IMPLEMENTING THE CHRONIC CARE MODEL TO IMPROVE DIABETES CARE IN THE COMMUNITY: TRANSLATING THEORY TO PRACTICE

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Diabetes mellitus is a prevalent, costly condition associated with substantial morbidity and mortality. It is an important public health problem as it is equally burdensome to individuals and to society, and disproportionately affects disadvantaged people and nations. Despite the number of possibilities for reducing much of this burden, the incidence of diabetes continues to grow. New approaches to how diabetes care is delivered are needed to improve care at the patient, provider, community, and health systems levels. It was therefore our objective to explore the effectiveness of implementing a multifaceted diabetes care intervention, based on the Chronic Care Model, into an underserved community, with the goal of changing the way diabetes care is delivered to improve outcomes in patients who receive their diabetes care in the primary care setting. A marked decline in HbA1c was observed in the multifaceted intervention group (-0.6%, p=0.008) but not in the other groups. The magnitude of the association remained strong after adjustment for clustering (p=0.01). The same pattern was observed for a decline in Non-HDL-c and for the proportion of participants who self-monitor blood glucose (SMBG) in the multifaceted intervention group (Non-HDL-c: -10.4 mg/dl, p=0.24; SMBG: +22.2%, p<0.0001) with statistically significant between group differences in improvement (Non-HDL-c: p=0.05; SMBG: p=0.03) after adjustment. The multifaceted intervention group also showed improvement in diabetes knowledge test scores (+6.7%, p=0.07), and empowerment scores (+2, p=0.02). Secondary analyses revealed that psychosocial and psychological factors accounted for

a greater amount of the variation in HbA1c, Non-HDLc, and blood pressure values than clinical factors, and are important in contributing to improvement. The improvements observed in HbA1c, systolic and diastolic blood pressure, and the proportion of participants who self monitor their blood glucose at 12-month follow-up were sustained at 36-month follow-up in all study groups. Additional improvements occurred in Non-HDLc levels in all study groups, and quality of well-being scores in the multifaceted intervention group, but not the other groups. These findings are important as they help to close a gap in the literature on improving the quality of care for people with diabetes through redesigning the process of diabetes care delivery.

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PREFACE

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1.0 INTRODUCTION

Diabetes is characterized by high blood glucose levels, which result from defects in insulin production, action, or both. Now the sixth leading cause of death, diabetes is a serious, costly disease that continues to rapidly increase (1). Approximately 13.2 million people in the United States have been diagnosed with diabetes of all types (2; 3). Type 1 diabetes (T1D) accounts for ~5-10% of these cases, while Type 2 diabetes (T2D) accounts for nearly 90% to 95% of all diagnosed cases (2). Additionally, there are approximately 5.2 million Americans who remain undiagnosed. The remaining 1-2% of cases develops secondary to other conditions (2; 3).

Characterized by excessive morbidity and mortality rates, diabetes represents a major public health challenge due to the enormous impact on the affected individuals, families, health care system, and on society as a whole (1). However, results from landmark clinical trials have demonstrated that diabetes related morbidity and mortality could be prevented or delayed by controlling risk factors (4-6).

The Diabetes Control and Complications Trial (DCCT) and the United Kingdom Prospective Diabetes Study (UKPDS), both, have demonstrated that reductions in diabetes complications can be achieved with tight control of blood glucose by, both, clinical (drug treatment intensification) and behavioral change (4;5). Most recently, three studies (6-8) have demonstrated the importance of behavioral change in diabetes prevention. The Da Qing trial (7), the Finnish Diabetes Prevention Study (DPS) (8), and the Diabetes Prevention Program (DPP) (6) have all demonstrated that intervention groups who underwent lifestyle modifications (intense diet and exercise regimens) had a significantly lower risk of developing diabetes compared to those who did not make lifestyle changes (6-8).

The results of these landmark studies clearly demonstrate that positive outcomes can be achieved through, both, clinical and behavioral change. However, for the full potential of these studies to be achieved, a bridge between these trials and the "real-world" must be created to allow for translation of the aforementioned findings into the community and into the health care system. Implementation of models of chronic care, which focus on a more informed, activated patient and a prepared, proactive practice team may help in this much needed transition. Translation/effectiveness research and its influence on processes and outcomes, and the sustainability of long-term implementation of findings in real-world settings, with the goals of efficiency, equity, and facilitation of optimal health and health care for as many people as possible, is critical to attempt to curtail diabetes-related morbidity and mortality (9).

