.

Next Follow-up Date: June 17, 99

Thanks [redacted]

Participant: _____ Pharmacist: [redacted]

68

SHOPPERS DRUG MART
RICHARD B. HACKMAN DRUGS LTD. 6317
KINGSWAY GARDEN MALL
109TH ST. & PRINCESS ELIZABETH AVE. PHONE: (403) 478-6619
EDMONTON, ALBERTA T5G 3A6 FAX: (403) 478-6090

Date: [redacted]

Name: [redacted]

Blood Sugar Level: ____

Appointment: ☐ Initial Visit
☑ Follow-up 30 MINS.
☐ Phone Follow-up

[redacted] B.E.P., C.D.E.

[redacted] B.Sc. Pharm., C.D.E.

Dr [redacted]

Diabetes Care Program

Pharmacist provided teaching on:

- ☑ Diabetes & Complications
- ☐ "Hypo" & "Hyper" Reactions
- ☐ Monitoring Glucose Levels
- ☐ Use of Blood Glucose Monitor
- ☐ Use of Blood Pressure Monitor
- ☐ Diet/ Nutrition/ Weight Management
- ☐ Exercise
- ☐ Insulin Use
- ☐ Insulin Devices
- ☑ Medication Use
- ☐ Foot Care
- ☑ Glycosylated Hb
- ☑ cholesterol levels.
- ☑ kidney checks results

Other pharmacist services:

- ☐ Evaluate Teaching Needs
- ☑ Address Participant Concerns
- ☐ Pre-fill Insulin Syringes/ Insulin Pens
- ☐ Ensure Adequate Coverage
- ☑ Measured Blood Sugar Level
- ☑ Review Blood Sugar Levels
- ☐ Review Medication Profile
- ☐ Advise on OTC Prescription Use
- ☐ Dispose Insulin Syringes/ Lancets
- ☑ Contact Physician: Dr. Arnold
- ☐ Contact Member of Diabetes Team: _____
- ☑ discussed adding lipid drug.
- ☑ Referral back to metabolic center @ U of A. via Dr. Arnold.

Recommendations:

1. mr. [redacted] and I reviewed his most recent blood work at this visit.
According to most recent cholesterol guidelines, mr. [redacted]'s LDL levels and Total / HDL Ratios are both elevated. -
mr. [redacted] would like to examine is food intake but feels his diet is generally low fat.
considering his risk factors for C.A.D, you may want to consider starting lipid lowering therapy at your next visit with him.
Enclosed - is a breakdown of all the "Statins" and their specific effects on lipoproteins.
mr. [redacted] was interested in Lipitor & Baycol"

Next Follow-up Date: June 17, 99

Participant: _____ Pharmacist: _____

40