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## PREDICTORS OF READINESS TO INITIATE INSULIN THERAPY IN PATIENTS WITH TYPE 2 DIABETES WHEN ORAL MEDICATIONS FAIL TO CONTROL HYPERGLYCEMIA

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PREDICTORS OF READINESS TO INITIATE INSULIN THERAPY  
IN PATIENTS WITH TYPE 2 DIABETES WHEN ORAL  
MEDICATIONS FAIL TO CONTROL HYPERGLYCEMIA

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DISSERTATION

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A dissertation submitted in partial fulfillment of the  
requirements for the degree of Doctor of Philosophy in the  
College of Nursing  
at the University of Kentucky

By  
Pamela Lynn Phares

Lexington, Kentucky

Director: Dr. Sharon Lock, Associate Professor of Nursing

Lexington, Kentucky

2011

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## ABSTRACT OF DISSERTATION

### PREDICTORS OF READINESS TO INITIATE INSULIN THERAPY IN PATIENTS WITH TYPE 2 DIABETES WHEN ORAL MEDICATIONS FAIL TO CONTROL HYPERGLYCEMIA

Type 2 diabetes (T2DM) has reached epidemic levels worldwide during the past two decades. It affects nearly 26 million adults in the U.S. Advances in both the treatments for T2DM and guidelines for its optimal management are extensive. Despite these advances, barely half of type 2 diabetics achieve recommended glycemic targets.

#### Specific Aims:

The specific aims were to:

1. Describe the available research on clinical inertia and interventions that have been implemented to reduce it.
2. Analyze various behavioral theories that explain and predict self-care practices in diabetes in order to develop a conceptual model on which to base an investigation of predictors of readiness to initiate insulin therapy in type 2 diabetics.
3. Determine predictors of readiness to initiate insulin therapy in patients with T2DM when oral medications fail to control hyperglycemia using the conceptual model based on Self-Determination Theory (SDT) as a framework.

#### Results:

A review of research articles published from 1990 to 2010 concluded that clinical inertia of primary care providers treating T2DM resulted in a majority of patients experiencing unnecessary chronic uncontrolled hyperglycemia. Behavioral theories were analyzed for their ability to predict self-care behaviors in type 2 diabetics. A conceptual model was developed based on the major constructs of SDT in order to guide the design of study to investigate predictors of readiness to begin insulin therapy in T2DM. Finally, a descriptive, correlational study was performed to determine readiness to initiate insulin therapy in patients with T2DM when oral medications fail to control hyperglycemia.

Results of the study revealed that participants who had a friend or family using insulin were 5.5 times more likely to rate their readiness to initiate insulin as high than those who had neither ( $p=.020$ ). In addition, those with greater negative beliefs and attitudes toward insulin therapy were more likely to rate their readiness to initiate insulin as low ( $p=.012$ ). A majority (58%) of participants rated their readiness to begin insulin therapy as immediate if it would give them better control over their hyperglycemia. The study also confirmed findings from previous studies that clinical inertia was present in this setting.

**KEY WORDS:** clinical inertia, insulin therapy, Self-Determination Theory, type 2 diabetes

Pamela L. Phares, MSN

Student's Signature

November 18, 2011

Date

PREDICTORS OF READINESS TO INITIATE INSULIN THERAPY  
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This work is dedicated to my husband Chris  
and my sons, Evan and Patrick

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## CHAPTER ONE

### Introduction

This year, the United Nations General Assembly recently convened the inaugural Summit on Non-communicable Diseases (NCD) which met in September 2011 in New York City (Beaglehole, Bonita, Horton, Adams, Alleyne, et al., 2011). The goal of the summit was two-fold: to increase awareness of NCDs and to reach common ground among heads of states and governments on directed efforts to prevent and control cardiovascular diseases, cancers, chronic respiratory diseases, and diabetes. Initially linked to rapidly changing lifestyles and urbanization in high-income countries, these diseases have now reached epidemic levels in middle- and low-income nations as emerging nations struggle with highly fluid population dynamics and increased urbanization (Probst-Hensch, Tanner, Kessler, Burri & Künzli, 2011). A case in point, India now accounts for nearly one-third of the global type 2 diabetes (T2DM) burden, with diabetes incidence continuing to increase at an alarming rate (Beaglehole et al.). Global prevalence of diabetes is projected to rise from the current 6.4% of the world's population in 2010 to 7.8% of the world's population by 2030 (World Diabetes Foundation, 2011). Some believe its prevalence worldwide may actually be higher by 2030 in light of current trends (Probst-Hensch et al., 2011).

Because NCDs heavily impact health-related quality of life (HRQOL) of the individuals affected by them and jeopardize the socioeconomic productivity of populations, they have become the focus of researchers worldwide (Probst-Hensch et al., 2011; World Economic Forum, 2011). The human and economic benefits of preventing NCDs are enormous, but instituting preventative measures is perhaps, the greatest

challenge to nations, especially for low- and middle-income countries. Primary prevention presents a lower-cost alternative than the long term and expensive tertiary management of these diseases that currently pervades health care systems worldwide (Geneau, Stuckler, Stachenko, McKee, Ebrahim, et al., 2010). Low cost, effective solutions for prevention are readily available, but as Geneau et al. argue, the failure to respond is largely political, not technical.

In the U.S. the emphasis is primarily on treatment of NCDs with a disproportionate amount of limited health care dollars directed at treating, rather than preventing, NCDs (Harkness & DeMarco, 2011). Despite the emphasis on treatment of NCDs, health care providers in the U.S. have not effectively used the pharmaceutical resources and evidence-based guidelines to implement treatment of these diseases, particularly in the case of T2DM. The state of pharmaceutical science for treating T2DM and the dissemination of guidelines for optimal treatment of diabetes to prevent or slow the development of its numerous sequelae have never been better (American Diabetes Association [ADA], 2011; Kunt & Snoek, 2009; U.K. Prospective Diabetes Study [UKPDS] Group, 1998). In fact, many experts believe that improvements in the outcomes of T2DM will have less to do with new treatments, and everything to do with how effectively health care providers implement the current drugs, technology, and knowledge available (Barag, 2011; Brown, Nichols & Perry, 2004).

### **Scope and Importance of the Diabetes Problem**

#### **Prevalence**

Current estimates place diabetes prevalence rates at 8.3% of the U.S. population, roughly 26 million Americans, which has increased from previous estimates of 7.8% of

the U.S. population in 2007 (National Diabetes Information Clearinghouse [NDIC], 2011). Approximately 90-95% of diabetes cases are type 2. Sedentary lifestyles, poor diet, and increased obesity of the population have contributed to the increasing incidence and prevalence rates of type 2 diabetes (Cobble, 2009; Cornell, 2011). Once considered an adult-onset health problem, it is now increasingly being diagnosed in school-age children (NDIC).

### **Cost**

The human costs of diabetes are significant. Diabetes increases risk of stroke and death from heart disease to rates that are two to four times those of nondiabetics (NDIC, 2011). Diabetes is also the leading cause of new cases of blindness, kidney disease, and nontraumatic lower limb amputations (NDIC). The morbidity associated with diabetes doubles the risk for depression in this population (Anderson, Freedland, Clouse & Lustman, 2001).

The burden of diabetes also presents a crisis in terms of health care costs, both direct and indirect. Direct medical expenditures were estimated to be \$116 billion in 2007 while indirect costs from disability, work loss, and premature death were an additional \$58 billion (NDIC, 2011). Future costs have been projected to escalate significantly. By 2034, diabetes-related healthcare costs are expected to reach an estimated \$336 billion in direct expenditures (Huang, Basu, O'Grady & Capretta, 2009). Disability related to complications of diabetes also affects the nation's productivity (Geneau et al., 2010).

## **Type 2 Diabetes**

### **Pathophysiology and Criteria for Diagnosis**

Type 2 diabetes is a progressive disease affecting multiple organ systems within the human body (Cefalu, Gerich & LeRoith, 2004). It is strongly associated with obesity; obesity, in turn increases risk for cardiovascular disease, which is the major cause of morbidity and mortality in T2DM. Pathophysiologic changes that occur in T2DM are characterized by a progressive decline in pancreatic  $\beta$ -cell function, insulin resistance, lack of suppression of post-prandial glucagon secretion, and apoptosis of pancreatic  $\beta$ -cells from sustained hyperglycemia (Cefalu et al., 2004; Cornell, 2011). Diabetes is best conceptualized and managed as a global vascular disease with treatment focused on reversing abnormal glucose levels, dyslipidemia, inflammatory endothelial dysfunction, and accelerated atherosclerosis (Mirza, 2007). The net effect of this approach is preventing, or at least delaying, common sequelae of T2DM which include myocardial infarction, hypertensive heart disease, retinopathy and blindness, kidney insufficiency and failure, neuropathy, and lower extremity amputations (Cefalu et al.; Cornell).

Current criteria for the diagnosis of diabetes should include one of the following ADA (2011) accepted tests: (1) glycosylated hemoglobin (HbA1c)  $\geq 6.5\%$ , (2) fasting plasma glucose  $\geq 126$  mg/dl with minimum fasting interval of eight hours, (3) an oral glucose tolerance test (OGTT) yielding a two-hour plasma glucose level  $\geq 200$  mg/dl following an initial glucose load containing 75grams of anhydrous glucose dissolved in water, or (4) a patient who exhibits classic signs of hyperglycemia or hyperglycemic crisis and a random plasma glucose  $\geq 200$  mg/dl.



## Recommended Management

The most effective means of preventing or delaying complications of diabetes is for an individual to monitor blood glucose levels frequently (3 to 4 times daily) and to maintain consistent control of blood glucose levels (ADA, 2011; UKPDS, 1998).

Glycemic control should be monitored daily by the patient using finger-stick blood glucose testing. Diabetes clinicians assess long-term glycemic control by monitoring serial serum glycosylated hemoglobin levels ( $HbA_{1c}$ ); typically drawn every three months in patients who are not meeting glycemic goals or every six months in patients who are well controlled, in order to assess the effect of patients' lifestyle changes and medically prescribed interventions (ADA; Cefalu et al., 2004). Optimal benefit and increased likelihood of preventing complications from T2DM are seen when patients'  $HbA_{1c}$  values are maintained below 7%. However, barely one-half of people with T2DM maintain their  $HbA_{1c}$  at goal (Cobble, 2009).

Generally, clinicians follow a stepped-approach to treating new-onset T2DM, beginning with nonpharmacologic interventions such as dietary changes, weight loss, and increased physical activity (Cefalu et al., 2004). Oral medications are instituted when lifestyle modifications have not proven successful for keeping  $HbA_{1c}$  at goal. Frequently a single oral agent is trialed initially and additional oral medications are added as tolerated based on  $HbA_{1c}$  values. In many circumstances, insulin therapy is often reserved as a last resort by many clinicians when lifestyle modifications and multiple oral agents have failed to control hyperglycemia; a treatment practice that patients often equate with personal failure on their part to control their T2DM, worsening of their disease, or both (Cobble, 2009; Reach, 2008).

More aggressive intensification of diabetes therapy has been advocated earlier in the course of the disease because experts contend that T2DM has likely been present for years, maybe even a decade, before it is formally diagnosed due to the asymptomatic nature of the illness in its early stages (Barag, 2011; Cobble; Dewitt & Hirsch, 2003). Unnecessarily delaying intensification of treatment regimens or delaying initiation of non-oral therapeutic agents in type 2 diabetics who have poor control of their hyperglycemia in early stages of disease will result in increased morbidity, and possibly premature mortality (Brown et al., 2004).

Up to 60% of type 2 diabetic patients will require insulin within six to ten years or perhaps sooner if they have experienced long-standing disease prior to diagnosis (Barag, 2011). Recently, newer non-insulin injectable medications have been developed and are being more widely used with type 2 diabetic patients who are unable to maintain HbA<sub>1c</sub> at goal on multiple oral agents (Hinnen, Nielsen, Waninger & Kushner, 2006). These new drugs show promise in their ability to bring hyperglycemia under control and may possibly halt pancreatic  $\beta$ -cell destruction.

### **Problems with Current Management of Diabetes Care**

Increasing numbers of people with T2DM will experience disability related to their illness if the current paradigm of diabetes care does not change. Once considered the domain of diabetes specialists and endocrinologists, the medical management of T2DM continues to expand into the realm of primary care (Barag, 2011; Harris, Kapor, Lank, Willan & Houston, 2010). Patients were often referred to specialists who initiated and managed their insulin therapy. Now primary care physicians are far more likely to initiate and adjust patients' insulin as they assume more responsibility for management of

patients' diabetes care. This shift in management responsibility for the care of patients with diabetes presupposes that primary care clinicians feel competent and knowledgeable in managing T2DM, when in fact, many of them have demonstrated or admitted they are neither (Harris et al., 2010; Kunt & Snoek, 2009; Peyrot et al., 2005; Wallace & Matthews, 2000).

The paradigm shift in medicine over the last few decades, from an infectious disease model focused on eradicating disease to a model that focuses on managing chronic illnesses, also contributes to the under-treatment of many chronic illnesses and the frequent failure of care in type 2 diabetes. Failure of care in diabetes results from multiple factors. These factors include discordance between patient and provider goals, failure to communicate effectively, lack of adherence to current guidelines for treatment of T2DM, patients' refusal to engage effectively in diabetes self-care practices, and lack of knowledge on the part of patients and health care providers (Reach, 2008).

Diabetes care requires a great deal of continuous participation from the patient in order to maintain effective glycemic control. Experts contend that people with diabetes provide about 95% of their own care (Anderson et al., 1995). Diabetics are involved in a constant struggle to maintain normal blood glucose levels. Self-management remains the cornerstone of T2DM care and it is believed by researchers that improving patient self-efficacy is a crucial factor for improving patient outcomes (Lorig & Holman, 2003; Sarkar, Fisher & Schillinger, 2006). It is therefore essential to foster autonomy and confidence in patients to perform diabetes self-care, particularly self-care related to insulin therapy. Many experts agree that insulin is the most powerful and effective pharmacologic tool available to treat hyperglycemia and it will eventually be a necessary

component of treatment for effective control of blood glucose in a substantial number of patients with T2DM in reaction to  $\beta$ -cell failure as a natural course of the disease (Cobble, 2009; Riddle, 2002).

Clinicians are charged with the responsibility of initiating insulin therapy in a timely manner when indicated by the patient's illness status (ADA, 2011; Cobble, 2009). Changing the way in which type 2 diabetics view insulin as part of their diabetes care is also part of that responsibility. The current diabetes care paradigm has failed in both respects thus far, which suggests that a shift in paradigms is warranted.

### **Introduction to the Dissertation**

This dissertation consists of three manuscripts found in Chapters Two through Four. Chapter Two of this dissertation presents an integrative review of the available research evidence exploring the reluctance of health care providers to initiate insulin therapy when indicated by chronic hyperglycemia in adult patients with type 2 diabetes, more recently termed *clinical inertia*. Specific aims of this literature review were: (1) to identify factors that have been shown to contribute to clinical inertia of primary care providers initiating insulin therapy in type 2 diabetes, (2) to identify strategies that have successfully decreased clinical inertia in primary care providers initiating insulin therapy in the care of type 2 diabetics, and (3) to identify individual-level strategies employed by primary care providers with type 2 diabetic patients to overcome clinical inertia and facilitate patient use of insulin therapy earlier in the disease course.

Multiple factors were found to contribute to clinical inertia. Common barriers such as nonadherence to published diabetes care guidelines, lack of knowledge regarding these guidelines, frustration with patients over real or perceived regimen nonadherence,

lack of time during visits with patients, competing needs in primary care, and misconceptions of providers' perceptions of patient barriers to insulin therapy adoption were among the findings.

Studies evaluating healthcare system-level interventions and their effects on diabetes care and outcomes dominated the literature. Modest but significant improvements in HbA<sub>1c</sub> were realized by these interventions. However, HbA<sub>1c</sub> in all studies remained above the ADA (2011) recommended goal of < 7%. Individual-level intervention studies were not found. It was this latter finding that inspired the direction of the dissertation research. Recommendations for direction of future research in this area are discussed.

Chapter Three presents a critical analysis of several theoretical frameworks that have previously been used by researchers to explain and predict health and self-care behaviors in chronic illness, of which diabetes is one. The analysis was important for selection of the an appropriate theoretical framework on which to base an investigation of predictors of readiness for persons with type 2 diabetes who require transition to insulin therapy when oral medications have failed to control their hyperglycemia. No previous studies investigating insulin therapy readiness, and more specifically, none that used a behavioral theory framework were found; though a number of studies using behavioral theories to explain diabetics' engagement in self-care practices and the effect of those practices on subsequent glycemic outcomes in T2DM are discussed.

Among some of the theories other researchers have used to explain diabetes self-care behaviors and outcomes are the Health Belief Model (HBM), the Theory of Planned Behavior (TPB), Social Cognitive Theory (SCT), and Self-Determination Theory (SDT).

Research using SDT as a framework to explain diabetes self-care behaviors has yielded convincing evidence to support its application as a framework for future studies aimed at identifying factors hypothesized to influence patients to engage in self-care activities, namely the use of insulin therapy. Existing measures based on the major constructs of SDT were used in these studies and determined to be valid and reliable for use in the dissertation research. An explanation of the application of these measurements is presented in this chapter.

Because no research had been conducted to identify predictors of readiness to initiate insulin therapy explained within a behavioral framework, a conceptual model was developed to illustrate and explain how the study variables of interest were linked to the major constructs of SDT. This conceptual model strongly influenced the study's design. Major study variables were operationalized using existing measures including the Perceived Competence in Diabetes Scale (PCDS), the Health Care Climate Questionnaire (HCCQ), the Treatment Self-Regulation Questionnaire (TSRQ), and the Insulin Therapy Appraisal Scale (ITAS). The validity and reliability of these measures are discussed in this chapter.

In Chapter Four, results of a study using SDT as a framework for identifying modifiable predictors of readiness to initiate insulin therapy when oral medications fail to control hyperglycemia in patients with T2DM are reported. The specific aim of the study was to determine if perceived autonomy-support, perceived diabetes competence, motivational orientation, and appraisal of insulin therapy were predictors of readiness to initiate insulin therapy in persons with T2DM when oral therapy fails to control hyperglycemia.