Therefore, the overall focus of this thesis will be on improving health outcomes in people with diabetes who receive care in the primary care setting, through implementation of a model of care focused on provider education, patient empowerment, and enhancement of the patient-provider partnership. More specifically, this thesis will examine the effect of a diabetes education intervention for, both, patients and providers, on patient clinical (A1c, HDL, Non-HDL, and blood pressure), behavioral (self-monitoring of blood glucose), and psychological/psychosocial (quality of well-being and empowerment) outcomes at 12 months following the intervention, overall, and across three study groups. The thesis will then determine what patient characteristics, including psychological/psychosocial and clinical factors, work alone or in tandem to predict the improvements in the aforementioned outcomes at 12 months following the intervention, overall and across three study groups. Finally, the thesis will determine if the improvements observed at 12 months post-intervention were able to be sustained

at 24 months post-intervention, overall, and across three study groups; and if so, what factors contributed to the sustained improvements.

2.0 DIABETES MELLITUS

Diabetes mellitus is a clinically and genetically heterogeneous group of disorders that is characterized by abnormally high levels of glucose in the blood due to either insulin deficiency or to resistance of the body's cells to the action of insulin (10). There are two main types of diabetes. Type 1 diabetes is an autoimmune disease, which develops when the body's immune system destroys pancreatic beta cells, the only cells in the body that make insulin (2; 3). When most beta cells are destroyed, the clinical symptoms of type 1 diabetes appear. Type 2 diabetes is distinguished by the failure of the pancreas to secrete sufficient insulin, distinguishing it from Type 1 diabetes. It is characterized by chronic hyperglycemia, insulin resistance, and increased hepatic glucose output (10).

2.1 TYPE 1 DIABETES MELLITUS

2.1.1 Epidemiology

Type 1 diabetes mellitus is one of the most common, chronic childhood diseases. Occurring during childhood and adolescence, it accounts for approximately 5% to 10% of all diagnosed cases of diabetes (2). Although prevalence data is limited in the total population, it can be estimated that nearly 120,000 individuals aged 19 and under living in the United States are affected by type 1 diabetes, and that the disease affects between 300,000 and 500,000 individuals of all ages (11). Although type 1 diabetes is believed to occur predominately in youth, the disease can affect people of all ages. A study from the Second National Health and Nutrition Examination Survey (NHANES II) estimated that among all people diagnosed with diabetes between the ages of 30 and 74, approximately 7.4% had type 1 diabetes (11).

Over the past twenty years, epidemiologic research in type 1 diabetes has focused on determining the incidence of the disease. There are approximately 30,000 new cases of type 1

diabetes diagnosed annually, with peak incidence around the time of puberty (12). The incidence of type 1 diabetes in people nineteen years and younger who live in the United States is estimated at nearly 13,000 new cases annually, while approximately 17,000 cases develop in persons greater than 19 years of age each year (11).

With the rising incidence of type 1 diabetes observed in the late 1980s and early 1990s, considerable attention was given to the development of diabetes registries (11). The development of registries, using standard methodology, as in the DiaMOND study (13), a multi-national project for childhood diabetes, made it possible to comparably collect data. This project established population-based registries with a formal assessment of ascertainment of cases. Incorporated, as part of the registries is a technology known as capture-recapture. This technology determines the completeness of the registry by formally evaluating undercount, permitting adjustment to produce corrected incidence rates (11). The DiaMOND registries monitor the global incidence of type 1 diabetes, evaluate geographic and temporal variation, assess mortality, and evaluate the socioeconomic aspects of type 1 diabetes (11). These registry data demonstrate a more than a 50-fold geographic variation in the annual incidence of type 1 diabetes (11).

2.1.1.1 Geographic Variation

There is extraordinary variation in the incidence of type 1 diabetes by geographic location, race, ethnicity, gender, age, and by season of the year. The remarkable geographic variation observed in the incidence of type 1 diabetes makes it one of the largest observed for any noncommunicable disease (11). Incidence rates range from the very lowest observed in the Asian countries including Japan, China, and Korea to the very highest observed in Finland and Sardinia, Italy (12). The Native American, Cuban, and Chilean and Mexican populations also

have extremely low rates of type 1 diabetes. In most other Caucasian populations in Europe and the Americas, incidence rates are moderate. For example, the incidence is only 0.7 per 100,000 in Shanghai China, while it is 18.2 per 100,000 in Allegheny County, Pennsylvania, and 35 per 100,000 in Finland; 26-fold and 50-fold increases respectively (11). When Japan is compared to, both, the United States and the United Kingdom (17 per 100,000), there is at least a two-fold difference in incidence in the United States and the United Kingdom compared to Japan (0.8-1.1 per 100,000) (14); however nearly 40% of this variation can be explained by the heterogeneous population in the United States, compared to the very homogeneous nature of the population in Japan (11). Dorman and colleagues (15) further examined large variation in the incidence of type 1 diabetes by testing the hypothesis that the geographic differences in type 1 diabetes incidence reflect population variation in the frequency of type 1 diabetes susceptibility genes, including DQA1 and DQB1 as part of a molecular epidemiology sub-project of the WHO DiaMOND study (13). Data revealed considerable variation in the frequencies of the susceptibility genes across countries, which likely contribute to the global patterns of type 1 diabetes incidence (15).

2.1.1.2 Gender and Race/Ethnicity Variation

Along with geographic variation in the incidence of type 1 diabetes, there are clear racial/ethnic, gender, and age differences, both, nationally and internationally. When racial/ethnic differences were examined nationally, the highest incidence of type 1 diabetes was among Non-Hispanic whites and Hispanic children, followed by African American and Mexican-American children respectively (11). African Americans and Hispanics generally have lower incidence rates than Caucasians living in the same community. When examined by sex and age, incidence rates for males and females are similar, although a female preponderance has

been observed in low-risk populations, such as the Japanese (12). However, in populations where risk is high, such as Finland, an excess risk for males was observed (12). Finally, seasonal variation in the incidence of type 1 diabetes has been observed in most countries as lower rates have been reported for the late spring and early summer, coupled with higher rates in the winter for populations in, both, the northern and summer hemispheres (12).

Temporal trends in the incidence of type 1 diabetes have also been examined. A significant increase in incidence has been reported by many population-based registries in Northern and Central Europe, as well as those in Asian and Western Pacific populations (12). However, there is no evidence for changing incidence in the United States. This variation in temporal trends lends credence to the suggested epidemics of type 1 diabetes, which may also account for the overall increase in incidence (11).

2.1.2 Etiology

Evidence of a rise in incidence in certain countries, along with the suggestion of epidemics, leaves many unanswered questions with regard to the etiology of type 1 diabetes. Moreover, reasons for the geographic and ethnic differences appear to reflect differences in both genetic and environmental risk factors. Although type 1 diabetes is an autoimmune disorder, the etiology remains unclear (10). However, there is substantial evidence that both genetic and environmental factors are major determinants.

2.1.2.1 Genetics

Genetic evidence has accumulated regarding diabetes susceptibility. The most relevant genetic locus controlling type 1 diabetes susceptibility is the Major Histocompatability Complex (16). This set of genes, known as HLA, controls several aspects of immune function. Genes that confer susceptibility to T1D are located in the HLA region of chromosome 6, which contains

genes that encode class I (HLA-A, B, C), class II (HLA-DR, DQ, DP), and class III antigens, which control the immune response (17). When the class II antigens were discovered, associations between the DR locus antigens and type 1 diabetes arose, as approximately 95% of patients with type 1 diabetes had DR3 or DR4 (17). People with type 1 diabetes who have inherited DR3 develop diabetes at an older age and tend to have antibodies against pancreatic beta cells but not against insulin. In contrast, those people who have inherited DR4 tend to develop diabetes earlier in life and have an immune reaction against insulin (16). Individuals having both DR3 and DR4 are particularly susceptible to type 1 diabetes in most populations. These individuals develop type 1 diabetes at the youngest ages and have the highest levels of antibodies against insulin (16). Racial differences are apparent in the class II antigens as there are associations between DR7 and type 1 diabetes susceptibility in African Americans, DR5 in Hispanics, and DR9 in Chinese and Japanese (17). Additionally, individuals who inherit DR3 or DR4 also tend to inherit a form of the DQ gene that adds to their risk of developing diabetes.

Stronger than the association between type 1 diabetes and HLA-D3 and D4 is the association between type 1 diabetes and the DQA1 and DQB1 genes contained on the DQ locus (12; 17). DQA1 and DQB1 encode alpha and beta glycoproteins respectively (12). The risk of developing the disease is markedly increased for individuals who are homozygous for both DQB1 and DQA1 (18). Further, two-thirds of the incidence of type 1 diabetes can be attributed to DQB1 and DQA1 in most populations. In comparison, those individuals who are heterozygous at one of the two genetic loci have a risk that is comparable to the general population (18).

It has also been demonstrated that the insulin gene region, located on chromosome 11p15.5, contains the second major susceptibility locus for type 1 diabetes (12). There are two

common alleles in this region. The shorter class I allele predisposes to type 1 diabetes, while the longer class III allele appears protective. The effect of the insulin gene appears to vary widely by ethnicity. It has been reported that class I insulin alleles are significantly associated with type 1 diabetes in Caucasians, borderline significant in Tanzanian Blacks, and non-significant in Japanese (15). Further studies examining the ethnic variation in the association between the insulin gene and type 1 diabetes are warranted.

Clearly, the genetics of type 1 diabetes is complex, involving many diabetes susceptibility genes. It is thought that up to 15 other genetic regions make up, in combination with one another, the susceptibility to type 1 diabetes (19). Future research is necessary to determine the precise location and identity of these other hypothesized diabetes susceptibility genes. The confirmation of these genetic regions and narrowing them down by genetic studies in families of diabetes patients is thus a large but essential task.

2.1.2.2 Environment

Studies have demonstrated that genetic susceptibility to type 1 diabetes is necessary, but it is not the only causal factor in the development of the disease (17). This is due to the concordance for type 1 diabetes only occurring in approximately 36% of monozygous twin pairs, thus supporting the role of the environment in the etiology of the disease (17). Epidemiologic patterns, including an increase in incidence rates by race and ethnic group and the increase in risk at puberty and during the winter, lend credence to viral infections, dietary factors, ante- and perinatal risk factors, and stressful life events playing a role in the etiology of type 1 diabetes (17; 20).