Findings from a descriptive, correlational study of 73 participants with T2DM showed that beliefs and attitudes regarding insulin therapy and whether or not they had a friend or family member who used insulin were significant predictors of insulin readiness ( $p = .012$  and  $p = .020$ , respectively). Although perceived diabetes competence, perceived autonomy-support in the clinical environment, and motivation orientation were not found to be significant predictors of insulin readiness, the findings related to these measures have important implications, both in this study and for future research. A discussion concerning the usefulness of SDT for studying readiness to initiate insulin therapy, as well as recommendations for future research of this phenomenon are addressed in this chapter.

### **Chapter Summary**

This chapter provided sufficient evidence to support the scope and importance of type 2 diabetes as an important public health problem, now and in the future. Review of available literature and justification for the dissertation research were provided. An overview of Chapters Two through Four was provided for the reader to describe the relationship between the various manuscripts contained in the dissertation.

## CHAPTER TWO

### Clinical Inertia of Type 2 Diabetes in Primary Care: An Integrative

#### Review of the Literature

**OBJECTIVE:** The objective of this paper is to review the available research evidence regarding the reluctance of providers to initiate insulin therapy when indicated (clinical inertia), in the care of adult patients with T2DM. In addition, future directions for research to improve glycemic control for this population of patients are recommended.

**METHOD:** A literature search was conducted using the US National Library of Medicine's MEDLINE database for studies published between 1990 and 2010. Cross-reference searching using references from reviewed articles, PubMed, and CINAHL was also conducted for additional articles until saturation was reached.

**RESULTS:** Fifteen studies were found to meet the criteria for inclusion in this review. Interventions to improve glycemic control were employed in five of the studies and demonstrated modest but significant improvements in patients' HbA<sub>1c</sub> levels. Eight studies used prospective designs to evaluate change in HbA<sub>1c</sub>, and one used a retrospective cohort design to analyze previous practice related to patient outcomes. The remainder of studies used cross-sectional methods of data collection to evaluate attitudes and barriers toward insulin use.

**CONCLUSIONS:** Multiple factors contributing to clinical inertia have been identified. Although results of intervention studies to date demonstrate modest but significant improvements in HbA<sub>1c</sub> levels, more research is indicated, as the majority of patients in these studies do not achieve recommended glycemic goals. Studies examining individual-



level provider interventions to increase patients' acceptance of insulin therapy have yet to be conducted.

**KEY WORDS:** type 2 diabetes; clinical inertia; insulin therapy; diabetes guidelines

## Introduction

Type 2 diabetes mellitus (T2DM) affects both insulin secretion and insulin action. The defect in insulin secretion is progressive and is accompanied by concomitant insulin resistance, which is believed to begin years before diagnosis (Dewitt & Hirsch, 2003). As a consequence of these events, adequate glycemic control in T2DM will eventually require exogenous insulin replacement. Up to 60% of diabetic patients will require insulin within six to ten years; perhaps sooner if they have experienced long-standing disease prior to diagnosis (Barag, 2011). The UK Prospective Diabetes Study (UKPDS), a sentinel study demonstrating improved outcomes with intensive blood glucose control, has affirmed that insulin therapy is an integral part of achieving tight glycemic control, thus decreasing risk of complications in T2DM (UK Prospective Diabetes [UKPDS] Group, 1998).

Despite increasing evidence from clinical trials demonstrating markedly improved outcomes for diabetes when glycemic control is maintained, a large proportion of patients never achieves or maintains glycemic goals (Riddle, 2002). Many experts agree that insulin is the most powerful and effective pharmacologic tool available to treat diabetes and its potential to lower plasma glucose is limited only by hypoglycemia (Cobble, 2009). Insulin is grossly underutilized in the U.S. (Riddle, 2002). Insulin therapy in T2DM is more often employed only as a last resort when all else has failed, rather than used as a highly effective intervention when employed earlier in the disease process. Health care providers' reluctance to prescribe and patients' reluctance to use insulin are often cited as the two major reasons for delay in timely initiation of insulin therapy. Delay in initiating insulin in patients who are unable to reach optimal glycemic control

with oral diabetic agents increases their risks of microvascular and macrovascular complications (Cobble, 2009).

Estimated prevalence of diabetes, as of 2007, is 7.8% of the U.S. population, or 23.6 million Americans (American Diabetes Association [ADA], 2009). Approximately 90-95% of these cases are type 2 diabetes. Diabetes is a common medical problem and as such has been widely researched in terms of best practices related to its treatment. Well-researched practice guidelines exist for managing diabetes; yet a wide gap exists between recommended medical practices and the care patients actually receive in the clinical setting. The role of primary care providers in managing T2DM continues to expand and they are more likely than specialists to initiate and manage insulin therapy in these patients (Barag, 2011). Many primary care providers rate effective treatment of diabetes as one of the most difficult and time consuming of patient health problems dealt with in practice (Brunton, 2009). In fact, the cross-national Diabetes Attitudes, Wishes, and Needs (DAWN) study found that a large number of U.S. primary care physicians were inclined to delay initiation of insulin in their diabetic patients (Peyrot et al., 2005). Furthermore, evidence suggests that U.S. primary care providers typically do not initiate insulin therapy until a patient's glycosylated hemoglobin (HbA<sub>1c</sub>) level reaches  $\geq 9\%$  which corresponds to an average serum glucose of 243 mg/dl (Brown, Nichols & Perry, 2004).

Effective management of hyperglycemia through intensification of therapy has been well demonstrated by researchers, but poorly implemented in practice (Peyrot et al., 2005; UKPDS, 1998). A major reason for poor glycemic management has been identified as the phenomenon of *clinical inertia*, which is defined as the failure of healthcare

providers to initiate or intensify diabetes therapy when indicated in the course of the disease (Perlin & Pogach, 2006). The purpose of this paper is to review the available research evidence regarding the reluctance of providers to initiate insulin therapy when indicated in adult patients with T2DM. Specific aims of this literature review are: (1) to identify factors that have been shown to contribute to clinical inertia of primary care providers starting insulin therapy in T2DM, (2) to identify strategies that have successfully decreased the clinical inertia of primary care providers initiating insulin therapy in the care of patients with type 2 diabetes, and (3) to identify individual-level strategies employed by primary care providers with type 2 diabetic patients to overcome clinical inertia and facilitate patient use of insulin therapy earlier in the disease course. While acknowledging the importance of patient factors contributing to the avoidance or delay of insulin therapy initiation, the focus of this review is on the provider aspect of this clinical issue.

Specific aims of this review were guided by the following questions: (1) What factors are related to the clinical inertia of healthcare providers avoiding or delaying insulin therapy in patients with type 2 diabetes? (2) What strategies have been successful in diminishing clinical inertia of healthcare providers when the patient's clinical condition warrants insulin therapy? (3) What individual-level interventions have been used by healthcare providers to increase patient acceptance of insulin therapy?

### **Method**

The literature search was conducted using the US National Library of Medicine's MEDLINE database. The search included articles published in English only, beginning in 1990 and ending in 2011. Cross-reference searching using references from reviewed

articles, PubMed, and CINAHL was also conducted to identify additional articles. The search was discontinued when saturation was evident from repetition of articles appearing in the various searches. Key words and phrases used in the search included: diabetes treatment, type 2 diabetes, barriers to treatment, facilitators of insulin prescribing, insulin initiation, clinical inertia, insulin avoidance, hypoglycemia, beliefs, attitudes, perceptions, transition to insulin, glycemic control, resistance to insulin therapy, psychological resistance, physician, nurse, and misconceptions regarding insulin. No limitations were placed on the type of study design or size of the sample. Articles pertaining specifically to T2DM were targeted. A total of 152 citations were retrieved from the initial MEDLINE search and cross-referenced searches. After reviewing abstracts, 43 articles were analyzed for content related to clinical inertia. Studies were included if they were: (1) primary sources and (2) they specifically addressed investigations pertaining to clinical inertia in the treatment of adult patients with T2DM. Fifteen studies were found to meet the criteria for inclusion in this review and are described in Table 2.1.

## **Results**

### **Factors Contributing to Clinical Inertia**

Clinical inertia has been defined as the failure of clinicians to appropriately initiate or intensify diabetes therapy when indicated in the course of the disease (Perlin & Pogach, 2006). Intensification can be defined as an increase in the dosage, number, or type of antiglycemic agents necessary to maintain near-normal blood glucose levels in diabetic patients (Cobble, 2004). Diabetes therapy is considered to be failing when glycosylated hemoglobin (HbA<sub>1c</sub>) exceeds 7% according to ADA standards (2011).

Since the majority of patients with T2DM are managed in primary care settings, much of the concern with clinical inertia is centered on whether timely and appropriate clinical decisions are being made regarding intensification of diabetes treatment using insulin (Cobble, 2004; Pearson & Powers, 2006). The clinical endpoint most often used to gauge efficacy of diabetes treatment established by the ADA is HbA<sub>1c</sub>, as it is considered a reliable measure of a diabetic's long-term glycemic control (ADA, 2009; Dewitt & Hirsch, 2003). Most of the studies examining clinical inertia in the primary care setting also used HbA<sub>1c</sub> as a measure of the effectiveness of diabetes care and interventions.

### **Competing demands in primary care**

Ziemer and colleagues (2005) conducted a large prospective observational study to compare management of diabetic patients in a primary care clinic versus a diabetes specialty clinic. Findings from the study showed that when serum glucose levels were high, therapy of diabetic patients in the primary care clinic was much less likely to be advanced or intensified compared to diabetics in the specialty diabetes clinic (32% vs. 65%,  $p < .0001$ ). In this same study, intensification rates for insulin therapy in patients currently using insulin were strikingly lower in the primary care clinic than the diabetes clinic (28% vs. 75%,  $p < .02$ ). Researchers conducting the study concluded that the low rates of therapy intensification for patients in the primary care clinic were a function of their comorbid health problems and other primary care patient concerns that are necessarily addressed in that environment, but are not typically addressed in a specialty clinic. Similarly, a study by Parchman and colleagues (2007) found that for each additional patient concern in a primary care office, there was a 49% reduction in the

likelihood of a medication change, and once the number of patient concerns exceeded four, none of the observed patient encounters had a change in medication regardless of HbA<sub>1c</sub> value. However, researchers found that when a medication change occurred during a patient encounter, not only were fewer patient concerns discussed at the visit ( $p = .04$ ), but patients also had a higher HbA<sub>1c</sub> value than in those encounters not involving medication changes ( $p = .001$ )

### **Lack of training and failure to follow published guidelines**

Many of the studies reviewed examining clinical inertia were conducted in response to the Diabetes Quality Improvement Project (DQIP) initiated in 2001 to establish a set of comprehensive national quality measures for diabetes care (Fleming et al., 2001). Despite the publication and dissemination of expert guidelines for managing T2DM that resulted from the DQIP initiative, implementation of those guidelines and providers' knowledge of them remain quite variable (Perlin & Pogach, 2006). In an observational study involving 30 academic medical centers, researchers failed to identify specific factors explaining clinical inertia (Grant, Buse & Meigs, 2005). They found that only 34% of diabetic patients were maintained at HbA<sub>1c</sub> goal ( $< 7.0\%$ ). Given that most academic medical centers generally promote cutting-edge health care initiatives, serve as training grounds for new healthcare providers, and are centers of substantial clinical research and scientific inquiry, this finding is particularly concerning.

A descriptive epidemiologic study of insulin-dependent diabetic patients managed by resident physicians at a major teaching hospital was conducted by Giangola et al. (2008). Only 5.7% of the 105 diabetic patients who participated in the study exhibited adequate glucose control. The top three barriers to glycemic control identified by

researchers were: reluctance of the physician to increase insulin dosage, reluctance to follow the advice of the diabetic team nurses, and general lack of knowledge about insulin therapy. Although lack of knowledge and need for additional training were not identified by internal medicine residents in an academic medical center ( $n = 145$ ) as barriers to their implementation of national diabetes guidelines and getting patients' HbA<sub>1c</sub> levels to goal, Bernard, Anderson, Cook and Phillips (1999) found that fewer than half of the medical residents being studied selected an appropriate HbA<sub>1c</sub> goal for their patients. Findings also revealed that 51% of those patients who had been prescribed oral antiglycemic agents and 47% of those receiving insulin had recorded HbA<sub>1c</sub> levels in excess of 8%. Physicians' self-rated performance and knowledge regarding appropriate use of insulin in T2DM and correct implementation of national diabetic treatment guidelines were quite different from the actual practices observed by researchers conducting the study.

### **Physician attitudes and patient noncompliance**

Attitudes and misconceptions of primary care physicians have been identified in other studies as barriers to glycemic control in diabetic patients. Larme and Pugh (1998) surveyed 31 primary care providers treating T2DM patients who rated diabetes as harder to treat than other chronic diseases such as hypertension, hyperlipidemia, angina, and arthritis. Major attitudinal themes that emerged as barriers to glycemic control were complexity of treatment, time and expense, frustration over poor glycemic control, diagnosis and treatment protocols perceived to be unclear and eventual decline of the patient despite prescribed therapy.



Similar to the study by Larmer and Pugh, Drass et al. (1998) surveyed 370 primary care providers who managed diabetic care of their patients and also found time and expense, complexity of diabetes care, and perceived lack of clear care guidelines to be barriers to effective medical management of patients with T2DM. Additionally, providers in this study rated patient nonadherence to treatment as the most problematic barrier to glycemic control. A subsequent prospective cohort study of 2,065 patients with T2DM by Grant et al. (2007) highlighted the important relationship linking patient behavior (adherence) and physician action (intensifying diabetes therapy). Researchers in this study found that patients in the highest baseline medication adherence quartile had 53% greater odds of having their therapy intensified relative to rising HbA<sub>1c</sub> when compared to those patients in the lowest quartile ( $p < .0001$ ). The authors point out however, that even among the most adherent patients with rising HbA<sub>1c</sub>, intensification of their diabetes regimen was delayed for almost two years in most cases. This study confirmed suspicions of researchers that poor adherence, or even perceived poor adherence, dooms some patients to inadequate management of their diabetes.

A descriptive study by Bernard et al. (1999) examined both the self-described and recorded behaviors of internal medicine (IM) residents ( $n = 161$ ) caring for T2DM patients ( $n = 140$ ) in an effort to target areas for improvement in the internal medicine residents' practice patterns regarding diabetes care. Results indicated that less than half (49%) of residents selected a targeted HbA<sub>1c</sub> range of 6.6% to 7.5% as attainable, but more than half of patients using either oral medications or insulin in the study had HbA<sub>1c</sub> values  $> 8\%$ . In addition, incremental years of additional practice had no effect on self-described versus recorded clinical performance of the resident trainees. Overall, IM

residents did not perceive themselves to need additional training in diabetic care when asked, as evidenced by average neutral ratings on a 5-point Likert scale ( $\mu = 3.1 \pm 0.4$ ) for all four questions that assessed perceived need for additional training. They were also neutral about their regard for patient autonomy in the clinical care setting ( $\mu = 3.3 \pm 0.6$ ). Similar to previous research findings, residents in this study rated patient nonadherence (71%) and time constraints (49%) as often or always a barrier to effective care.

Findings from the large, cross-national Diabetes Attitudes, Wishes, and Needs (DAWN) study revealed U.S. physicians ranked lowest among physicians in all but two nations, Japan and India, in their willingness to initiate insulin in their patients with T2DM (Peyrot, Rubin, Lauritzen, Skovlund, Snoek, et al., 2005). Both nurses and physicians who took part in this study identified insufficient training and lack of resources in the primary care setting as significant barriers. Perhaps the most shocking finding was that barely more than half of U.S. nurses ( $n = 1,109$ ) and physicians ( $n = 2,681$ ) interviewed in this study believed in the efficacy of insulin for T2DM. Diabetes specialists and clinical opinion leaders in this study were far more likely to initiate insulin therapy to control hyperglycemia, a finding consistent with that from the study by Perlin and Pogach (2006). Both non-belief in the efficacy of a treatment and lack of knowledge in the correct or optimal use of that therapy may strongly impact one's propensity to prescribe it, and may represent a substantial barrier to implementation of evidence-based guidelines in the management of diabetic patients in the primary care setting.

### **Misconceptions of barriers to insulin therapy**

Misconceptions held by healthcare providers which they attribute to a patient's reluctance to use insulin or fear of insulin therapy in general have been shown to

contribute to the clinical inertia of health care providers to prescribe insulin to patients. Nakar, Titzhaki, Rosenberg, and Vinker (2007) administered an open-ended questionnaire to 157 family physicians caring for type 2 diabetic patients in order to explore reasons for their reluctance to initiate insulin treatment. The most frequent explanations given by physicians were: the patient would not comply with treatment (92.3%), fear of hypoglycemia in a specific patient (79.7%), patients would not be able to cope with pain involved in blood testing (53.9%) and injecting (48.4%), and the patients being too old (47.4%). These barriers were in sharp contrast to the patients' most frequently perceived barriers to insulin therapy which were: diabetes is not a serious illness (46.7%) and fear of addiction to insulin (39%). Pain and hypoglycemia were very infrequently cited patient barriers (5.4% and 12%, respectively).

### **Strategies to Decrease Clinical Inertia and Improve HbA<sub>1c</sub>**

Few studies focusing on overcoming clinical inertia of primary care providers managing T2DM have been conducted. Selected studies for this review of the literature included those that implemented stepped-approach algorithms into clinical practice (Aubert et al., 1998; Benjamin, Schneider, & Hinchey, 1999; de Sonnaville et al., 1997) and those that evaluated the feasibility and outcomes of newly-formed collaborative care models between primary care providers and endocrinologists (Graber, Elasy, Quinn, Wolff & Brown, 2002; Phillips et al., 2005).