Gender does not appear to be a significant determinant of type 1 diabetes based on the similar incidence rates observed among males and females (17). However, age may play a

significant role as it may reflect exposure to infectious agents during childhood, growth spurts, or hormonal changes that occur during puberty (17). It has been observed that the risk of type 1 diabetes increases with age during childhood and adolescence, then declines during the adult years (20).

Viruses

Viruses, infant nutrition, and socioeconomic factors have been suggested as possible determinants of the disease. There have been several studies on the association between type 1 diabetes and various viruses over the past several decades (20). Viruses are believed to accelerate or precipitate the disease, functioning by direct or indirect methanisms. Moreover, viruses may directly attack the beta cells of the pancreas, directly causing type 1 diabetes (12), with or without autoimmunity. One of the most studied viruses in relation to type 1 diabetes is the Coxsackie B virus (17). Coxsackie virus B2, B3, and B4 have all been isolated from the sera in persons with newly diagnosed type 1 diabetes (17). The most recent studies on this association have been based on molecular analyses and have revealed positive associations between the presence enteroviral mRNA and the development of beta cell autoimmunity and type 1 diabetes (12).

Other viruses that have been associated with type 1 diabetes include enteroviruses, congenital rubella, and mumps (12; 20). As mentioned earlier, age at exposure may also increase disease risk as exposure to enteroviruses in utero increases the risk for developing the disease. Ten to twenty percent of children with congenital rubella, particularly those who carry the high risk HLA alleles, develop autoimmune type 1 diabetes (12). Congenital rubella is a classic example of virus-induced type 1 diabetes. Consistent with a viral component being part of the etiology of type 1 diabetes, Finnish investigators observed an increase in the incidence of type 1

diabetes two to four years after a mumps epidemic (12). However, if the mumps virus is a cause of type 1 diabetes, it is likely to be so only in a very small proportion of cases (17).

Nutrition

A number of ecologic studies have shown positive correlations between type 1 diabetes incidence and average milk consumption/breast feeding rates as an association has been observed between the vitamin D receptor and type 1 diabetes (21-24). Because type 1 diabetes is recognized as a T-cell-mediated autoimmune disease, and vitamin D compounds are known to suppress T-cell activation by binding to the vitamin D receptor, vitamin D receptor polymorphisms may be related type 1 diabetes (21). These observed associations make breast-feeding and exposure to cow's milk the most widely studied nutritional risk factor for type 1 diabetes. Moreover, a number of case-control studies have demonstrated weak positive associations between exposure to milk at an early age and type 1 diabetes (25-27). It is hypothesized that early exposure to cow's milk triggers an immune response that may lead to beta cell autoimmunity. Although there is considerable evidence in support of this hypothesis, concern has been raised by a short-term natural history study that showed no association between infant feeding patterns and the development of beta cell immunity (17). Thus, similar studies are needed to fully evaluate the role of infant diet and type 1 diabetes.

Other Factors

In addition to viruses and nutrition, other factors, including stress, maternal age, birth order, and socioeconomic status have been found to be associated with type 1 diabetes (20). Several investigators have reported that life events such accidents, pregnancy, and personal problems frequently occurred during the year prior to the onset of type 1 diabetes (28; 29). Mother's maternal age has also been considered as a risk factor for type 1 diabetes. Older

maternal age at birth and higher birth order, both, were found to be associated with a higher prevalence of type 1 diabetes. It has also been observed that for children with type 1 diabetes who have a parent with type 1 diabetes, the father is more likely to have the disease than the mother (19). Finally, socioeconomic status has been demonstrated as an important factor in the etiology of type 1 diabetes as a study in northern England demonstrated that incidence rates were highest in the most deprived areas and lowest in the least deprived areas (30).

It is clear that a number of epidemiologic patterns have emerged in the examination of the epidemiology and etiology of type 1 diabetes. Further studies involving the etiology of the disease are warranted as this may lead to prevention of the disease through risk factor modification in individuals who are genetically susceptible.

2.2 TYPE 2 DIABETES MELLITUS

2.2.1 Epidemiology

Type 2 diabetes mellitus is the most common form of diabetes, affecting approximately 18 million people in the United States today, with nearly 800,000 new cases diagnosed annually (2; 3). In addition to known cases, for every two diagnosed cases of type 2 diabetes, there is one undiagnosed case (31). It has been projected that by the year 2010, the number of persons with T2D will double, (32) due greatly in part to changing demographic factors. Largely the result of the combination of genetic factors and environmental exposures, T2D is distinguished by the body's inability to effectively use the insulin that is produced by the pancreas, distinguishing it from T1D (33; 34). It is characterized by chronic hyperglycemia, insulin resistance, reduced insulin response, and increased hepatic glucose output (33; 34).