#### **Integrating evidence into practice: stepped-approach algorithms**

Structured stepped-approach algorithms became more widely recommended by experts and opinion leaders following the UKPDS study (1998) in which researchers demonstrated markedly improved glycemic control through treatment intensification in

management of T2DM. Diffusion of these guidelines and recommendations into clinical practice has not been effectively accomplished (DeWitt & Hirsch, 2003; Hsu, 2009; Parchman et al., 2007). A study by de Sonnaville et al. (1998) tested the implementation of a fairly aggressive stepped approach to diabetes treatment intensification with physicians in a primary care setting. The prospective, experimental study included an intervention group of type 2 diabetic patients not treated with insulin ( $n = 350$ ) and a control group ( $n = 68$ ) of type 2 diabetic patients already using insulin. The two groups were followed over a two-year period. A step-up regimen of medication intensification was instituted within the study group with change in therapy triggered by a patient's HbA<sub>1c</sub> level exceeding 7.0%. The percentage of patients that were prescribed insulin increased from 3.56% at baseline to 20% in one year and almost 30% in two years. The majority of patients in the study group (54.3%) achieved HbA<sub>1c</sub> levels  $< 7.0\%$ , while the control group did not (44.1%). These differences were significant ( $p = 0.013$ ). Despite aggressive intensification of therapy for their diabetes, self-reported well-being of the treatment group participants remained unchanged and only four episodes of hypoglycemia occurred over the two-year period.

Aubert and colleagues (1998) studied a stepped-approach protocol of medication intensification using a randomized controlled trial design. Interventions with patients were implemented via a case management model using a certified diabetes nurse educator under the direction of a family physician and endocrinologist. The intervention group ( $n = 138$ ) received extensive teaching from the nurse case manager with reinforcement of behavioral changes; those taking insulin were contacted by phone twice per week by the nurse specialist. The control group received usual care, education, and follow-up. Change

in HbA<sub>1c</sub> value was the comparative outcome measure. The intervention group had a decrease in HbA<sub>1c</sub> of 1.7% ( $p = .001$ ), while the control group demonstrated only a 0.6% decrease in HbA<sub>1c</sub>. In addition, patients in the intervention group were more than twice as likely to report greater well being than patients in the control group ( $p = .02$ ). This particular finding was encouraging because decline in well-being has been cited by some experts as a barrier to insulin therapy.

A third study by Benjamin, Schneider, and Hinchey (1999) also employed a stepped-approach algorithm for medication regimen intensification. The study's design was a prospective controlled trial that used *firm systems*, which are separate but parallel, clinical group practices that share no patients and no providers. Firm systems are ideally suited to capture the impact of a disease management program. Researchers used these parallel practices as study and control groups for comparison of glycemic outcomes in diabetic patients. The intervention group ( $n = 67$ ) utilized a piloted practice guideline that intensified a patient's anti-glycemic therapy based on HbA<sub>1c</sub> levels exceeding the trigger point of 7.5%. The control group ( $n = 77$ ) received usual care. In addition, guideline adherence by physicians participating in the study was monitored by individual chart audit. There was a significant decrease in HbA<sub>1c</sub> for the intervention group at both nine and 15 months ( $p = 0.001$  and  $0.006$ , respectively). Not surprisingly, individual physician compliance with the intervention protocol was found to be variable (45% to 91%) on serial chart audits. It should be noted that although mean HbA<sub>1c</sub> improvement from baseline in the intervention group was significant, it was still well above the ADA goal of  $< 7.0\%$ .

All of the studies reviewed used experimental prospective designs with HbA<sub>1c</sub> as the clinical evaluation endpoint for efficacy of treatment. Although improvements in glycemic control were realized and were statistically significant in all studies, they were modest improvements at best. A large proportion of patients in all studies remained well above the ideal HbA<sub>1c</sub> goal set by the ADA, thus placing them at risk for serious disease sequelae (ADA, 2009).

### **Testing collaborative care-models**

While evidence-based treatment algorithms and guidelines are available to assist primary care physicians in the optimal treatment of T2DM and implementation of these has been demonstrated to improve glycemic control in diabetic patients, many primary care providers continue to rely on referrals to endocrinologists when patients require insulin therapy to manage their hyperglycemia (Peyrot et al., 2005). This is due in large part to primary care physicians' lack of training or knowledge, scheduling pressures, and inadequate resources for transitioning patients to insulin therapy (Larme & Pugh, 1998). The following two studies evaluated collaborative models of care between primary care providers and endocrinologists which have yielded some promising findings.

Phillips and colleagues (2005) conducted a controlled trial over a three-year period to examine the effects of patient-specific treatment recommendation reminders and short, retrospective bi-weekly face-to-face feedback sessions from endocrinologists on the clinical performance of resident physicians caring for type 2 diabetics in the study. No consultation services were offered by the endocrinologists regarding treatment recommendations. A structured treatment intensification algorithm consistent with ADA guidelines and recommendations was developed for residents to implement in the clinic

setting during the trial. The study took place in a large, urban academic medical center in Atlanta and involved 4,038 patients who were seen in continuity clinics for their T2DM by 345 medical residents. Residents were randomized to either the control or one of three intervention groups. The three intervention groups were: reminder system only, feedback on performance only, or a combination of both. The control group received usual care. Individual patient HbA<sub>1c</sub> values were used as the clinical endpoint for evaluation of residents' clinical performance in managing patients' diabetes care. The combined reminder system with feedback from endocrinologists was found to produce a significant reduction of HbA<sub>1c</sub> (0.6% reduction,  $p < 0.02$ ) compared with the control group and the two other intervention groups.

A somewhat different collaborative model was tested in a study by Graber and colleagues (2002). This study evaluated the effect of allocating endocrinology-directed resources for intensive educational intervention with type 1 and 2 diabetic patients referred by primary care physicians. The endocrinology-directed resources included a team of certified diabetic nurse educators and dieticians working with the department of endocrinology at an academic medical center in Nashville, Tennessee. The intervention included 12-weeks of multifaceted, intensive educational and behavioral counseling for diabetic patients with the dieticians and nurses under the direction of endocrinologists. A key feature of the intervention was frequent communication of patient progress and medication changes between the nurses and the primary care physicians in an effort to increase the primary physician's role and responsibility in management of their own patients. Efficacy of the intervention was determined by change in mean HbA<sub>1c</sub> levels from baseline with patients serving as their own controls. A total of 350 patients, 250 of

which were type 2 diabetics, completed the program. Mean HbA<sub>1c</sub> levels decreased by 1.7% ( $p = .000$ ). This finding was consistent with that of Phillips et al. (2005). Both studies demonstrated how accessibility of specialty diabetic services to primary care providers and shared management of these patients can result in improved glycemic control for patients.

### **Use of technology to improve patient outcomes**

Grant and colleagues (2006) identified two key barriers to optimal T2DM care that were considered amenable to technology-based intervention. These were (1) lack of patient engagement in their therapeutic care plans and (2) lack of medication intensification by physicians during clinical encounters with patients. The research group developed a comprehensive patient web portal that allows patients to interact directly with their electronic health record (EHR) into which their current clinical data is imported and integrated into an educational format. The educational format provides patient-tailored medical decision support and enables patients to design their individual “Diabetes Care Plan” which is visible to the patient’s clinician. The setting in which this T2DM web portal was implemented was a large urban healthcare network in Boston, Massachusetts that includes multiple hospitals, physician practices, and over one million total patients. Fourteen primary care practices within the targeted health network are currently participating in an ongoing randomized controlled trial evaluating this intervention. Results are expected soon.

### **Discussion and Conclusion**

Researchers have demonstrated that clinical inertia in primary care of type 2 diabetes is influenced by a variety of factors. Although relatively few studies of these



factors have been conducted, findings from these studies have been important. Perhaps the most important of these is the level of complexity required for treating type 2 diabetics, in addition to various other patient comorbidities, which leaves insufficient time for providers to appropriately address persistent hyperglycemia in a primary care setting. Since the majority of type 2 diabetic patients currently receive care from primary care providers, complexity may continue to hinder glycemic control unless structural changes occur in primary care settings. Concomitantly, lack of training, limited knowledge, and insufficient diabetes care resources add to perceived complexity, frustration, and resultant clinical inertia. Some researchers suggest that a paradigm shift from acute care focus to a chronic-illness care model needs to occur in primary care, so that needs of diabetes can be adequately addressed in that environment (Ziemer et al., 2005). This point is especially pertinent given the large proportion of patients who receive diabetes care and treatment from a primary care provider.

Patient adherence to medication regimens is problematic in all chronic illnesses and diabetes is no exception. However, it is incumbent upon health care providers to offer insulin therapy to diabetic patients who are not at HbA<sub>1C</sub> goal on oral therapy. The evidence suggests that poor medication adherence by patients, whether real or imagined, adversely affects a physician's tendency to intensify a patient's diabetic therapy, particularly so with initiation of insulin therapy. Research findings also suggest that physician attitudes toward insulin and misconceptions about perceived patient barriers to insulin therapy often deters them from considering insulin as an option for patients, despite its proven therapeutic efficacy as a powerful antiglycemic agent in T2DM (Grant et al., 2007).

Research findings from the studies reviewed suggest that disregard for established treatment guidelines, lack of belief in insulin efficacy, and lack of knowledge or insufficient training regarding insulin therapy are problem areas that are amenable to educational interventions, system changes, and open collaboration with experts in diabetes care (Aubert et al., 1998; Benjamin et al., 1999; de Sonnevile et al., 1997; Fleming et al., 2001; Grant et al., 2005; Nakar et al., 2007; Peyrot et al., 2005; Phillips et al., 2005). Although some of the intervention studies were small, their prospective experimental designs allowed for comparisons between usual care groups versus intervention groups, the latter of which showed improved outcomes. Whether these changes are sustainable over the long-term will still need to be evaluated through research.

Some evidence suggests that the content and extent of information shared between provider and patient is significantly associated with overall self-management success in diabetic patients (Graber et al., 2002). The manner in which the need for medication intensification, particularly insulin therapy, is communicated by the provider can strongly influence its acceptance by the patient (Barag, 2011). Further evidence indicates that when patients perceive negative attitudes from the provider towards insulin therapy, their willingness to consider it diminishes (Heisler, Bouknight, Hayward, Smith & Kerr, 2002). Patients require rationale for treatment, adequate and accessible information, and support from primary care providers to consider and embrace insulin therapy. Future research should focus not only on changing the paradigm of diabetes treatment in a primary care setting, but also on provider-initiated strategies to support

patient autonomy and encourage patient acceptance of timely initiation of insulin therapy to accomplish effective glycemic control in T2DM.

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Table 1.1 *Summary of Studies on Clinical Inertia*

Author	n	Mean Age (years)	Mean A1C	Study Type	Outcomes
de Sonnaville et al. 1997	T* = 350 C† = 68	65.3 64.6	7.4% 7.4%	Prospective cohort controlled trial	T Group: A1C decreased to 7.0% C Group: A1C increased to 7.6%
Drass et al. <sup>14</sup> 1998	370	n/a	n/a	Survey: questionnaire & Likert scale	33.3% response rate; primary care MDs w/ 24.5 yrs avg. experience; 92% felt A1C goal achievement was most important aspect of diabetic care (100%); Considered A1C goal of < 8.0% adequate (92%); Non-adherence to current regimen most common barrier to care
32 Larme & Pugh 1998	31	40.8-45.4	n/a	Survey: Likert scale and interviews	Diabetes rated as harder/more complex to treat than hypertension, angina, arthritis, hyperlipidemia; Major explanatory themes that emerged: inability to affect outcomes of disease despite intervention, complexity of care, lack of societal & healthcare system support to control diabetes
Aubert et al. 1998	T = 71 C = 67	53 54	8.8% 8.4%	RCT	T Group: A1C decreased by 1.7% which was significant comp. to control C Group: A1C decreased by 0.6%
Bernard et al. 1999	145	28	n/a	Survey & chart review	49% of residents selected correct A1C goal but chart review of their patients showed actual A1C in 51% of patients on oral meds and 47% on insulin were > 8.0%

\*T = Treatment Group; †C = Control Group

Table 1.1 *Summary of Studies on Clinical Inertia* (continued)

Author	n	Mean Age (years)	Mean A1C	Study Type	Outcomes
Benjamin et al. 1999	T = 67 C = 77	54.3 52.0	9.3% 9.21%	Prospective, controlled trial	T Group: A1C decreased to 8.42% at 9 mo. and was 8.68% at 15 mo. C Group: A1C increased to 9.41% at 9 mo. and decreased to 9.15% at 15 mo.
Graber et al. 2002	350	51	9.4	Prospective, intervention (no control)	1.7% decrease in A1C which was significant.
Peyrot et al. 2005	(RN) 1,109 (MD) 2,681	46 41	n/a	Survey & structured interview	U.S. RNs and MDs: significantly more likely to delay insulin until critical; more likely to use insulin if pt. adherent to current therapy; less likely to see insulin as efficacious
Ziemer et al. 2005	(MC) 438 (DC) 2157	63 59	8.6% 7.7%	Prospective observational	No difference in demographic variables between pts in medical clinic (MC) vs. diabetic clinic (DC); significant difference in A1C between clinics; significantly less use of insulin in MC than DC; MC pts significantly less likely to have medication regimen intensified
Grant et al. 2005	1,765 (MC) 1,175 (DC) 590	57.9 54	8.1% 7.9%	Retrospective cohort	Compared care of medical center (MC) and diabetes center (DC) pts in 30 academic centers around U.S. Results: only 34% of pts w/A1C < 7.0%; only 40.4% of pts had medication intensified if A1C > 7.0%; DC pts significantly more likely to have meds intensified

\*T = Treatment; †C = Control

Table 1.1 *Summary of Studies on Clinical Inertia* (continued)

Author	n	Mean Age (years)	Mean A1C	Study Type	Outcomes
Phillips et al. 2005	Total = 4138 T1 = 1,043 (REM) T2 = 1,049 (FB) T3 = 1,063 (FB + REM) C = 983	59	8.1%	Controlled trial	Followed pt. care of 345 medical residents: Significant decrease in A1C of pts in T3 which was FB (feedback) + REM (reminders); NS differences in demographic variables; T1 & T2 not significant
Nakar et al. 2007	Patients: T = 92 (no insulin) C = 101 (insulin) Physicians: 157	62.6 60.3 45	n/a	Case-control descriptive interviews	Illness not serious: TG (46.7%) v. CG (7%); fear of insulin addiction: TG (39%) v. CG (20.8%); hypoglycemia TG (12%) v. CG (4%)—all significant pt. barriers Physician barriers: Pt. noncompliance (92.3%), hypoglycemia (79.9%), pain w/blood tests (53.9%) and pain of injection (47.4%)
Parchman et al. 2007	177	59	>7.0% to >9.0%	Cross-sectional; direct observation	Encounters w/change in medication were longer, involved fewer pt concerns, had higher most recent A1C values; once the # of pt concerns exceeded 4, no changes in medications were made; those w/high A1C and no medication change were seen avg. of 8.6 days earlier on return visit
Grant et al. 2007	2,065	55.4	9.4%	Prospective cohort correlational	33.3% of cohort had medication intensified over 12 mo. period; Pts in highest A1C quartile significantly more likely than lowest quartile to have medication intensified; Pts w/high adherence to current regimen significantly more likely to have medication intensified

\*T = Treatment; †C = Control

Table 1.1 *Summary of Studies on Clinical Inertia* (continued)

Author	n	Mean Age (years)	Mean A1C	Study Type	Outcomes
Giangola et al. 2008	105	68	6.87%	Observational	Barriers to glucose control identified by diabetes care team in hospital setting; only 5.7% of pts had adequate glycemic control; nurses coded 398 barriers to the 202 patient interventions during hospitalization; major barriers identified: therapeutic reluctance, inappropriate prescribing & use, knowledge deficit, diabetes team not consulted in timely manner; outpatient diabetes meds not restarted after surgery

## CHAPTER THREE

### Self-Determination Theory as a Framework to Investigate Predictors of Readiness to Initiate Insulin Therapy in Type 2 Diabetes

#### **Introduction**

Diabetes is a multidimensional, complex chronic disease which is often not diagnosed until four to seven years after the onset of glycemic changes that are capable of causing damaging microvascular complications (Harris, Klein, Welborn & Knuiman, 1992). It is the insidious decline of pancreatic insulin secretion and the concomitant increase in plasma glucose levels that characterize the natural progression of type 2 diabetes mellitus (T2DM); making the disease largely asymptomatic in most individuals initially, until symptoms of macrovascular and microvascular organ damage begin to surface from continued uncontrolled hyperglycemia (Brietzke, 2007; Gerich, 2003). Meticulous and consistent control of serum glucose has been identified by diabetes researchers as the single most important intervention to prevent or delay diabetic complications (Blonde, 2004; Brietzke, 2007; Nakar, Yitzhaki, Rosenberg & Schlomo, 2007; UK Prospective Diabetes Study [UKPDS] Group, 1998).

Unfortunately, a large proportion of patients with T2DM does not achieve or maintain effective control of hyperglycemia for a variety of reasons. Prolonged poor control of serum glucose levels results in significant morbidity and poor quality of life (Alberti, 2002; Anderson, Freeland, Clouse & Lustman, 2001; UKPDS, 1998). Achieving optimal glycemic control requires patients with T2DM to fully engage in multiple life-long behavioral changes, focused primarily on lifestyle modifications and complex, daily self-management skills (monitoring symptoms, testing blood glucose levels, taking medications appropriately) from the outset of diagnosis. Due to the complexity of T2DM



management, as well as the asymptomatic nature of early disease, many patients, understandably, have substantial difficulty following the prescribed treatment regimen. This in turn exacerbates the severity of the illness and accelerates the need for treatment intensification, which often involves insulin therapy (IT), to avoid disease complications (Norris, Engelau & Narayan, 2001; Steed, Cooke & Newman, 2003). Patients are as reluctant to use insulin as health care providers are to prescribe it for T2DM (Peyrot et al., 2005). The purpose of this paper is to identify and apply an appropriate theoretical framework on which to base an investigation of predictors of readiness for persons with type 2 diabetes who require transition to IT when oral therapy fails to control hyperglycemia.

Traditional management approaches in T2DM often rely too long on conservative therapies, even in the face of continued escalation in patients' glycosylated hemoglobin (HbA<sub>1c</sub>) levels, instead of intensifying therapies earlier (Perlin & Pogach, 2006). In addition, health care providers tend to wait until multiple oral therapy combinations fail to control hyperglycemia before initiating insulin therapy despite expert recommendations to the contrary (Riddle, Rosenstock, Gerich & Insulin Glargine 4002 Study Investigators, 2003; Brietzke, 2007; Nakar et al., 2007). Many experts agree that insulin is the most powerful and effective pharmacologic tool available to treat hyperglycemia and it will eventually be necessary to effectively control blood glucose in a substantial number of patients with T2DM as beta cell failure progresses as a natural course of the disease (Cobble, 2009; Riddle, 2002).

Clinical inertia on the part of health care providers to initiate insulin therapy and reluctance or resistance on the part of patients to embrace insulin therapy as part of their treatment regimen are common reasons, well-supported in the literature, that contribute to

the underuse of insulin in the management of T2DM (Grant et al., 2007; Peyrot et al., 2005). Perhaps one of the most problematic contributors to provider clinical inertia identified during investigations of this phenomenon are the negative attitudes held by diabetes practitioners regarding their perceptions of patients' nonadherence to self-care practices. A study by Drass and colleagues (1998) surveyed 370 primary care providers who managed diabetic care found that time and expense, complexity of diabetes care, and lack of clear care guidelines to be barriers to effective care. In addition, providers rated patients' nonadherence to treatment as the most frustrating and problematic barrier to glycemic control. A subsequent prospective cohort study of 2,065 patients with type 2 diabetes by Grant, Buse and Miegs (2005) highlights the important relationship linking patient behavior (adherence) and physician action (intensifying diabetes therapy). Researchers in this study found that patients in the highest baseline medication adherence quartile had 64% greater odds of having their therapy intensified (including initiation of insulin therapy) relative to rising HbA<sub>1c</sub> than compared to those patients in the lowest quartile. Perceived poor adherence patterns may therefore doom some patients to inadequate management of their hyperglycemia due to their provider's negative attitudes and frustration toward misunderstood behaviors related to self-care regulation in these patients.

### **Compliance, Adherence, and Self Care in Type 2 Diabetes**

The concept of treatment compliance, or adherence, emerged from a health care paradigm representing a time when the majority of illnesses and diseases were acute in nature (Anderson & Funnell, 2000). This paradigm promulgates the notion that health care providers must assume the primary responsibility for ensuring that their patients engage in the prescribed treatments. In addition, this view presupposes that the health

care provider controls a patient's self-management decisions and engagement in optimal diabetes self-care activities.

Anderson and Funnell (2005) argue that under this acute-care paradigm, patients who fail to perform to a provider's expectations are labeled as noncompliant or nonadherent, which eventually leads to the development of dysfunctional and corrosive relationships between providers and patients to the disservice of both parties. They contend that a more effective and appropriate paradigm for diabetes care embraces a model that positions the patient at the center and in control of managing his or her disease, while the health care provider is positioned in the supportive roles of collaborator, facilitator, and educator.

Leading experts in diabetes care believe that patients with diabetes are fully responsible for the course and outcomes of their illness, because the most important choices affecting the health and well-being of the person with diabetes are made by those with the disease, not their health care provider or diabetes educator (American Diabetes Association [ADA], 2003; Anderson & Funnell, 2000; Funnell & Anderson, 2004; Steed et al., 2003; Weinger, 2007). Eliminating the concepts of compliance and adherence from the new paradigm of diabetes care involves incorporating a truly collaborative model between health care providers and their patients that maximizes patient autonomy. This will mean abandoning assumptions of power, control, judgment, and blame on the part of the health care provider, while instead empowering patients to choose and experiment with self-care interventions in deciding what works best for them in managing their diabetes in everyday life (Anderson et al., 2009; Anderson & Funnell, 2000; Barlow, Wright, Sheasby, Turner & Haisnworth, 2002).

In order to understand autonomous, agent-initiated self-care behavior in this new paradigm of diabetes care, an appropriate theoretical framework on which to base behavioral management strategies and treatment interventions for T2DM will need to be identified. A review of the literature was performed to investigate behavioral theories and frameworks that have been proposed in order to explain or understand diabetic patients' engagement in self-care behaviors, particularly with regard to insulin therapy.

### **Understanding Self-Care Behaviors in Type 2 Diabetes:**

#### **A Review of the Literature**

A variety of factors account for individual variations in self-care behaviors of people with chronic diseases. Early studies of health-related behaviors identified certain demographic variables associated with performing healthy behaviors including age, gender, race, socioeconomic status (SES), social support, and education (Conner & Norman, 2005; Harvey & Lawson, 2008). Consistently, it has been demonstrated in studies that those individuals who are white, wealthier, have more education, fewer stressors, and greater social support are significantly more likely to engage in healthy behaviors than those who are older, poorer, less educated, and non-white. While it is important to identify these individual behavioral risk factors, they are largely unchangeable and therefore not amenable to modification through clinical or behavioral interventions.

Various health belief theories emerged as behavioral scientists began to realize the importance of subjective psychological processes that affected health-promoting behaviors as well as illness-related behaviors (Becker & Maiman, 1975; Conner & Norman, 2005; Leventhal & Cameron, 1987). Since the mid-seventies, behavioral studies have focused extensively on social psychology, more specifically on social cognition

models, in which an emphasis is placed on understanding human self-regulatory processes and mechanisms by which social cognitive processes influence peoples' health behaviors (Conner & Norman, 2005). Self-regulation processes have been defined as "mental and behavioral processes by which people enact their self-conceptions, revise their behavior, or alter the environment so as to bring about outcomes in it in line with self-perceptions and personal goals" (Fiske & Taylor, 1991, p. 181).

Conceptual framing for many of the health behavior models and theories reviewed are very similar and their constructs are deeply intertwined (Conner & Norman, 2005; Rothman, 2000). Their relevance to the state of the science in relation to understanding initiation and maintenance of T2DM self-care behaviors will be reviewed.

### **The Health Belief Model**

The Health Belief Model (HBM) is one of the first and most widely used of the social cognition models (SCM) (Rosenstock, Strecher & Becker, 1988). Some social psychologists contend that the HBM is more of a loose association of variables than an actual formal model to predict health behavior (Conner, 1993; Rothman, 2000). The two major tenets related to individuals' representations of health proposed by the HBM are: (1) perceptions of illness threat and (2) evaluation of methods to counteract this threat (Conner & Norman, 2005). Perceptions of illness threat are influenced by domains of perceived susceptibility to the illness and perceived severity of the consequences of that illness, while evaluation methods to counteract threat involve consideration of the cost-versus-benefit of and barriers to taking action to reduce or extinguish the perceived threat. Together, these two precepts are believed to determine the likelihood of a person engaging in healthy behaviors mediated, of course, by demographic factors, individual personality traits, and social pressure (Rosenstock et al., 1988). Motivation and cues to

action also serve as mediators for health behaviors in this model although some experts observe that these two constructs have been relatively ignored in most health behavior studies until recently (Abraham & Sheeran, 2005).

The ability of the HBM to explain the variance in diabetes regimen adherence and glycemic control in type 2 diabetes has been inconsistent and disappointing (Harvey & Lawson, 2009). A study by Wooldridge et al. (1992) tested the major domains of the HBM and its relationship to diabetes self-care adherence and metabolic control using measures designed by other researchers based on major concepts of the HBM (Givens, Givens, Gallin & Condon, 1983; Wallston, Wallston & DeVellis, 1978). Researchers in the study by Wooldridge et al. (1992) observed no relationship between health beliefs and adherence, health beliefs and HbA<sub>1c</sub> levels, or adherence and HbA<sub>1c</sub> levels. Very small increases in perceived severity of diabetes scores and perceived benefits of treatment scores following a diabetes educational program were seen in study participants, but these accounted for little variance in measured diabetes outcomes.

Some diabetes experts have questioned the applicability of the HBM to the complex, multidimensional nature of T2DM for a number of reasons. First, due to the asymptomatic nature of early disease for many years (perhaps a decade or longer following diagnosis), in addition to the apparent lack of appropriate threat communication by health care providers regarding the seriousness of the illness, persons with T2DM may have a perceived misunderstanding that their diabetes is not serious (Perlin & Pogatch, 2006; Peyrot et al., 2005). Absence of perceived threat may translate into a lack of perceived benefits regarding necessary lifestyle changes, self-care practices, and treatment intensification to maintain glycemic control until an individual's diabetes is more advanced and overtly symptomatic (Dietrich, 1996). Studies examining the

relationship between high perceived threat in diabetes (seriousness of disease and vulnerability to its effects) have been associated with low self-care compliance and metabolic control (Bond, Aiken & Somerville, 1992; Brownless-Duffeck et al., 1987; Lawson, Bundy, Lyne & Harvey, 2004).

Second, there is a surprising, pervasive lack of belief in the efficacy of insulin among health care providers managing the care of patients with T2DM, and a commensurate failure to communicate to patients the important role of insulin in controlling hyperglycemia when oral medications do not (Peyrot et al., 2005; Ziemer et al., 2005). This phenomenon is prevalent across multiple countries and various health care settings (Nakar et al., 2007; Peyrot et al., 2005). It is therefore not surprising that studies based on the HBM, which purport to measure patients' health beliefs surrounding perceived efficacy of insulin to treat their illness, fail to demonstrate significant findings (Brietzke, 2007; Wallace & Matthews, 2000).

Third, emotional responses to T2DM, which are substantial, may influence or mediate some important domains of the HBM, such as perceived severity and cues to action, resulting in better regimen adherence in some patients or complete denial in others (Weinger, 2007). However, the HBM does not clearly address emotional response to illness threat and subsequent behavior (Conner & Norman, 2005; Harvey & Lawson, 2009). Depression and diabetes distress have been identified as two potent mediators of effective self-care management and glycemic control, and as such, must be considered in any theoretical framework underpinning studies that identify predictors for effective self-care engagement, including readiness to initiate insulin therapy (Ciechanowski, Katon, Russo & Hirsch, 2003; Lin et al., 2004; Polonksy et al., 2005).

## **Theory of Planned Behavior**

The Theory of Planned Behavior (TPB), an extension of the Theory of Reasoned Action (TRA), contends that proximal determinants of behavior are: (1) intention to engage in the behavior and (2) perceived control over the behavior (Ajzen, 1991; 2002).

Intentions represent a person's motivations in their conscious decision to engage in a specified behavior and the degree of effort they are willing to put forth to do so.

Perceived behavioral control is the person's assessment of whether he or she is capable of performing the behavior and is most closely associated with Bandura's (1977; 1982) construct of self-efficacy described in his Social Cognitive Theory (SCT). Difficulty of the behavior, as proposed by the TPB, is not dichotomous, but rather best conceptualized as a continuum of progressively more difficult behaviors to execute, according to Ajzen (2002). Behavioral intention is determined by attitudes toward the behavior (an overall evaluation of the behavior by the subject), subjective norms (what the subject feels significant others, spouse, health care provider thinks he or she should do), and perceived behavioral control (how easy or difficult a behavior is to execute).

Effective self-care in T2DM requires the person to perform a series of complicated skills, daily self-monitoring activities, and complex behavioral changes (Anderson & Funnell, 2000; Weinger, 2007; Whittemore, 2000). The TPB has not been used extensively in studies of diabetes in general, and T2DM specifically, for predicting intention to perform self-care behaviors (Conner & Norman, 2005; Harvey & Lawson, 2009). However, a small study of 64 type 1 diabetics demonstrated that a TPB-based model was able to predict 57% of the variance in subjects maintaining self-monitoring of their blood glucose (Shankar, Conner & Bodansky, 2007). Monitoring of blood glucose is a relatively easy maintenance behavior to execute and the sample was very small.



Therefore, findings from the study must be interpreted cautiously. An earlier study of type 1 diabetics, also using the TPB, revealed that positive attitude was the strongest predictor of self-care, and that knowledge and low orientation to powerful others mediated positive attitude (de Weerd, Visser, Kok & van der Veen, 1990).

Critics of the TPB assert that behavioral intention does not always translate into action, which may be influenced by multiple factors, as is the case in T2DM (Harvey & Lawson, 2009). Another criticism of this theoretical approach is that there is no distinction between decisions regarding initiation of a behavior and subsequently maintaining that behavior over time, which is paramount in diabetes self-management, particularly in relation to insulin therapy (Rothman, 2000). Some suggest that a person's prior behavior may be a better predictor of continued action, rather than current attitude or intentions regarding the behavior (Deci, Egharari, Patrick & Leone, 1994). Finally, the influence of social norms on persons with T2DM has been found in some cases to have the opposite effect on behavior than the TPB purports. In a study by Broom and Whittaker (2004), type 2 diabetics developed unhealthy defensive strategies in response to the intense scrutiny and criticism of their significant others and health care providers, rather than adopting proactive self-care behaviors.

### **Social Cognitive Theory**

Bandura's (1977; 1982) Social Cognitive Theory (SCT) is arguably the most prominent theoretical framework used in studies related to self-care in T2DM. This approach theorizes that human motivation and action are based on three contingencies and that there is an implied causal ordering of these contingencies. The first contingency is known as situation-outcome expectancy, which represents personal beliefs about susceptibility to health threats. The second is action-outcome expectancy, which

represents an evaluation of whether a behavior will or will not lead to a particular desired outcome. The third is self-efficacy contingency, which represents the belief that a behavior or action is or is not under the individual's control. It is the latter of these three constructs, self-efficacy (SE), which has served as a conceptual framework for multiple behavioral intervention studies related to diabetes self-care.

According to Bandura (1977), the concept of perceived SE holds a pivotal role in the causal structure of SCT. Self-efficacy beliefs influence whether people act in ways that are self-enhancing or self-hindering. It is belief in one's SE that determines what challenges individuals will undertake, how much effort they will put forth, and how long they will persevere in accomplishing those challenges. Bandura (2001) also emphasizes that SE beliefs directly guide and shape the course one's life takes by influencing the types of activities and environments in which he or she chooses to engage, such as health behaviors. Once engaged in health-enhancing behaviors, the social influences and environment must be conducive to reinforcing and promoting competencies, values, and interests of the individual (Kirchbaum, Aarestad & Buethe, 2003).

Researchers have extensively investigated the phenomenon of diabetes self-efficacy (DSE) in conjunction with a closely-related construct known as empowerment, in order to devise strategies to strengthen perceived DSE in persons with T2DM; the ultimate goal being improved diabetes self-care competence and by extension, improved diabetes outcomes (Anderson et al., 1995; Anderson & Funnell, 2000; Anderson, Funnell, Fitzgerald & Marrero, 2000; Anderson et al., 2009; Cherrington, Wallston & Rothman, 2010; Wallston, Rothman & Cherrington, 2007). Empowerment is the concept of "helping patients discover and develop the inherent capacity to be responsible for one's life" (Funnell & Anderson, 2004, p. 124). Empowerment insinuates collaboration

between healthcare providers and patients, while creating an autonomy-supportive environment in the clinical setting (Williams, Freedman & Deci, 1998).

Results of the various studies reviewed, exploring the theoretical application of SE and empowerment, have strongly supported the construct of SE as an integral underpinning for understanding diabetes self-care behavioral initiation and maintenance. Anderson and colleagues' (2009) two-year research trial that involved implementation of a diabetes empowerment intervention demonstrated significant increases in participants' diabetes quality of life, perceived DSE, perceived understanding of their disease, and satisfaction with their diabetes care than those not receiving the intervention. Most importantly, subjects in the empowerment intervention had significantly improved glycemic control of their diabetes over this two-year period.

As a central construct of SCT, perceived SE plays an important role in an individual's ability to carry out the necessary daily self-care behaviors related to T2DM is well-supported in various studies, but it does not explicate the determinants of behavioral motivation in type 2 diabetics who exhibit high self-care competency versus those who exhibit low competency. Why are some patients empowered through interventions, while others are not? Many psychologists argue that psychological needs play an important role in motivation and patient outcomes (Anderson, Chen & Carter, 2000; Williams et al., 2009).

### **Self-Determination Theory**

Self-efficacy and empowerment are corresponding constructs of an approach to human motivation and personality known as Self-Determination Theory (SDT) (Ryan & Deci, 2000). The major premise of SDT posits that humans are motivated toward physical and psychological health. Self-motivation and personality integration are driven

by three basic needs, all of which are impacted by social factors: competence (synonymous to self-efficacy), relatedness (needs satisfaction and congruence with self), and autonomy (similar to empowerment). According to this theory, motivations are either autonomous (intrinsic) or controlled (extrinsic). Intrinsic motivation produces greater positive consequences and is associated with engagement in behaviors that are of the most interest to an individual. Behaviors emanating from autonomous motivation are more likely to yield long-term persistence of those behaviors (Vallerand, 2001; Williams, Rodin, Ryan, Grolnick & Deci, 1998).

Motivation, whether intrinsic or extrinsic, is theorized to take place within the individual at three hierarchical levels: global, contextual, and situational (Ryan & Deci, 2000; Vallerand, 2001). Global motivation is conceptualized as an individual's overall personality orientation toward intrinsic or extrinsic motivation. Contextual motivation refers to domain-specific orientations such as education, interpersonal relationships, or inner needs. Finally, situational motivation is primarily a "state" motivation, such as living with a chronic disease, for example. An autonomy-supportive environment, whether originating from family, friends, or healthcare providers, fosters intrinsic motivation. Intrinsic motivation is also referred to as autonomous self-regulation, wherein the individual experiences a sense of volition in performing the behavior for the inherent satisfaction of the activity itself (Deci, Eghrari, Patrick & Leone, 1994; Williams et al., 1998). Conversely, those whose behavior is perceived to be controlled externally or by some interpersonal force (spouses, friends, or health care professionals) feel pressured to perform a behavior in order to satisfy an external demand or some conditional reward without really valuing the goal or behavior; also known as controlled self-regulation.