The symptoms of T2D develop gradually. Some people may be asymptomatic, while others may suffer from one or a combination of the following symptoms: fatigue, nausea,

polyuria, polydypsia, weight loss, blurred vision, frequent infections, and slow healing of wounds (10; 35). Harris and colleagues (36) suggest that the onset of type 2 diabetes may occur between nine and twelve years before its clinical diagnosis as they demonstrated that the onset of detectable retinopathy occurred four to seven years before diagnosis of type 2 diabetes in two population-based groups of white patients with type 2 diabetes in the U.S. and Australia (36). Harris concluded that significant morbidity was present at diagnosis and for years before diagnosis of type 2 diabetes.

A multitude of studies have found associations between T2D and older age, obesity, family history of diabetes, impaired glucose tolerance, decreased physical activity, and race/ethnicity (37). Particularly high-risk racial/ethnic groups are African Americans, Hispanic/Latino Americans, American Indians, and some Asian/Pacific islanders (37). Additionally, T2D is increasingly being diagnosed in children and adolescents (38).

There still remains substantial variation in the prevalence of T2D worldwide, ranging from less than 1% in the Bantu in Africa to nearly 50% in the Pima Indians in the United States (33). Within the U.S., the burden of T2D has increased substantially over the past decade. It has rapidly increased across all regions, demographic groups, and nearly all states resulting in epidemic proportions of affected individuals (39). Temporal trends have been observed in the prevalence and incidence of T2D (32). Centers for Disease Control researchers found that the prevalence of diagnosed cases increased by 33% nationally between 1990 and 1998 (32). A 70% increase was observed in those people aged 30-39, a 40% increased was found in those aged 40-49, and a 31% increase among those aged 50-59. One in five adults over the age of 65 have T2D (32; 39). The prevalence of T2D among people over 65 years of age is nearly four times as great

as that for younger populations. Over 6 million older adults have been diagnosed with T2D, while another 3 million remain undiagnosed (10).

Overall, there does not appear to be a gender difference in the prevalence of T2D (40). However, marked racial and ethnic differences exist (40). Based on the estimates from the National Health Interview Survey (NHIS), T2D is more prevalent in non-whites than in whites at all ages, with the largest disparity in prevalence observed in the 65-74 age group (41). Prevalence rates for white and non-white women are consistently higher than those for white and non-white men. Additionally, the rates of T2D are higher for persons of Mexican and Puerto Rican descent in the 45-74 year old age group as compared to non-Hispanic whites and African Americans (10; 37; 40). These increases are due in part to the aging of the U.S. population, a decline in diabetes-related mortality, and lifestyle factors, more specifically the increasing rate of obesity and physical inactivity.

2.2.2 Etiology

T2D is a heterogeneous disease thought to be the result of a combination of genetic factors, including a defect in beta cell function (33), and external/environmental exposures. The external exposures include reduced physical activity and an increase in fat consumption. The impact of reduced physical activity and excessive caloric intake is the basis for obesity and the insulin resistance syndrome and the global epidemic increase of T2D (33).

2.2.2.1 Genetics

Genetic studies, including twin studies, family studies, and admixture studies lend support to the importance of genetic factors in the development of T2D (33). The high incidence of T2D in certain populations and among first-degree relatives of type 2 diabetes patients, as well

as the high concordance rate of 90% or more for monozygotic twins, provides strong evidence that genetic factors underlie susceptibility to T2D (33; 42; 43).

Unlike autoimmune T1D, no clear relationship has been found between human leukocyte antigen (HLA) genes and T2D (42; 43). There have been numerous association and linkage studies comparing the prevalence of the genetic markers in people with T2D. However, research has yet to find major associations between the genes for insulin, insulin receptor, glucose transporters, or islet amyloid polypeptide and T2D in the general population (43), although certain genes have been identified, including the six MODY genes in which MODY2 is caused by a mutation in the glucokinase gene on chromosome 7 (44). The limitations, in understanding the genetics of T2D, are due to the genotypic and phenotypic heterogeneity of T2D, misclassification of T2D, premature mortality, late age at onset, age-dependent penetrance of the T2D phenotype, and multiple polymorphisms, which are not all in linkage disequilibrium (42). Due to these limitations, the mode of inheritance of T2D still remains uncertain. A single, specific locus does not explain the inheritance of the disease. Because T2D is genetically complex, it involves multiple genes, which may be involved with causal mechanisms, and multiple gene-environment interactions (33; 34; 42; 43).

2.2.2.2 Environment

There is no single cause of T2D. Several non-genetic risk factors have been studied extensively throughout the world that may increase the risk of developing the disease in genetically susceptible individuals. These include obesity and sedentary lifestyle (33; 34; 37; 45), diabetic intrauterine environment (46), formula feeding (33), and low birth weight (33; 45; 47).

Lifestyle Factors

Obesity and sedentary lifestyle are, however, clearly the major risk factors for T2D (34; 37). Both risk factors interact multiplicatively in the development of the disease. Obesity is a reflection of both body mass index (BMI) and waist-hip ratio (WHR) (34). WHR indicates the distribution of fat deposition. Studies have demonstrated that both the distribution and extent of obesity influence the risk of developing T2D (34). A study done in Gothenberg, Sweden, among many, demonstrated that men with similar BMIs but greater WHRs were at higher risk for developing type 2 diabetes (34). The greater WHRs are a reflection of a more central distribution of body fat. When estimating the prevalence of obesity and diabetes, Mokdad et al.(32) found that increases in obesity and diabetes among U.S. adults continue in both sexes, all ages, races, educational levels, and smoking levels (32). In studies of physical activity, subjects who were the least active of the population had a three fold increased prevalence of T2D compared to those who were active (34).

The association between obesity and physical inactivity in relation to the development of T2D has been studied extensively through randomized controlled trials (34). The Da Qing trial demonstrated that intervention groups who were given advice and took action about diet and exercise modification had a 40% lower incidence of developing T2D as compared to the control group. A lower incidence was also seen in those with lower BMIs (7). Similar to the Da Qing trial, the Finnish Diabetes Prevention Study (DPS)(8) examined whether the onset of T2D could be prevented through lifestyle modification in middle-aged, overweight subjects. After a modest (4.7%) weight loss, those in the intervention group had a 58% reduction in incidence of diabetes over ~3 years (8). Moreover, blood pressure, triglycerides, and high-density lipoprotein cholesterol levels also improved significantly (8). The Diabetes Prevention Program (6)

demonstrated similar results. Intensive lifestyle modification reduced the incidence of T2D in persons at high risk by 58% in comparison to the metformin study group in which incidence was reduced by 31%. Moreover, the intensive lifestyle intervention was significantly more effective than the metformin intervention in reducing the incidence of T2D (6).

Intrauterine Environment

Evidence suggests that events that happen early in life are directly related to the development of T2D later in life, especially formula feeding and low birth weight (33). Studies have suggested that the intrauterine environment has a great effect on the development of T2D (33). The prevalence of T2D among offspring of mothers who have gestational diabetes at the time of birth is much higher than among the offspring of mothers who did not have gestational diabetes at the time of birth, but later developed diabetes, and in those mothers who never developed diabetes (33; 34). Evidence has demonstrated that it is necessary for meticulous glycemic control during pregnancy for optimal maternal and fetal outcomes to be achieved (33). The target for HbA1c in a pregnant woman is less than six percent in comparison to the target for those people with type 2 diabetes, which is less than seven percent (48). Tight control of blood glucose will decrease the likelihood for adverse effects on the fetus during pregnancy and later in life (48).

Formula Feeding

Formula feeding, instead of breast-feeding, is also thought to be a risk factor for T2D (33). When comparing subjects who were breast-fed during infancy to those who were formula-fed, breast-feeding was associated with more than a 50% reduction in the prevalence of T2D in young adults less than forty years of age after controlling for other factors (33).

High and Low Birth Weight

Finally, very low and very high birth weight have been found to be inversely proportional to the prevalence of impaired glucose tolerance and diabetes (33; 45; 49). In a study done among the Pima Indians, infants with very low or very high birth weight had two-fold higher risk of developing T2D later in life than those with normal birth weights (33). This results in a U-shaped curve with higher diabetes rates in both tails of the distribution. These disparities are likely due to differences in the environment, both in utero and postnatally (47). The increased risk found among the higher birth weight group could, however, be due to the effects of diabetes on pregnancy. Barker et al. (45) argued that the risk of T2D is highest in people who had low weight at birth or during infancy and became obese adults. Further, Hales and Barker have demonstrated that the risk of T2D, combined with hypertension and hyperlipidemia, is ten times higher among men whose birth weight was 6.5 lbs or less than in men whose birth weight was more than 9.5 lbs. (45). Not only does low birth weight have an effect on the risk of developing T2D, but fetal under-nutrition may also have an effect, inducing insulin resistance in tissues (45). Babies who are thin at birth, tend to be insulin resistant as adults, and therefore have a high prevalence of T2D (45).

2.3 COMPLICATIONS IN PERSONS WITH DIABETES

Much of the morbidity and mortality associated with T2D is due to complications (2; 39). There are both acute and chronic diabetes complications. Acute complications include diabetic ketoacidosis (DKA), hyperosmolar non-ketotic coma (HNC), lactic acidosis (LA), and hypoglycemia, while chronic complications are likely a manifestation of prolonged hyperglycemia (38; 50-56). Chronic complications are both microvascular and macrovascular in nature (57). Microvascular complications involve conditions related to the retina or kidney, or

neuropathy, which involves changes in the central nervous system (50; 57). Macrovascular complications (cardiovascular disease) include coronary artery disease, cerebrovascular disease or lower extremity arterial disease. Just recently, researchers have recognized that cognitive impairment maybe another serious complication of T2D (58-60). All of these complications have major clinical, social, and economic implications.