Extrinsic motivation, which may be the predominant motivation orientation in self-care behaviors of persons with chronic illness, does not preclude adoption of certain identified regulations into the individual's long-term behavioral repertoire. Integrated regulation, the most autonomous form of extrinsic motivation, is a process by which the individual internalizes identified goals or regulations and assimilates them to the self, typically in stages over time (Ryan & Deci, 2000). This process may result in a person adopting a behavior if that behavior is perceived to have related importance to them and if it can be brought into congruence, or synthesis, with the individual's goals and values.

Behavioral regulations may be internalized at any point in time, but are theorized to be heavily influenced by prior experiences, knowledge, and current situational factors (Deci et al., 1994). Ryan and Deci (2000) also assert that the range of internalized behaviors or goals that an individual assimilates over time increases as a function of his or her perceived competence in being able to perform an identified behavior and whether that behavior has goal relatedness: meaning the behaviors are either valued by the individual or they are valued by one's significant others or peer group. In fact, some research has shown that reciprocal peer support among type 2 diabetics can significantly increase rates of insulin initiation or intensification of insulin therapy; suggesting that an individual's concerns about insulin are most effectively addressed by other individuals coping personally with insulin management (Heisler, Vijan, Makki & Piette, 2010).

Research that has applied SDT as a framework has thus far yielded some convincing evidence for supporting its use as a framework in future studies targeting modifiable factors to improve self-care in T2DM and glycemic control. A previous study by Heisler and colleagues (2003) demonstrated that the stronger the individual's belief in the efficacy of their prescribed treatments and the more autonomy-supportive the clinical

environment was perceived to be, the stronger the concordance between the provider's and patient's goals. In addition, the study showed that greater agreement between patient and provider goals led to significant increases in the patient's perceived diabetes competence and reported autonomous self management. Another study found that patients who rated their diabetes care providers as affording them a high autonomy-supportive environment had significant increases in autonomous motivation and perceived diabetes self-care competence (Williams, McGregor, Zeldman, Freedman & Deci, 2004). Subjects in that study who exhibited high autonomous motivation and high perceived competence also manifested significantly lower HbA<sub>1c</sub> levels. Patients' HbA<sub>1c</sub> levels have been shown to correspond to more effective diabetes self-care practices (ADA, 2003). A later study by Williams and his colleagues (2009) applied the SDT model of health behavior to predict medication adherence, quality of life, and glycemic control in a sample of type 2 diabetic adults. All three outcomes were positively associated with a perceived autonomy-supportive environment and perceived competence for diabetes self-management.

### **Self-Determination Theory and Readiness to Initiate Insulin Therapy**

After review and evaluation of theoretical frameworks that have been used to study self-care behaviors in T2DM, it appears that SDT may provide the most appropriate framework for exploring factors that predict readiness to initiate insulin therapy when oral therapy has failed to control hyperglycemia in T2DM. This framework incorporates constructs that address critical factors influencing decisions to initiate new self-care behaviors, as well as maintain those behaviors over time, in persons with T2DM. Self-care competency, autonomous self-care agency, and autonomy-supportive collaboration with one's health care provider are all modifiable factors within a paradigm of diabetes

care that enhances volitional integration of self-care regulation in patients, rather than focusing solely on the products of medical care, such as adherence and compliance, which are dehumanizing and counterproductive in changing behavior (Anderson & Funnell, 2000, 2005).

A conceptual model has been developed to illustrate the relationship of the study variables of interest to the major constructs of SDT and it is depicted in Figure 3.1. The overarching goal of research using this model is to identify modifiable variables that may predict increased readiness to initiate insulin therapy when hyperglycemia is no longer controlled by oral anti-diabetic agents in T2DM. According to SDT, autonomy support encourages persons' autonomous self-regulation and perceived competence for engagement in diabetes self-care behaviors. In testing major constructs of SDT through biobehavioral research, the adoption of insulin therapy in individuals with T2DM unresponsive to oral therapy is the self-care regulation of interest and readiness of individuals to initiate insulin therapy is the outcome variable. Several measures have been developed and used to test major constructs of SDT, but have yet to be studied with respect to the proposed outcome variable: readiness to initiate insulin therapy.

### **Perceived Autonomy Support**

Although initiation of insulin therapy may be a high-priority goal of the provider, the priority of insulin therapy as an internalized goal of the patient must also be determined. Heisler and her colleagues (2003) demonstrated that diabetic patients who reported sharing greater responsibility with their health care provider in making treatment decisions were significantly more likely to be in agreement with the provider's priority goals for treatment. Therefore measuring patients' perceptions of the degree to which their health care provider provides an autonomy-supportive environment will be

important in determining its predictive value in patients' readiness to initiate insulin therapy.

The Health Care Climate Questionnaire (HCCQ) is a psychometric tool that was developed to evaluate the patient's perceptions of the degree to which their health care provider is autonomy supportive (Heisler et al., 2003; Williams, Freedman, et al., 1998; Williams et al., 1998; Williams et al., 2009). The HCCQ has been shown to be a valid and reliable ( $\alpha = 0.80$  to  $0.96$ ) measure of perceived autonomy support. Subjects rate their response to each of the 15 questions using a 7-point Likert scale (1 = "strongly disagree" to 7 = "strongly agree"). Scores range from 15 to 105 with higher scores indicating more equally-shared decision making between the patient and health care provider, provider trust, and perceived respect from the provider.

### **Perceived Behavior Competence**

Patients' perceived competence in being able to perform a behavior is an essential theoretical construct of SDT because it facilitates an individual's goal attainment and provides him or her with a sense of need satisfaction from engaging in an activity at which they feel effective. Perceived competence has been well-supported in multiple studies as an important predictor of agent-driven behaviors related to diabetes self-care success (Anderson et al., 1995; Anderson et al., 2000; Heisler et al., 2003; Kirchbaum et al., 2003; Norris et al., 2001; Williams et al., 2009).

Diabetes self-care management is complex and demanding for any patient. Beginning insulin therapy and adopting the increased self-monitoring, surveillance, and planning that is required in order to avoid adverse effects, especially early in the course of therapy, requires self-perceived efficacy in those behaviors and skills (Rosenstock & Riddle, 2004; van der Ven et al., 2003). Measuring subjects' perceived overall



competence for diabetes management will be necessary in order to evaluate whether this variable is a predictor for readiness to start insulin therapy in T2DM. It would be logical to reason that if overall diabetes competency is low, then readiness to begin a more complex behavior, such as insulin therapy, would also be low.

The Perceived Competence in Diabetes Scale (PCDS) is a psychometric instrument which was developed to evaluate the patient's perceptions of his or her confidence in performing diabetes self-care. The PCDS is a four-item scale that has been shown in various studies to be a valid and reliable ( $\alpha = 0.80$  to  $0.88$ ) measure of this construct (Heisler et al., 2003; Williams et al., 1998; Williams et al., 2009). Subjects rate their confidence in performing diabetes self-care using a 7-point Likert scale for each question (1 = "not at all true" to 7 = "very true"). Scores range from four to 28, with higher scores indicating greater perceived confidence.

### **Autonomous Versus Controlled Regulation of Behavior**

The degree to which a person's motivation for health behaviors is autonomous is another major construct of SDT. Goals of diabetes treatment, or self-regulations, must be internalized and assimilated to the self in order for the person to experience maximum autonomy in diabetes self-management. For behavioral integration and volitional persistence of a particular self-regulation, for example using insulin therapy, it must be synthesized within the individual's behavioral repertoire (Deci & Ryan, 2000). Synthesis is more likely to occur if the individual perceives insulin as personally important, the behavior of using insulin is consciously valued, and there is a perception of insulin therapy being congruent with the situational context of his or her illness (Deci et al., 1994). Therefore motivation orientation of type 2 diabetic patients must be assessed in order to determine its influence on subjects' readiness to start insulin.

The Treatment Self-Regulation Questionnaire (TSRQ) was developed to measure the motivation orientation of individuals. The TRSQ has demonstrated both validity and reliability ( $\alpha = .90$ ) in measuring aspects of autonomous versus controlled regulation of behavior in studies with type 2 diabetic patients (Williams et al., 1998; Williams et al., 2009). It contains 19 statements in which subjects rate their agreement with each using a 7-point Likert scale (1 = “not at all true” to 7 = “very true”). The TSRQ is comprised of two subscales: the autonomous regulation subscale that measures intrinsic motivation orientation and the controlled regulation subscale that measures extrinsic motivation orientation. In order to determine an individual’s dominant motivation orientation, a relative autonomy index (RAI) score is derived by subtracting the average autonomous subscale score from the average controlled subscale scale score (Williams et al., 1998). Higher RAI scores indicate a greater autonomous motivation orientation.

### **Beliefs and Attitudes Associated with Insulin Therapy**

Snoek and colleagues developed the Insulin Treatment Appraisal Scale (ITAS) to measure beliefs and attitudes associated with insulin therapy in diabetic patients (Snoek, Skovland & Pouwer, 2007). This instrument has been useful for identifying negative feelings and misconceptions that diabetic patients have regarding insulin therapy (Snoek et al.; Makine et al., 2009). The ITAS has been shown to be a valid and reliable ( $\alpha = .82$  to  $.90$ ) measure of patients’ beliefs and attitudes related to insulin therapy (Makine et al., 2009; Snoek et al.). It is appropriate to use with patients contemplating insulin therapy initiation as well as those who are currently using insulin therapy.

The ITAS contains 20 statements regarding common beliefs and attitudes related to insulin therapy in which subject’s rate their agreement with each statement using a 5-point Likert scale (1 = “strongly disagree” to 5 = “strongly agree”). Four of these

statements are positively-worded and reverse-scored before totaling and 16 are negatively-worded. Lower total scores on the ITAS indicate more positive or favorable attitudes and beliefs regarding insulin therapy.

### **Enhancing Readiness to Initiate Insulin Therapy**

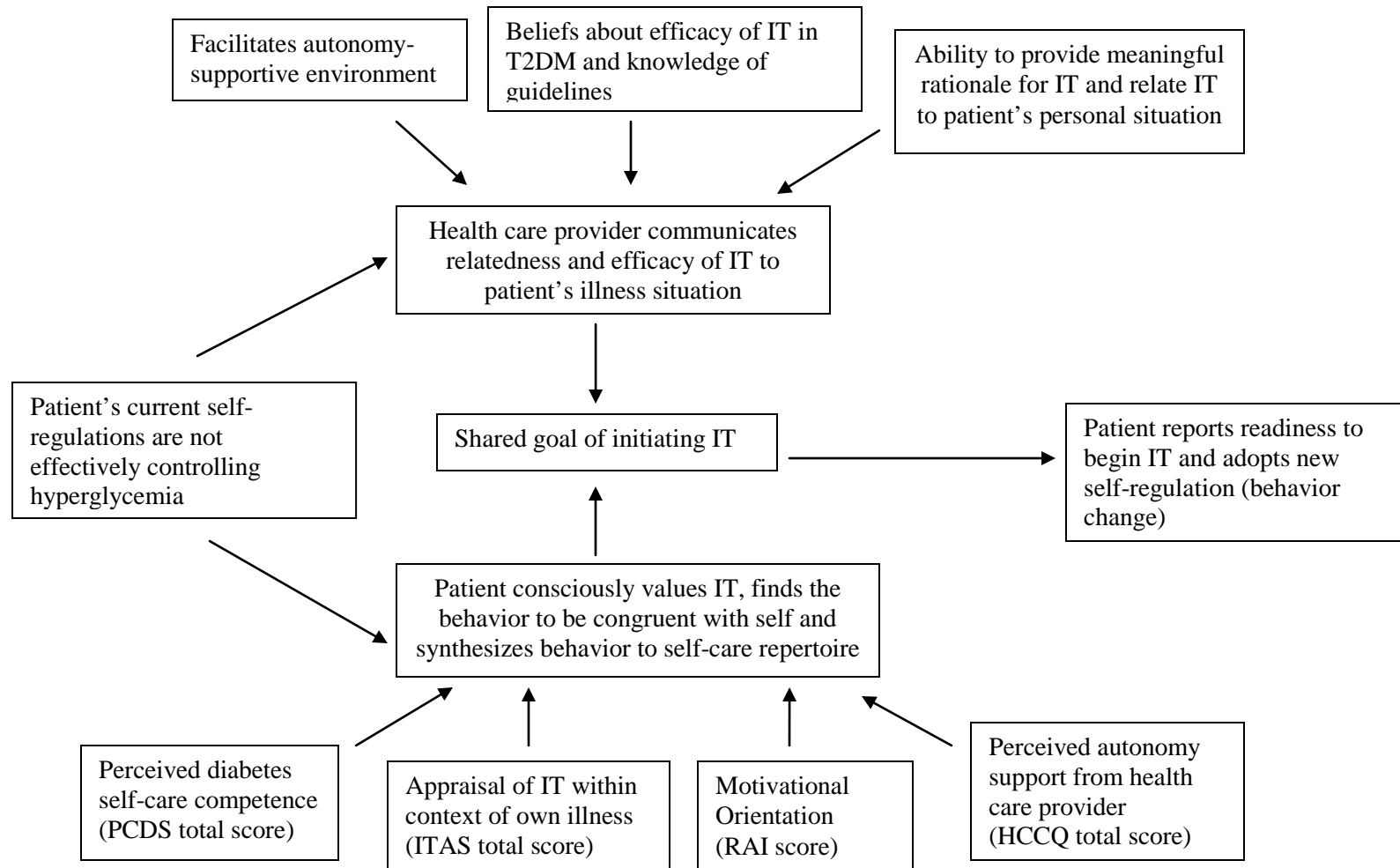
Motivation toward authentic self-regulation is a complex construct influenced by many individual variables and contextual factors (Ryan & Deci, 2000). It is important to understand conditions or circumstances that may potentially encourage rather than discourage intrinsic motivation of type 2 diabetics in a therapeutic clinical setting. It has been shown that support of authentic, autonomous self-regulation produces the committed self-care behaviors that health care providers desire for their patients (Ryan & Deci; Williams et al., 1998; Williams et al., 2009). Building competence in an autonomy-supportive care environment is essential for facilitating intrinsic self-regulation in patients with chronic illnesses who are required to perform numerous, complicated, and often unpleasant self-care behaviors (Anderson & Funnell, 2000; Williams et al., 2005).

Discussions between providers and their patients regarding initiation of insulin therapy are heavily value-laden (Hunt, Valenzuela & Pugh, 1997; Peyrot et al., 2005). Perceived insinuations of failure in managing one's diabetes and worsening disease are not uncommon among patients with T2DM. Consequently it is important to understand the effects of psychosocial contexts, patient-provider relationships, motivational orientation, and attitudes towards insulin on a diabetic patient's readiness to begin insulin therapy when it becomes necessary to do so for effective control of hyperglycemia. Self-determination theory appears to address these myriad influences on a patient's decision to adopt insulin therapy and persevere with the self-care behavior required.

## Conclusion

In conclusion, SDT provides a promising theoretical framework for investigating factors that may predict readiness of patients with T2DM to initiate insulin therapy when their current self-regulations are not effectively controlling their hyperglycemia. Because the decision to begin insulin therapy is difficult for most patients, especially those diabetic patients who currently “feel fine” yet have chronic poor glycemic control, identification of modifiable influencing factors that can make this transition smoother is necessary. Through better understanding of psychosocial factors, individual needs, and personal motivations related to adoption of insulin therapy in persons with T2DM, health care providers may find their discussions with patients to be easier to initiate much earlier in the course of their disease.

Figure 3.1. Conceptual model linking constructs of Self-Determination Theory to main study variables.



## CHAPTER FOUR

### Predictors of Readiness to Initiate Insulin Therapy in Patients with Type 2 Diabetes

#### When Oral Medications Fail to Control Hyperglycemia

**OBJECTIVE:** The objective of this study was to use Self-Determination Theory (SDT) as a framework for identifying modifiable predictors of readiness to initiate insulin therapy when oral medications fail to control hyperglycemia in patients with type 2 diabetes (T2DM). Specifically, the aim was to determine if perceived autonomy-support, perceived diabetes competence, motivational orientation, and appraisal of insulin therapy were predictors of readiness to initiate insulin therapy in persons with T2DM when oral therapy fails to control hyperglycemia.

**DESIGN:** Descriptive correlational study using cross-sectional data collection methods.

**SETTING:** Adult medical clinics of large urban primary healthcare facilities in Southwest Ohio and Northern Kentucky.

**PARTICIPANTS:** Adult patients ( $n = 73$ ) with T2DM using only oral antidiabetic medications for their diabetes.

**METHODS:** Data for demographic characteristics, pertinent clinical information, exposure to insulin therapy, psychometric measures of perceived autonomy-support (HCCQ), perceived diabetes competence (PCDS), motivational orientation (TSRQ), and appraisal of insulin therapy (ITAS), and readiness to initiate insulin therapy were collected on each person.

**RESULTS:** Bivariate logistic regression revealed two significant predictors of readiness: (1) participants who had a friend or family member using insulin therapy were 5.5 times more likely to rate their readiness to initiate insulin as high compared to those who had

neither and (2) for each unit increase in ITAS score participants were 8.4 % more likely to rate their readiness as low.

**CONCLUSION:** Exposure to friends or family using insulin and negative appraisal of insulin therapy are significant predictors of readiness to initiate insulin for patients with T2DM.

**KEY WORDS:** Self-Determination Theory; insulin readiness; autonomy-support; type 2 diabetes

## Introduction

Type 2 diabetes mellitus (T2DM) has become a public health crisis, not only in the U.S., but also worldwide. Nearly 26 million people in the U.S. alone are affected by diabetes, 90% to 95% of which is T2DM (National Diabetes Information Clearinghouse [NDIC], 2010). The burden of diabetes also presents a crisis in terms of health care costs, both direct and indirect. Direct medical expenditures were estimated to be \$116 billion in 2007 while indirect costs from disability, work loss, and premature death were an additional \$58 billion (NDIC). Future costs have been projected to escalate exponentially. By 2034, diabetes costs are expected to reach an estimated \$336 billion in direct healthcare expenditures (Huang, Basu, O'Grady & Capretta, 2009).