2.3.1 Acute Complications

Acute metabolic complications of diabetes consist of DKA, HNC, LA, and hypoglycemia (50). While DKA and HNC are related to insulin deficiency, hypoglycemia results from the treatment of diabetes with either oral agents or insulin. LA is associated with other risk factors of diabetes, such as cardiovascular disease (50). The acute complications of diabetes have a number of precipitating risk factors, which include acute illness or co-morbidities and poor compliance or treatment errors. Treatment for these acute complications often entails hospitalization or ambulatory care, which increases healthcare costs. Therefore, prevention is an important component in reducing the healthcare cost related to these disorders.

2.3.1.1 Diabetic Ketoacidosis

Diabetic ketoacidosis is defined by absolute insulin deficiency with hyperglycemia, increased lipolysis, ketone production, hyperketonemia, and acidosis (50). DKA most often occurs in those people with type 1 diabetes; however, it can occur in people with type 2 diabetes, but rarely does, unless the person is under a great deal of stress or is suffering from an acute illness. Incidence rates of DKA have been estimated between 4.6-13.4 per 1,000 diabetic person-years (50; 61; 62) with rates being the highest in the youngest age groups (< 30 years of age). It is thought that DKA may be the initial manifestation of type 1 diabetes in 20-30% of

DKA cases (62). Infection is the most common precipitating factor in the development of DKA (50).

The most important aspect of managing DKA is prevention (50). Prevention of DKA can be accomplished through diabetes education, improved self-care behaviors, attention to clinical and laboratory values, and the recognition of impending or actual DKA and providing prompt treatment (50). Studies have demonstrated a 40-50% reduction in diabetes hospitalizations among those who received formal diabetes education in the ambulatory care setting (63; 64). However, for severe cases of DKA, treatment entails hydration, insulin therapy, and electrolyte repletion (50). Under treatment of DKA can lead to coma and eventually death. It has been estimated that DKA-related mortality ranges from 5-45% (65-67) with the highest rates occurring in those aged 75 years and older.

2.3.1.2 Hypersolmolar Non-Ketotic Coma

HNC is defined by the presence of relative insulin deficiency and hyperglycemia (usually greater than 1000 mosm/kg), elevated serum osmoality, dehydration, and stupor progressing to coma if untreated (50). HNC occurs rarely, as documented by hospital discharge data, and usually affects those with type 2 diabetes, who are Caucasian, female, and greater than 65 years of age. Cases of HNC maybe precipitated by dehydration, medications such as steroids or thiazides, acute illness, cerebral vascular disease, advanced age, and rarely a new diagnosis of diabetes (50).

HNC can be prevented in those persons with diabetes through diabetes education, self-care behaviors, and avoidance of dehydration. Patients with this complication respond to hydration and small doses of insulin as treatment in the ambulatory care setting. This treatment will prevent mental disorientation from occurring (50).

2.3.1.3 Lactic Acidosis

LA is characterized by elevated lactic acid with acidosis (pH ≤ 7.3) without ketoacidosis (50). Nearly half of all reported cases of LA occurred in people with diabetes, however, LA is currently rarely seen since Phenformin was withdrawn from the market (50). When LA occurred, it was predominantly observed in individuals > 45 years of age, women, and in Caucasians who had a precipitating condition such as hypoxia or were currently taking Phenformin .

Prevention of LA is difficult due to its predisposing condition of hypoxia. Due to the acute nature of hypoxia, it is likely that immediate prevention may not be beneficial. Long-term prevention, including control of modifiable risk factors is often the only amenable solution (50). LA can be treated just as DKA is treated: hydration, electrolyte restoration, and correction of acidosis with careful monitoring of abnormal pathophysiology. The most important issue in the management of LA is making physicians aware of the disorder. Paying close attention to laboratory findings will help to decrease the number of LA-related hospitalizations and to ultimately decrease much of the morbidity, including cerebral edema and neurologic impairment, and high mortality associated with LA (50).

2.3.1.4 Hypoglycemia

Hypoglycemia is a very common acute complication in people with diabetes, usually occurring in patients who are treated with insulin, but can also occur in those people with diabetes who are on oral agents (50). Patients who have renal, adrenal, or pituitary insufficiency are at increased risk for developing hypoglycemia. Hypoglycemia can range from a very mild lowering of blood glucose levels (60-70 mg/dl) to severe hypoglycemia with very low levels of blood glucose (<40 mg/dl). Blood glucoses this low have the potential to cause neurologic damage (50). The incidence of hypoglycemia is often misleading because, often, only severe

cases that require medical attention are used for analyses, since the definition of hypoglycemia varies. The Diabetes Control and Complications Trial (5) reported 62 hypoglycemic episodes per 100 patient-years from 1983-1989 in which assistance was required in the provision of treatment in the intensive therapy group, as compared with 19 such episodes per 100 patient-years in the conventional therapy group. However it must be taken into consideration that the intensive-therapy group was intensively treated with insulin. This incidence rate is likely to be lower in the general population as patients are less likely to be this intensively treated (68).