Diabetes increases risk of stroke and death from heart disease to rates two to four times those of nondiabetics (NDIC, 2011). Diabetes is also the leading cause of new cases of blindness, kidney disease, and nontraumatic lower limb amputations (NDIC). This morbidity is associated with double the risk for depression in this population (Anderson, Freedland, Clouse & Lustman, 2001). Experts suggest that clinicians should discard the notion that diabetes is simply a disease of hyperglycemia, and instead regard and treat diabetes as a more global vascular disease that includes treatment interventions that address abnormal glucose levels, dyslipidemia, inflammatory endothelial dysfunction, and accelerated atherosclerosis (Mirza, 2007). Clinicians must also understand and communicate clearly to patients that T2DM is a progressive disease. Informing patients at the time of diagnosis, that even in the face of optimal glycemic management in the initial phase of treatment,  $\beta$ -cell function and physiologic insulin response will continue to erode over time to the point at which exogenous insulin



administration will be necessary in many cases (Barag, 2011; Harris, Kapor, Lank, Willan & Houston, 2010).

Clinical knowledge, published treatment guidelines, and the therapeutic arsenal for controlling T2DM are extensive (Cefalu, Richards & Menendez-Ramirez, 2009; Mirza, 2007). Despite these achievements, poor control of hyperglycemia remains a significant problem in the medical management of T2DM largely due to the underuse or inappropriately delayed use of insulin (Peyrot et al., 2005). Both reluctance of patients to use insulin and healthcare-provider clinical inertia in initiating insulin therapy, have been identified as major underlying components of this problem (Harris et al.; Kunt & Snoek, 2009; Reach, 2008). Even clinicians who intend to prescribe insulin for their patients with type 2 diabetes struggle to determine when patients are ready to consider it. The objective of this study was to use Self-Determination Theory as a framework to identify modifiable predictors of readiness to initiate insulin therapy when oral medications fail to control hyperglycemia in patients with T2DM. Specifically, the aim was to determine if perceived autonomy-support, perceived diabetes competence, motivational orientation, and appraisal of insulin therapy predicted readiness to initiate insulin therapy in persons with T2DM when oral therapy fails to control hyperglycemia.

### **Clinical Inertia, Non-adherence, and Type 2 Diabetes Care**

Clinical inertia on the part of health care providers to initiate insulin therapy and reluctance or resistance on the part of patients to embrace insulin therapy as part of their treatment regimen are common reasons that contribute to the underuse of insulin in the management of T2DM (Grant et al., 2007; Harris et al., 2010; Peyrot et al., 2005; Ziemer et al., 2005). Perhaps one of the most problematic factors contributing to clinical inertia of health care providers identified during investigations of this phenomenon are the

negative attitudes held by diabetes practitioners regarding their perceptions of patients' nonadherence to self-care practices. A study by Drass and colleagues (1998) surveyed 370 primary care providers who managed diabetic care and found that time and expense, complexity of diabetes care, and lack of clear care guidelines were barriers to effective care. In addition, providers rated patients' nonadherence to treatment as the most frustrating and problematic barrier to glycemic control.

A subsequent prospective cohort study of 2,065 patients with type 2 diabetes by Grant, Buse and Miegs (2005) highlights the important relationship linking patient behavior (adherence) and physician action (intensifying diabetes therapy). Researchers in this study found that patients in the highest baseline medication adherence quartile had 53% greater odds of having their therapy intensified (including initiation of insulin therapy) relative to rising A1C than compared to those patients in the lowest quartile. Perceived poor adherence patterns may therefore doom some patients to inadequate management of their hyperglycemia due to their provider's negative attitudes and frustration toward misunderstood behaviors related to self-care regulation in these patients.

Adherence to medication regimens is problematic in all patients with chronic illnesses and diabetes is no exception. Diabetic patients require rationale for intensification of treatment therapies, adequate time to discuss their diabetes regimen and changes with their healthcare provider, shared decision-making opportunities and ongoing support from primary care providers in order to foster effective self-care practices in this population of patients, particularly with regard to adoption of insulin therapy (Anderson & Funnell, 2000). It is therefore important to identify factors that may

increase patients' willingness and readiness to initiate insulin therapy when conservative treatment regimens fail to adequately control their T2DM.

### **Theoretical Framework**

#### **Self-Determination Theory, Diabetes Self-Care, and Insulin Therapy**

The concept of treatment compliance, or adherence, emerged from a health care paradigm representing a time when the majority of illnesses and diseases were acute in nature (Anderson & Funnell, 2000). This paradigm promulgates the notion that health care providers must assume the primary responsibility for ensuring that their patients engage in the prescribed treatments. In addition, this view presupposes that the health care provider controls a patient's self-management decisions and engagement in optimal diabetes self-care activities. Anderson and Funnell (2005) argue that under this acute-care paradigm, patients who fail to perform to the provider's expectations are labeled as noncompliant or nonadherent, which eventually leads to the development of dysfunctional and corrosive relationships between providers and patients.

Leading experts in diabetes care believe that patients with diabetes are fully responsible for the course and outcomes of their illness, because the most important choices affecting the health and well-being of the person with diabetes are made by those with the disease, not their health care provider or diabetes educator (Anderson & Funnell, 2000; Funnell & Anderson, 2004; Steed, Cooke & Newman, 2003; Weinger, 2007). Eliminating the concepts of compliance and adherence, which undermine the patient-provider relationship, from diabetes care involves incorporating a truly collaborative model between health care providers and their patients that maximizes patient autonomy. This will mean abandoning assumptions of power, control, judgment, and blame on the part of the health care provider, while instead empowering patients to choose and

experiment with self-care interventions in deciding what works best for them in managing their diabetes in everyday life (Anderson et al., 2009; Anderson & Funnell, 2000; Barlow, Wright, Sheasby, Turner & Hainsworth, 2002). In fact, patients' perceived competence has been well-supported as an important predictor of agent-driven behaviors related to diabetes self-care success in multiple studies (Anderson et al., 2009; Anderson, Funnell, Fitzgerald & Marrero, 2000; Kirchbaum, Aarestad & Buethe, 2003; Norris, Engelau, Naryan, 2001; Williams et al., 2009).

Self-efficacy and empowerment are parallel constructs of a behavioral approach to human motivation and personality known as Self-Determination Theory (SDT) (Ryan & Deci, 2000). The major premise of SDT posits that humans are motivated toward physical and psychological health. Self-motivation and personality integration are driven by three basic needs, all of which are impacted by social factors: competence (similar to self-efficacy), relatedness (needs satisfaction and congruence with self), and autonomy (similar to empowerment). According to SDT, motivations are either autonomous (intrinsic) or controlled (extrinsic). Intrinsic motivation produces the most positive behavioral outcomes because they are generally of the most interest to the individual. Behaviors emanating from autonomous motivation (self-agency) are more likely to yield long-term persistence of those behaviors (Vallerand, 2001; Williams, Rodin, Ryan, Golnick & Deci, 1998).

Prior studies based on SDT have demonstrated that the stronger the individual's belief in the efficacy of their prescribed treatments and the more autonomy-supportive the clinical environment was perceived to be, the stronger the agreement between provider's and patient's shared goals (Heisler et al., 2003). Likewise, greater agreement between patient and provider goals led to significant increases in the patient's perceived diabetes

competence and reported autonomous self-management. Another study found that patients who rated their providers as providing a high autonomy-supportive environment had significant increases in autonomous motivation and perceived diabetes self-care competence (Williams, McGregor, Zeldman, Freedman & Deci, 2004). Subjects that exhibited high autonomous motivation and high perceived competence also manifested significantly lower A1C levels, which have been shown to correspond to more effective diabetes self-care practices. A later study by Williams et al. (2009) applied the SDT model of health behavior to predict medication adherence, quality of life, and glycemic control in a sample of type 2 diabetic adults. All three outcomes were positively associated with a perceived autonomy-supportive environment and perceived competence for diabetes self-management.

Because prior studies based on a SDT framework have not focused specifically on insulin initiation, a study that explores the influence of competence, relatedness, and motivational orientation on a type 2 diabetic person's perceived readiness to begin insulin therapy when oral therapy fails is necessary if the model of diabetes care is to change and glycemic control is to be achieved. In addition to testing major constructs of SDT, determining the contribution of attitudes and beliefs regarding insulin therapy in relation to these constructs will also be important as prior studies have found patients' appraisal of insulin to play a significant role in their willingness to adopt insulin therapy and believe in its efficacy as a treatment for T2DM (Makine et al., 2007).

## **Methods**

### **Design**

The study used a descriptive correlational design via cross-sectional data collection. Data for this study were collected using a questionnaire format. Purposive

sampling of type 2 diabetic patients currently using oral medications to control their diabetes was used.

### **Sample and Setting**

A total of 73 study participants were recruited from primary care offices and ambulatory outpatient clinical facilities in Southwest Ohio and Northern Kentucky. Primary care sites were targeted specifically because insulin initiation and management for T2DM is becoming increasingly more frequent in primary care and it is in this setting that clinical inertia has been demonstrated to be most problematic (Hayes, Fitzgerald & Jacober, 2008; Kunt & Snoek, 2009; Hsu, 2009). Participants were recruited primarily from the adult medical clinics in an urban primary care health facility with two locations in Southwest Ohio ( $n = 65$ ). The medical director and his physician colleagues agreed to participate fully in the study and allowed access to their patients scheduled each day in clinic. This institution has been designated as a federally qualified health center (FQHC) and its patients are predominantly African American. A few participants were also recruited from an internal medicine practice located in an outpatient facility in Northern Kentucky ( $n = 8$ ). The sample size was based on a power analysis to ensure sufficient power for the study ( $\alpha = .05$ ,  $p = .05$ , one-tail). Patients were recruited between June 2011 and October 2011.

### **Inclusion and Exclusion Criteria**

Patients were eligible to participate in the study if they: (1) were  $\geq 18$  years old, (2) were able to speak and read English, (3) had a diagnosis of type 2 diabetes made by a physician or nurse practitioner using American Diabetes Association (ADA) criteria (Gerich, 2004), and (4) were currently being treated with oral antiglycemic agents.

Patients were excluded if they: (1) were  $< 18$  years old, (2) were pregnant, (3) had

cognitive impairment, (4) unable to speak or read English, or (5) were currently using insulin in addition to oral agents.

## **Measurements**

### **Perceived Competence in Diabetes Scale**

Participants rated perceived competence in providing self-care for their diabetes using the Perceived Competence in Diabetes Scale (PCDS). They responded to each of the four statements by rating their agreement on a 7-point scale that range from 1 “not at all true” to 7 “very true”. Scores can range from four to 28. Higher scores indicate greater perceived competence in diabetes self-care (Williams, Freedman & Deci, 1998).

### **Health Care Climate Questionnaire**

Participants were asked to respond to 15 statements regarding various aspects of their interactions with, trust in, and shared decision-making with the healthcare provider treating them for their diabetes. The Health Care Climate Questionnaire (HCCQ) was developed to capture the degree of perceived autonomy in patient-provider decision-making process regarding the clinical management of chronic illnesses. Participants rated their agreement with each of the statements on a 7-point scale that range from 1 “strongly disagree” to 7 “strongly agree”. Scores can range from 15 to 105. Higher scores indicate a greater autonomy-supportive environment (Williams, Freedman & Deci, 1998; Williams et al., 1998).

### **Treatment Self-Regulation Questionnaire**

Participants were asked to respond to 19 statements representing motivations for performing different aspects of diabetes self-care. The Treatment Self-Regulation Questionnaire (TSRQ) contains two subscales: autonomous regulation scale (8 questions) and controlled regulation scale (11 questions). Participants rated their agreement with

each of the 19 statements using a 7-point scale that ranged from 1 “not true at all” to 7 “very true”. Subscale scores were then averaged. A relative autonomy index (RAI) score was derived for each participant by subtracting their controlled regulation subscale average from the autonomous regulation subscale average. Higher RAI scores indicate greater autonomous motivational orientation (Williams, Freedman & Deci, 1998; Williams et al., 1998).

### **Insulin Treatment Appraisal Scale**

Participants were asked to respond to 20 statements representing beliefs and attitudes about insulin. The Insulin Therapy Appraisal Scale (ITAS) was developed to capture the T2DM patient's current appraisal of insulin therapy and assesses both positive and negative attitudes (Snoek, Skovlund & Pouwer, 2007). Participants were asked to indicate on a 5-point Likert scale to what extent he or she agrees with each statement, from 1 “strongly disagree” to 5 “strongly agree”. The four positive statements are reversed-scored before totaling. Scores can range from 20 to 100. Lower scores represent more positive attitudes and beliefs about insulin therapy. This scale has been shown to be a valid measure in patients contemplating insulin therapy as well those currently using insulin therapy (Hermanns, Mahr, Kulzer, Skovlund & Haak, 2010; Larkin et al., 2008; Makine et al., 2007).

### **Readiness to initiate insulin therapy**

In order to measure the outcome variable, readiness to initiate insulin therapy, participants were asked to consider a situation in which their blood glucose was not being effectively controlled with oral antidiabetic agents and that insulin was considered by their health care provider to be an alternative medication that would effectively bring their blood glucose levels under better control. They were then asked to rate how soon



they would be ready to initiate insulin therapy. Choices ranged from 0 (representing immediate readiness) to 12 months (representing indeterminate readiness). This variable was dichotomized into the following categories of readiness for purposes of analysis: high readiness ( $\leq 3$  months) was represented by choices 0, 1, and 3 months and low readiness ( $\geq 6$  months), represented by choices 6, 9, and 12 months on the questionnaire.

### **Measurement of other variables of interest**

Demographic and clinical data were collected to fully describe and characterize the subjects, as well as account for possible confounders. Demographic variables included age, race, gender, whether or not the participant lived alone or with someone, education, income level, and type of insurance. Clinical variables included number of oral diabetes medications currently being taken, duration of diabetes, length of time with current diabetes provider, and the two most recent serum glycosylated hemoglobin (HbA<sub>1c</sub>) values. The HbA<sub>1c</sub> value serves as an indicator of an individual's glycemic control in the 90 to 120 days preceding the lab draw (ADA, 2009). Clinicians use HbA<sub>1c</sub> to estimate a patient's average serum glucose during that time period.

Because a patient's attitudes and beliefs about insulin therapy may be influenced by prior exposure to insulin, such as someone they know uses insulin, they have injected insulin for someone else, or they have discussed insulin with their provider, four additional questions of interest were included on the questionnaire (Kunt & Snoek, 2009). These questions asked participants to indicate if (1) his or her primary care provider (PCP) had discussed the eventuality of insulin therapy to treat his or her T2DM at the time of diagnosis, (2) his or her PCP had ever discussed using insulin at any time during treatment for T2DM, (3) whether or not a family member had been diagnosed with T2DM, and (4) whether anyone they knew (friend or family member) used insulin to treat

his or her T2DM. These questions were coded as either being affirmative (1) or negative (0).

### **Procedures**

Permission for conduct of the study was obtained from the University of Kentucky's Institutional Review Board (UKIRB). Once UKIRB permission was granted, permission to recruit participants and conduct the study in the adult medical clinics of the HealthCare Connection (HCC) was obtained from the institution's medical director and chief executive officer. Concurrent IRB permission was sought from St. Elizabeth Medical Center (SEMC) for a secondary collection site in Northern Kentucky. Permission was eventually obtained but various difficulties arose during the process that resulted in significantly fewer patients being recruited from this site.

All patients with T2DM who attended the adult medical clinics of the HCC were given a flyer explaining the study and were invited by the medical assistant checking them in or by the physician during their visit to participate in the study that day. Interested patients were directed to an exam room located on the premises in which the investigator was located. Once eligibility for the study was determined, informed consent and permission for release of medical information were obtained by the primary investigator from participants. The investigator remained available to answer participants' questions. Questionnaires were checked for completeness prior to participants leaving the study site at which time they received a ten-dollar gift card as compensation for their time and participation in the study. The two most recent HbA<sub>1c</sub> values and type of insurance were extracted from the patient's chart and recorded on the front page of the questionnaire. The same procedure was followed at the SEMC site with

the exception that an institutional employee was required to extract the necessary medical information from the chart.

### **Data Management and Analyses**

Because logistic regression analysis was used, no assumptions of normal distribution, linearity, or equal variances regarding the distributions of predictor variables were considered. However, as in all types of multiple regression, logistic regression is sensitive to high correlations among predictor variables, therefore continuous independent variables were assessed for multicollinearity (Mertler & Vannatta, 2005). Tolerance for all these variables exceeded 0.1 indicating that multicollinearity was not a problem. In addition, data were examined to determine whether or not to collapse some categories of variables in which too few cases existed before analysis. Based on this examination, income was collapsed into two categories: less than \$30,000/year and  $\geq$  \$30,000/year. Only four cases in the highest income category ( $>$  \$60,000/year) were represented. Number of medications was collapsed into three categories: one, two, and three or more medications. Finally, race of participants was collapsed into two categories: African American and Caucasian, the latter of which included the single Latino participant. Complete sample characteristics were presented as either means ( $\pm$  SD) or frequencies and percentages appropriate to the level of measurement used.

Bivariate logistic regression was performed using the forward likelihood ratio (LR) method to determine which independent variables were predictors of readiness to initiate insulin therapy. The LR method of variable selection was used as it is one of the most common, yet conservative, methods of entering variables into the regression model (Mertler & Vannatta, 2005). All categorical variables were dummy-coded before entry into the regression analysis. Independent variables were entered in three blocks. Block

one contained the demographic variables (age, gender, race, income level, education, and whether or not the participant lived with someone) and clinical variables (duration of diabetes, number of oral antidiabetic medications, length of time with current diabetes provider, and average serum glucose). Block two contained the insulin exposure variables that included whether or not insulin was discussed as a potential therapy at diagnosis, insulin was ever discussed as a therapy during treatment, the patient had a family member with T2DM, or they knew a friend or family member using insulin. Block three contained the psychometric measurement variables of specific interest: PCDS total score, HCCQ total score, ITAS total score, and RAI score. The forward LR selection method of variable entry into the model designated a significance level of  $\leq .05$  as the cut-off value for entry of variables into the model.

## **Results**

### **Characteristics of Sample**

Seventy-three participants with T2DM were included in this study, the majority of which were African American (71%) and female (70%). Their mean age was approximately  $57 \pm 11.9$  (range 22 to 81) with the majority being 50 years of age or older. Just over half of those participating in the study cohabited with someone. Average education level was  $11 (\pm 2)$  years. Seventy-seven percent of participants earned less than \$30,000 per year. Descriptions of the sample's demographic characteristics can be found in Table 4.1.

More than half of participants (56%) had publicly-funded health insurance. Most of those participating were taking one oral antidiabetic medication (59%). The mean duration of diabetes was  $6.5 \pm 5.8$  years (range 0.5 to 25). The mean value of average serum glucose for the sample during the preceding six months was nearly 203 mg/dl  $\pm$

65.3 mg/dl (range 104 to 441) which translates to a mean HbA<sub>1c</sub> value of approximately 8.7%. The ADA (2009) recommends that patients maintain a HbA<sub>1c</sub> goal of < 7% to prevent serious disease sequelae from hyperglycemia. The mean number of years participants had been with the same diabetes care provider was  $5.3 \pm 5.6$  (range 0.5 to 21). The majority (69.9%) of participants had been with their diabetes care provider for five years or less. Clinical characteristics of the sample are described in Table 4.2.

The number of participants who had discussed insulin as a potential therapy for their T2DM at diagnosis, had ever discussed it as therapy for their T2DM, and had a friend or family member who used insulin were almost evenly split with those who had not. Two-thirds of respondents (68.5%) had a family member with T2DM. Statistics describing insulin exposure may also be found in Table 4.2.

Nearly 58% of participants ( $n = 42$ ) rated their readiness to initiate insulin therapy as immediate. Overall 70% of the sample rated their readiness to initiate insulin therapy as high ( $n = 51$ ).

### **Psychometric Measurement Results**

The mean total score for the PCDS was  $23.6 \pm 5.2$  (range 4 to 28) which was very close to the maximum possible score for the scale. Similarly, the mean HCCQ total score was  $96.9 \pm 10.5$  (range 39 to 105), also very close to the maximum possible score for that scale. More variance was seen in mean scores for the ITAS and RAI. The mean total score for the ITAS was  $57.5 \pm 11.7$  (range 27 to 83). The mean RAI score for the sample was  $-2.3 \pm 20.1$  (range -88 to 72). These results are described in Table 4.3.

### **Logistic Regression Results**

Forward logistic regression using the forward LR method was conducted in three blocks to determine which IVs were predictors of readiness to initiate insulin therapy.

Data screening revealed no extreme outliers. Demographic (age, gender, race, education, income, and lives with status) variables and clinical variables (duration of diabetes, length of time with MD, number of antidiabetic meds, and average serum glucose) were entered in block one. Regression results in this block indicated that one predictor, average serum glucose, was the only significant predictor that was statistically reliable in distinguishing between high and low readiness groups (-2 Log Likelihood = 84.132, Goodness-of-Fit = 5.165;  $\chi^2(1) = 5.223, p = .022$ ). This model correctly classified 75.3% of the cases, but only accounted for 9.8% of the variance in the dependent variable.

Questions relating to insulin exposure were added in block two. These questions included whether or not insulin therapy was discussed at diagnosis as a potential therapy to treat T2DM, insulin therapy was ever discussed during treatment, the participant had a family member with diabetes, and the participant had a friend or family member who used insulin therapy. Regression results in this block indicated that the model fit of five variables (average serum glucose, insulin discussed at diagnosis, insulin ever discussed, family member with diabetes, and having a friend or family member using insulin) was statistically reliable in distinguishing between high and low readiness to begin insulin therapy (-2 Log Likelihood = 76.899, Goodness-of-Fit = 3.996;  $\chi^2(5) = 12.456, p = .029$ ). This model correctly classified only 69.9% of cases, but accounted for 22.2% of the variance in the dependent variable (readiness).

In the final block, after accounting for all other covariates and confounding variables, the predictor variables of specific interest (PCDS total score, HCCQ total score, ITAS total score, and RAI score) were regressed on the dependent variable. The resulting overall model of six variables (average serum glucose, insulin discussed at diagnosis, insulin ever discussed, family member with diabetes, friend or family member

using insulin, and ITAS total score) was statistically reliable in distinguishing between high and low readiness to begin insulin therapy (-2 Log Likelihood = 69.060, Goodness-of-Fit = 4.118;  $\chi^2(6) = 20.295$ ,  $p = .002$ ). This model correctly classified 79.5% of cases and accounted for 34.4% of the variance in the dependent variable. Results of the final bivariate logistic regression model are described in table 4.4.

Findings revealed that participants were 5.5 times more likely to rate readiness to initiate insulin therapy as high if they had a friend or family member who used insulin for his or her T2DM ( $p = .020$ ) compared to those who had neither. In addition, for every unit increase in ITAS total score, participants were 8.4% more likely to rate their readiness to initiate insulin therapy as low ( $p = .012$ ).

### Discussion

The objective of this study was to use Self-Determination Theory as a framework for identifying modifiable predictors of readiness to initiate insulin therapy when oral medications fail to control hyperglycemia in patients with T2DM. Specifically, the aim was to determine if perceived autonomy-support (HCCQ\_total), perceived diabetes competence (PCDS\_total), motivation orientation (RAI\_score), and appraisal of insulin therapy (ITAS\_total) were predictors of readiness to initiate insulin therapy in persons with T2DM when oral therapy fails to control hyperglycemia.

In this investigation ITAS total score was the only significant modifiable predictor of insulin readiness, although the odds ratio for this predictor was fairly small. This finding supported previous research that has shown the ITAS to be a valid and reliable measure of insulin beliefs and attitudes in patients with T2DM that affect patients' perceptions of barriers to insulin use (Hermanns, et al., 2010; Makine et al., 2009; Snoek et al., 2007).

Results of the study also showed that participants who had a friend or family member were more than five times as likely to rate their readiness to initiate insulin therapy as high, but this variable is not considered a modifiable predictor of insulin readiness. Exposure to insulin therapy in this way may represent a subjective norm for those participants, suggesting that insulin therapy is an eventuality in the treatment of one's T2DM. Further investigation of the mechanism through which this variable exerts its effect on readiness to initiate insulin is warranted. The remaining three insulin exposure questions remained in the final regression model but were not significant predictors of insulin readiness.

PCDS total scores were not found to predict readiness to initiate insulin therapy. The mean PCDS score for the study sample was very high. High scores would suggest that participants held high levels of competence in performing their diabetes self-care, which should correspondingly translate to lower average serum glucose levels which has been demonstrated in previous studies (Kirchbaum et al., 2003; Williams et al., 1998, 2004, 2009), but was not supported in this study. Mean HbA<sub>1c</sub> for this sample was substantially higher than the ADA (2009) recommendations for target HbA<sub>1c</sub> goal.

Mean HCCQ score for the study sample suggests that most participants perceived an autonomy-supportive environment during visits with their diabetes care provider. Despite this finding, perceived autonomy support did not predict readiness to initiate insulin therapy as it had predicted engagement in diabetes self-care practices and glycemic control in earlier studies (Williams et al., 1998, 2004, 2009). The HCCQ not only evaluates dimensions of shared decision-making, patient satisfaction, and the diabetes provider's respect of the patient and his or her opinions regarding treatment decisions, but also evaluates the patient's trust in their provider. The high mean HCCQ



score in this sample was an unexpected finding given the high proportion of African American participants in this study combined with the knowledge that all of the diabetes care providers were Caucasian. Previous studies have found that African American patients regularly report fewer participatory visits with physicians, fewer transparent signs of respect, less trust, and less satisfaction with their care when racial discordance exists between patient and healthcare provider (Cooper-Patrick, Gallo, Gonzales, Vu, Powe et al., 1999; Doescher, Saver, Franks & Fiscella, 2000; LaVeist & Nuru-Jeter, 2002).

RAI mean score computed by subtracting the average controlled regulation subscale scores from the average autonomous regulation subscale scores of the TSRQ in the sample yielded a negative number, indicating a tendency among participants to have a comparatively greater extrinsic motivation orientation. Mean RAI score did not predict readiness to initiate insulin therapy as it had predicted diabetes self-care practices and glycemic control in earlier studies (Williams, Freedman & Deci, 1998; Williams et al., 1998).

One's initial impression may be that the study's results did not support the use of SDT as a framework for identifying predictors of readiness to initiate insulin therapy in T2DM, but it would be premature to discard this theory on the findings of a single study. A deeper analysis of the study's data provides evidence to support the use of SDT as a framework in future studies. The HCCQ scores from the study reflect a prevailing autonomy-supportive clinical environment in which the study participants receive their diabetes care, which may explain the large number of patients who rated their readiness to begin insulin therapy as high. Autonomy-support has been identified as a critical component of SDT that promotes increased competence in performing a behavior as well

as increasing patients' feelings of relatedness to a behavior (Ryan & Deci, 2000; Heisler et al., 2007; Williams et al., 2004). Likewise, the ceiling effect seen in mean PCDS score for the study sample may also have been influenced by the preponderance of autonomy-support participants perceived from their providers in the clinical setting in which the study took place (Heisler et al.; Williams et al., 2004).

Although PCDS scores did not exhibit an inverse relationship to average serum glucose levels in the sample as expected, this finding does not necessarily insinuate that patients in the study lacked diabetes self-care competence. An alternative explanation might be that patients in the sample were indeed competent in performing the treatments prescribed by their physicians; but the treatments their physicians prescribed were inappropriate given the severity of their T2DM. In support of this argument, the majority of study participants rated their readiness to initiate insulin therapy as high ( $\leq 3$  months) and nearly 60% were ready to do so immediately. Further analysis of a subgroup of 31 patients in the sample who were both taking a single oral medication for their T2DM and who rated their readiness to begin insulin therapy as immediate (0 months) comprised 43% of the total study sample; despite documented HbA<sub>1c</sub> values in the records of these 31 patients confirming the presence of persistent hyperglycemia during the preceding six months (mean serum glucose = 170mg/dl  $\pm$  38). This study's findings confirmed previously reported problems of clinical inertia among diabetes care providers in primary care settings (Parchman, Pugh, Romero & Bowers, 2007; Peyrot et al., 2005; Ziemer et al., 2005). Testing SDT with more demographically diverse populations of patients and larger samples may support the theory's usefulness for predicting readiness to initiate insulin in T2DM.

## **Limitations**

There are a number of limitations to this study, therefore results should be interpreted with caution. First, even though a large number of participants expressed readiness to initiate insulin therapy immediately or within three months, a person's expressed intention to adopt a behavior and actually doing so may not correlate well with one another, especially when the behavior requires a series of complicated steps, such as using insulin (Harvey & Lawson, 2009). The cross-sectional design employed in this study does not allow for evaluation of actual versus planned insulin therapy adoption by subjects. A prospective design that follows patients from expressed intent to start insulin therapy and forward would be better suited to analyze this relationship. Second, the sample in this study was predominantly older, female, poorer, and African American, so findings may not be generalizable to populations of patients who do not share these characteristics. A larger and more demographically diverse sample may have yielded a significantly different final regression model. Third, although the psychometric instruments (PCDS, HCCQ, and TSRQ) used in this study have been demonstrated to be valid and reliable measures of the major constructs of SDT in previous studies, they have not been extensively tested in patients with T2DM regarding self-care practices, particularly with regard to insulin therapy. Further testing in this population of patients is necessary to determine their usefulness in explaining and predicting self-care behaviors in T2DM.

## **Implications for Practice and Future Research**

The significant influence of friends' and family members' use of insulin had on participant's perceived readiness to initiate insulin therapy can be used by clinicians to identify patients who may be targeted for early adoption of insulin. Simply asking the

question at the time of diagnosis would identify these patients. A related finding from previous research showed that reciprocal peer support among type 2 diabetics significantly increased rates of insulin initiation or intensification of insulin therapy; suggesting that an individual's concerns about insulin are most effectively addressed by other individuals coping personally with insulin management (Heisler, Vijan, Makki & Piette, 2010). Further understanding of the mechanism behind the influence of friends and family on readiness to initiate insulin may guide diabetes clinicians and researchers in designing prospective randomized trials that evaluate interventions which capitalize on this influence.

This study confirmed that diabetes treatment intensification is not occurring despite the presence of documented chronic hyperglycemia, even though HbA<sub>1c</sub> goals and therapy intensification guidelines are readily available to clinicians (Nathan et al., 2006). A large majority of participants in this study indicated high levels of readiness to initiate insulin therapy but only about half of them recalled having a conversation about insulin with their doctor. Discussions of insulin's role in the treatment of T2DM must occur with patients at the time of diagnosis and continue throughout the course of treatment. Research investigating diabetes care models that reduce or eliminate clinical inertia are still needed.

Finally, more research testing SDT as a framework for understanding diabetes self-care practices, especially insulin therapy, will be needed in the future. This study was unable to show that perceived autonomy support, motivation orientation, and perceived diabetes competence were significant predictors of readiness to initiate insulin therapy. This theoretical framework holds promise for testing innovative models of diabetes care that respect the self-agency of people with T2DM.

## Summary and Conclusion

This study adds to the body of literature in a number of ways. Findings support prior research that insulin beliefs and attitudes affect type 2 diabetics' perceptions regarding insulin therapy. This study provides further evidence that negative beliefs and attitudes toward insulin predict lower readiness to initiate insulin therapy. Study findings also suggest that patients who have friends or family members using insulin therapy are significantly more likely to adopt insulin therapy sooner when oral antidiabetic agents are unable to control their hyperglycemia. Further evidence that clinical inertia exists in primary care was presented by this study, even when patients indicated that they were ready to begin insulin immediately as this study's findings demonstrated. This research also supported previous study findings that insulin is often not discussed by diabetes care providers as an eventual therapy for treating T2DM at the time of diagnosis, nor is it routinely discussed at any time during treatment even though patients' HbA<sub>1c</sub> is not at goal. Finally, findings from this study provided conflicting evidence from prior research regarding racial discordance between patients and providers. Findings from this research revealed that patients trusted their diabetes care providers, felt respected by them, were satisfied with the care they received, and shared in decision-making about their treatment, despite the presence of racial discordance between patients and providers.

Substantial morbidity and mortality result from the mismanagement of T2DM in the current diabetes care model; much of it preventable with the institution of timely interventions. Given the rapidly escalating incidence and wide prevalence of T2DM, the model of care must change if there is to be hope for improving diabetes outcomes as well as the health and quality of life of the population as a whole.

Table 4.1 *Demographic Characteristics*

Variable	Mean ( $\pm$ SD)	Frequency (%)	Range
Age (years)	57.3 (11.9)		22 – 81
Education (years)	11.0 (2.1)		8 – 16
Race			
African American		52 (71)	
Caucasian		20 (27.5)	
Latino		1 (1.5)	
Gender			
Male		22 (30)	
Female		51 (70)	
Cohabitation			
Lives alone		34 (47)	
Lives with someone		39 (53)	
Income			
< \$30,000/year		56 (77)	
$\geq$ \$30,000/year < \$60,000/year		13 (18)	
> \$60,000/year		4 (5)	

Table 4.2 *Clinical Characteristics and Exposure to Insulin*

Variable	Mean ( $\pm$ SD)	Frequency (%)	Range
Average Serum glucose (mg/dl)	202.9 (65.3)		104 – 441
Duration of diabetes (years)	6.5 (5.8)		0.5 – 25
Years with current doctor	5.3 (5.6)		0.5 – 21
Number of oral diabetes medications			
One		43 (59)	
Two		20 (27.5)	
Three		9 (12)	
Four		1 (1.5)	
Insurance status			
None (self-pay)		11 (15)	
Public (Medicaid/Medicare)		41 (56)	
Private		21 (29)	
Insulin discussed w/MD at diagnosis			
Yes		35 (48)	
No		38 (52)	
Insulin ever discussed w/MD			
Yes		35 (48)	
No		38 (52)	
Family member with diabetes			
Yes		50 (68.5)	
No		23 (31.5)	
Friend or family member uses insulin			
Yes		35 (48)	
No		38 (52)	

Table 4.3 *Psychometric Measurement Scores*

Variable	Mean ( $\pm$ SD)	Minimum	Maximum	Range
Total PCDS	23.6 (5.2)	4	28	24
Total HCCQ	96.9 (10.5)	39	105	66
Total ITAS	57.3 (11.7)	56	83	56
RAI	- 2.3 (20.1)	-88	72	160



Table 4.4 *Final Logistic Regression Model*

Variable	$\beta$	Wald	df	p	OR
Avg. serum glucose	.009	3.436	1	.064	1.009
Insulin discussed at diagnosis	-.877	1.529	1	.216	.416
Insulin ever discussed	-.581	.694	1	.405	.559
Family member with T2DM	-.989	1.880	1	.170	.372
Friend/family member uses insulin	1.698	5.373	1	.020	5.461
ITAS total score	.081	6.312	1	.012	1.084
Constant	-7.541	11.346	1	.001	.001

## CHAPTER FIVE

### Discussion, Implications, and Future Research

Type 2 diabetes is a significant public health problem that has reached epidemic levels both in the U.S. and globally (National Diabetes Information Clearinghouse [NDIC], 2011; Wild, Roglic, Green, Sicree & King, 2004). Nearly 26 million Americans are diagnosed with diabetes, 90 to 95% of which are type 2 diabetes (T2DM). People with T2DM are two to four times more likely to have a stroke or die from heart disease than are people without diabetes. In addition, they are twice as likely to suffer clinical depression than someone without diabetes (NDIC). The NDIC recently estimated direct costs from T2DM are \$116 billion and indirect costs are \$58 billion annually. These costs are projected to exceed well over \$300 billion by 2034 (Huang, Basu, O'Grady & Capretta, 2009).

Published evidence-based diabetes care guidelines clearly delineate the process and outcome criteria for effectively managing diabetes care to prevent unnecessary morbidity and mortality in T2DM (American Diabetes Association [ADA], 2011). Target HbA<sub>1c</sub> level and the means by which to achieve glycemic goal have been identified and extensively communicated to clinicians through the National Diabetes Education Program (2009) targeting all health care providers who manage T2DM care. Despite a number of effective medications and clear guidelines explicating their use in the clinical management of T2DM, barely half of type 2 diabetics ever achieve recommended HbA<sub>1c</sub> goals (Cobble, 2009).

The current paradigm of diabetes care within the U.S. healthcare system has demonstrated inadequacy for achieving optimal patient outcomes in T2DM (Anderson & Funnell, 2005; Brown, Nichols & Perry, 2004; Grant, Buse & Meigs, 2005; Heisler,

Bouknight, Hayward, Smith & Kerr, 2002; Perlin & Pogach, 2006). Chronic uncontrolled hyperglycemia that results as a consequence of failure to appropriately manage patients' T2DM causes serious and debilitating sequelae that diminish patients' health-related quality of life (HRQOL) and place them at risk for premature death (NDIC, 2011).

In this dissertation, three manuscripts were presented to provide an initial understanding to the problem of T2DM and problems with its current clinical management in the U.S. The chapters of this dissertation critically reviewed the available literature regarding clinical inertia in primary healthcare providers managing T2DM, described the development of a conceptual model to explain and predict readiness of patients with T2DM to initiate insulin therapy, and reported findings from a study that investigated predictors of readiness to initiate insulin therapy in patients with T2DM when oral agents fail to control hyperglycemia using the conceptual model as a framework for this study.

In Chapter Two, the available literature regarding clinical inertia was reviewed and analyzed. Four themes emerged from the analysis to explain reasons for clinical inertia in management of T2DM in primary care: (1) competing demands in primary care, (2) lack of training and failure to follow published guidelines, (3) physician attitudes and patient noncompliance, and (4) physicians' misconceptions of patient barriers to insulin therapy.

The health care problems experienced by most diabetic patients treated in primary care place multiple competing demands on a clinician's time and attention (Parchman, Pugh, Romero & Bowers, 2007; Ziemer et al., 2005). It is unlikely that this situation will improve under the current paradigm of diabetes care (Anderson & Funnell, 2005; Reach, 2008). However, research testing novel collaborative care models described in the

integrative review show promise for improving the pressure primary care clinicians experience while improving outcomes for their diabetic patients (Graber, Elasy, Quinn, Wolff & Brown, 2002; Phillips et al., 2005). Research efforts to develop and test novel collaborative care models must continue.

Lack of sufficient training and failure to follow published diabetes guidelines is a pervasive problem in the U.S. as demonstrated by a number of previous studies (Benjamin, Schneider & Hinchey, 1999; Fleming et al., 2001; Giangola, Olahan, Longo, Goldstein & Gross, 2008; Grant, Buse & Meigs, 2005; Perlin & Pogach, 2006; Riddle, 2002). Several researchers have designed studies to evaluate various methods for integrating evidence into practice environments in a variety of settings using HbA<sub>1c</sub> as the clinical evaluation endpoint (Aubert, Herman, Waters, Moore, Sutton, et al., 1998; de Sonnaville, Bouma, Colly, Deville, Wijkel & Heine, 1997). All of the studies reported modest yet significant reduction in participants' HbA<sub>1c</sub> values ( $p = .001$  to  $.02$ ), though none of the interventions were able to bring a majority of participants' HbA<sub>1c</sub> levels to ADA goal ( $< 7\%$ ). Further methods for integrating evidence into practice will need to be developed and tested, especially prospective, longitudinal studies to evaluate effects on practices over time.

Physicians' attitudes towards patients' nonadherence to therapy, whether real or imagined, was a major reason for clinical inertia identified in the literature. (Drass et al., 1998; Grant et al., 2007; Larme & Pugh, 1998; Peyrot et al., 2005). Poor attitudes toward patient nonadherence adversely affected a physician's tendency to intensify a patient's diabetic therapy, particularly so with initiation of insulin therapy. Autonomy-supportive clinical environments that respect the self-agency of patients will need to be developed for effective engagement of patients in their care.

Finally, misconceptions on the part of physicians regarding patients' perceived barriers and fears about insulin versus actual barriers and fears identified by patients played a significant role in physicians' reluctance or failure to prescribe insulin therapy when patients' clinical disease warranted doing so (Nakar, Yitzhaki, Rosenberg & Vinker, 2007). The ITAS is a valid and reliable instrument for measuring patients' beliefs and attitudes regarding insulin therapy and it needs to be used consistently by clinicians to determine what patients' actual feelings are.

In Chapter Three, behavioral theories, namely social cognition theories, were critically analyzed to determine their appropriateness for use as an underpinning theoretical framework for investigating predictors of readiness to initiate insulin therapy in patients with T2DM. Conceptual framing for many of the health behavior models and theories reviewed were very similar and their constructs are deeply intertwined (Conner & Norman, 2005; Rothman, 2000). Models and theories considered were the Health Belief Model (Rosenstock, Strecher & Becker, 1988), the Theory of Planned Behavior (Ajzen, 1991; 2002), Social Cognitive Theory (Bandura, 1977; 1982; 2001), and Self-determination Theory (Deci & Ryan, 2000).

Although widely used in many studies attempting to understand health behaviors, the ability of the Health Belief Model (HBM) to explain the variance in diabetes regimen adherence and glycemic control in studies of type 2 diabetes were found to be inconsistent and disappointing (Harvey & Lawson, 2009). Researchers observed no relationship between health beliefs and adherence, health beliefs and HbA<sub>1c</sub> levels, or adherence and HbA<sub>1c</sub> levels (Woolridge, Wallston, Graber, Brown & Davidson, 1992). Because of the asymptomatic nature of T2DM during the first several years of the disease, the two major tenets related to individuals' representations of health proposed by

the HBM, perceptions of illness threat and evaluation of methods to counteract this threat, are typically absent until symptoms have appeared and diabetes is quite advanced (Conner & Norman, 2005). Absence of perceived threat may translate into a lack of perceived benefits regarding necessary lifestyle changes, self-care practices, and treatment intensification to maintain glycemic control until an individual's diabetes is more advanced and overtly symptomatic, making it a poor choice to predict insulin readiness (Dietrich, 1996).

The Theory of Planned Behavior (TPB), an extension of the Theory of Reasoned Action (TRA), contends that proximal determinants of behavior include intention to engage in the behavior and perception that one has control over the behavior (Ajzen, 1991; 2002). Only a single study using type 1 diabetics ( $n = 64$ ) employing a TPB-based model to predict adherence to blood glucose monitoring was found (Shankar, Conner & Bodansky, 2007). Although a substantial amount of the variance (57%) in subjects maintaining self-monitoring of their blood glucose was explained by this model, it is a relatively simple maintenance behavior compared to complexity of the behaviors and skills needed for competent use of insulin in T2DM. In addition, stated intention to act does not always result in action being taken as many clinicians know first-hand.

Social Cognitive Theory (SCT) (Bandura, 1977; 1982; 2001) was most frequently used in studies of diabetes self-care behavior. One of the theory's major constructs, self-efficacy (SE), which represents the belief that a behavior or action is or is not under the individual's control, has served as a conceptual framework for multiple behavioral intervention studies related to self-care in type 2 diabetes; termed diabetes self-efficacy (DSE) (Anderson et al., 1995; Anderson & Funnell, 2000; Anderson, Funnell, Fitzgerald & Marrero, 2000; Anderson et al., 2009; Cherrington, Wallston & Rothman, 2010;

Wallston, Rothman & Cherrington, 2007). Studies reviewed have supported DSE as an important predictor of routine diabetes self-care, but it has not been specifically tested as a predictor of readiness to initiate insulin therapy. In addition, the concept of DSE alone does not fully encompass the myriad influences and processes by which diabetes self-care practices are incorporated into one's behavioral repertoire.

The major premise of Self-Determination Theory (SDT) posits that humans are motivated toward physical and psychological health (Ryan & Deci, 2000). Although SDT and SCT share similarities, SDT appears to consider a more global approach to understanding adoption of behaviors, particularly when it has used as the theoretical framework for studying the adoption and maintenance of self-care behaviors in T2DM (Heisler et al., 2002; Williams, Freedman & Deci, 1998; Williams, McGregor, Zelman, Freedman & Deci, 2004; Williams et al., 2009; Williams, Rodin, Ryan, Grolnick & Deci, 1998). The conceptual model based on SDT presented in Chapter Three illustrates the multiple influences that impact both patients and providers as they come together to form shared goals, changing the current paradigm to reflect and value human self-agency (Heisler et al., 2002).

In Chapter Four, findings from a descriptive correlational study of predictors of readiness to initiate insulin therapy in patients with type 2 diabetes are reported. The objective of this study was to use SDT as a framework to identify modifiable predictors of readiness to initiate insulin therapy when oral medications fail to control hyperglycemia in patients with T2DM. Specifically, the aim was to determine if perceived autonomy-support, perceived diabetes competence, motivational orientation, and appraisal of insulin therapy were predictors of readiness to initiate insulin therapy in persons with T2DM when oral therapy fails to control hyperglycemia. Significant

predictors of readiness to initiate insulin therapy in patients with T2DM were attitudes and beliefs about insulin ( $p = .012$ ) measured by the Insulin Therapy Appraisal Scale (ITAS total score) and whether or not participants had a friend or family member that used insulin ( $p = .020$ ). The odds of a participant rating readiness to initiate insulin therapy as high were 5.5 times more likely if that participant had a friend or family member who used insulin for his or her T2DM compared to those who had neither. In addition, for every unit increase in ITAS total score, participants were 8.4% more likely to rate their readiness to initiate insulin therapy as low. This finding confirms results from previous studies using the ITAS as a measure of beliefs and attitudes toward insulin.

The study also found that most participants rated their readiness to initiate insulin therapy as high and nearly 60% stated they would begin insulin immediately if it would control their hyperglycemia. However, the study sample's mean HbA<sub>1c</sub> was 8.7% over the preceding six months of the study, a finding that supported previous studies' findings that appropriate intensification of diabetes therapy in the presence of documented chronic hyperglycemia is not occurring in primary care settings.

Although the autonomy-support, motivation orientation, and perceived competence were not found to be significant predictors of readiness to initiate insulin, SDT is still an appropriate theoretical framework for future study of this phenomenon within a diabetes care paradigm that respects self-agency. This is only the first study using SDT in the context of understanding what increases the readiness of type 2 diabetics to begin insulin therapy. Further study is recommended.

The current mode of diabetes management in primary care cannot continue. The human misery, healthcare costs, and disability caused by clinical inertia are unconscionable. Clinicians have effective pharmacotherapeutic tools and cutting-edge



science that have been demonstrated to be powerful in achieving the best outcomes in T2DM. Future research must target interventions that put these powerful tools into action.

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## Vita

### Pamela L. Phares

#### **Education:**

<b>Institution</b>	<b>Degree</b>	<b>Dates</b>	<b>Field of Study</b>
Northern Kentucky University Highland Heights, KY	Post-M.S.N. Nurse Practitioner	2007	Nursing (Adult)
University of Cincinnati Cincinnati, OH	Post-M.S.N. Nurse Practitioner & Midwife	2001	Nursing (Women's Health and Midwifery)
University of Cincinnati Cincinnati, OH	Post-M.S.N. Nurse Practitioner	1993	Nursing (Pediatrics)
University of Cincinnati Cincinnati, OH	M.S.N. Clinical Specialist	1991	Nursing (Medical-Surgical Oncology)
University of Cincinnati Cincinnati, OH	B.S.N.	1989	Nursing
University of Cincinnati Cincinnati, OH	B.S.	1986	Speech Pathology and Audiology
Good Samaritan Hospital School of Nursing Cincinnati, OH	Diploma of Nursing	1985	Nursing

#### **Faculty Appointments/Experience:**

<b>Dates</b>	<b>Institution and Location</b>	<b>Position</b>
2007-Present	Northern Kentucky University School of Nursing and Health Professions Highland Heights, KY	Assistant Professor
2006-2007	Thomas More College School of Nursing Crestview Hills, KY	Adjunct Clinical Faculty

2004-2008	Indiana University Family Practice Residency Program Indianapolis, IN	Adjunct Clinical Faculty
1991-1992	Good Samaritan College of Nursing Cincinnati, OH	Senior Lecturer

### **Clinical Work Experience**

06/07-12/08	The Healthcare Connection Lincoln Heights & Mount Healthy Family Practice Center Lincoln Heights, OH Nurse practitioner—family practice	
07/06-11/07	KW Care Group, PC Fishers, IN Nurse practitioner—women’s health	
01/05-08	SouthSide OB/GYN Indianapolis, IN 46237 Nurse practitioner—women’s health	
10/03-10/04	TriHealth Nurse Midwives Cincinnati, OH 45229 Staff midwife & women’s health practitioner	
03/03-12/08	Clarian Health Systems/HealthNet Indianapolis, Indiana 46202 Staff midwife & women’s health practitioner	
11/01-12/02	Trover Clinic Foundation: Clinic Division Center for Women’s Health Madisonville, Kentucky Staff midwife & pediatric nurse practitioner	
06/00-09/00	Planned Parenthood of Southwestern Ohio and Northern Kentucky, Cincinnati, Ohio Nurse practitioner—women’s health	
10/93-05/00	Pediatric Associates of Fairfield and Hamilton, Fairfield, Ohio Nurse practitioner—pediatric & adolescent	
02/92-09/93	Children’s Hospital Medical Center, Cincinnati, Ohio Pediatric Nurse Practitioner, Bone Marrow Transplant	

1990-1991	University of Cincinnati Hospital, Cincinnati, Ohio Clinical Nurse I, Supplemental Staffing, part-time
09/90-06/91	Tri-State Home Therapeutics, Inc., Cincinnati, Ohio Clinical nurse specialist—oncology
1988-1990	Children's Hospital Medical Center, Cincinnati, Ohio Clinical nurse—critical-care
1987-1988	City of Cincinnati Health Department, Cincinnati, Ohio Public Health Nurse II
1985-1986	Children's Hospital Medical Center, Cincinnati, Ohio Clinical nurse—adolescent medicine

#### **Funded Research Activities:**

1991 "Effectiveness of the Sensor Pad on Lump Detection in Simulated Breast Models". P. Phares (PI) Sigma Theta Tau International, Beta Iota Chapter. \$500.

#### **Publications:**

Boerio M.F., Brooker J., Freese L., Phares P., & Yazvec S. (2000). That itchy, scratchy rash. *Nursing Clinics of North America*, 35, 147-157.

#### **Published Abstracts:**

Phares, P. (1991). Effectiveness of the Sensor Pad on lump detection in simulated breast models. *Oncology Nursing Forum, Suppl*, 18.

#### **Presentations (refereed):**

Phares, P. (1991, May). *Effectiveness of the Sensor Pad on lump detection in simulated breast models*. Abstract presented at the Oncology Nursing Society Congress, San Antonio, TX.

#### **Presentations (invited):**

Phares, P. (2007, June). *Obtaining the pediatric history and performing an advanced pediatric assessment*. Professional presentation as part of a lecture series at the University of Cincinnati College of Nursing and City of Public Health Department collaborative educational initiative for school nurses learning to perform advanced health assessment skills. Cincinnati, OH.

#### **Professional Organizations:**

2008-Present: Southern Nursing Research Society  
2008-Present: Council for the Advancement of Nursing Science  
2007-Present: National League for Nursing  
2006-Present: American College of Nurse Practitioners  
2000-Present: Nurse Practitioners in Women's Health  
1991-Present: Ohio Association of Advanced Practice Nurses



### **Certification/Licenses**

- Certified adult nurse practitioner, American Nurses Credentialing Center (2007 to present)
- Certified nurse midwife, American Midwifery Certification Board (2001 to present)
- Certified women's health nurse practitioner, National Certification Corporation (2000 to present)
- Certified pediatric nurse practitioner, National Certification Board of Pediatric Nurse Practitioners and Nurses (1993 to present)
- Licensed Registered Nurse in Ohio, Kentucky and Indiana (all current)
- Ohio Board of Nursing, Certificate of Authority to practice as a nurse practitioner in pediatrics, women's health, and adult health (current)
- Ohio Board of Nursing, Certificate to Prescribe (current)
- DEA License to prescribe Schedule II through V controlled substances (current)

### **Educational Activities**

- Courses taught: Pharmacology; Health Care Research; Holistic Health Assessment & Lab; Nursing Care of the Child and Family; Concepts of Community & Public Health Nursing; Principles of Research for Application to Professional Nursing; Wellness Care of Infants & Children (NP); Primary Pediatric Care (NP); Primary Care of the Geriatric Patient (NP); Geriatric Pharmacology (NP); Advanced Practice Role Development (NP).
- NKU Undergraduate research pilot project member (2011)
- Graduate student clinical preceptor for pediatrics (1994 to 2008)
- Graduate student clinical preceptor for midwifery (2001 to 2008)
- Family practice resident supervision for intrapartum clinical rotations (2004 to 2008)
- Faculty advisor for undergraduate BSN students (2008 to present)
- Master's thesis committee member, Penny McLean Nowinski, MSN, 2010
- Master's thesis committee member, Emily McKenna, MSN, 2011

### **Committee Assignments/Boards**

- ABSN/BSN Program Committee (2007 to present)
- Curriculum BSN, ad hoc committee for curriculum revision (2008 to 2010)
- General Education Subcommittee, ad hoc committee to address general education core hours reduction (Fall semester, 2008)
- Admission, Progression, and Graduation Committee (ABSN/BSN)
- Program Evaluation Committee: College of Nursing (BSN/ABSN), secretary
- College of Health Professions, Chair of the Faculty Practice Policy Committee (2010 to present)
- College of Health Professions Steering Committee for Shared Governance (2011)
- Strategic Planning Committee, College of Health Professions (2010 to present) and Department of Nursing (2011)
- Northern Kentucky University Research Foundation, board member (3-year appointment—2011 to 2014)

- Northern Kentucky Nursing Research Collaborative member and judge

#### **Awards/Honors**

- Indiana University Family Practice Residency Program award for excellence in clinical teaching (2008)
- Sigma Theta Tau, Beta Iota & Rho Theta Chapters, International Honor Society of Nursing member (1990 to present)
- Phi Kappa Phi Honor Society membership (2010)
- Golden Key International Honor Society membership (2011)