Hypoglycemia is one of the largest contributors to hospitalizations in person with diabetes as nearly 64% of hospital records, of persons with diabetes, list hypoglycemia in the discharge summary (69). The National Hospital Discharge Survey (69) reported that hypoglycemia represents a greater proportion of hospitalizations for females, African American patients, and individuals 65 years and older.

Prevention of hypoglycemia depends almost solely on self-care behaviors (70). Frequent monitoring of blood glucose should reduce the frequency of hypoglycemic events as will a meticulous eating pattern, which includes not skipping meals and making adjustments to meals based on physical activity (71). Diabetes education also plays a major role in the prevention of hypoglycemic events, as awareness of factors and symptoms of hypoglycemia is crucial in order for the patient to make an informed decision regarding managing their hypoglycemia (71). In most circumstances, hypoglycemia can be treated with the consumption of a carbohydrate; however, if hypoglycemia is severe and requires hospitalization, the patient may become unresponsive, requiring intravenous glucose administration immediately (50). As long as treatment is timely, much of the major morbidity associated with hypoglycemia, such as neurologic deficit, coma and seizures, can be prevented.

2.3.2 Chronic Complications

2.3.2.1 Microvascular Complications

Microvascular disease is the hallmark consequence of exposure to chronic hyperglycemia (57). The Diabetes Control and Complications Trial (DCCT), a trial consisting of 1441 patients with type 1 diabetes who were recruited from 1983-1989, demonstrated that with a 2% decrease in HbA1c levels, there was a 63% decrease in the development of retinopathy, and a 54% reduction in the development of nephropathy in the intervention group, which received intensive therapy as compared to the control group, which received convention therapy (38; 57). The improvements observed were attributed to the use of intensive diabetes management in the intervention group, which included the administration of insulin three or more times daily by injection or an external insulin pump (5). The dosage of insulin was adjusted according to the results of self-monitoring of blood glucose performed at least three to four times daily, dietary intake, and anticipated exercise levels (5). The participants in the intensive management arm of the study visited the study center monthly and were contacted by phone to review and adjust their regimens frequently within the month (5). Similar associations were found in the Kumamoto study, a study of 110 patients with type 2 diabetes, who were randomly assigned to either a multiple insulin injection group or a conventional insulin injection group, who were followed for 8 years (72). The multiple insulin injection group included the use of an intensive diabetes management intervention very similar to the DCCT. The intervention in the Kumamoto study consisted of the administration of three or more daily injections of insulin (short-acting at each meal and intermediate-acting at bedtime), whereas the conventional insulin injection group received one or two injections of intermediate-acting insulin (72). Finally, the United Kingdom Prospective Diabetes Study (UKPDS) (4), a study of 4209 newly diagnosed patients with type 2

diabetes recruited between 1977 and 1991 demonstrated that with intensive glycemic control by either sulphonylureas or insulin substantially decreased the risk of microvascular complications, but not macrovascular complications (38; 57), although there was a borderline decrease for myocardial infarction. The intervention group in the UKPDS consisted of intensive management with a sulphonylurea or with insulin and ongoing dietary advice from a dietitian in comparison to conventional management, which consisted of dietary advice alone (4).

Retinopathy

There are two general stages of retinopathy: non-proliferative retinopathy and proliferative retinopathy (38). Retinopathy is characterized by alterations in the small blood vessels in the retina. Retinal blot hemorrhages, exudates, microaneuryisms, and other lesions can characterize the non-proliferative phase of retinopathy (38). Signs of proliferative retinopathy include the growth of abnormal blood vessels and fibrous tissues from the optic nerve or from the inner retinal surface (38). Bleeding may occur during the growth of the abnormal tissue, which leads to visual loss (38). Macular edema may occur in both phases of retinopathy. People with diabetes have a 40% risk of developing macular edema over their lifetime (38).

Retinopathy is the leading cause of blindness in people age 20-74 years in the United States (38; 57). With diabetes, there is a 25-fold increase in the risk for blindness. An estimated 97% of insulin-users, 80% of non-insulin users, and people who have had diabetes for greater than 15 years, have retinopathy (57). Untreated proliferative retinopathy progresses to blindness within five years in approximately 20% to 50% of cases Screening and care could prevent up to 90% of these cases of diabetes-related blindness. However, only approximately 60% of people with diabetes receive annual dilated eye exams (57).

Nephropathy

Nephropathy associated with diabetes is the most frequent cause of end stage renal disease (ESRD) in the U.S., Europe, and Japan (73). In the U.S alone, the incidence of nephropathy has increased by 150 percent in the past decade (73). This same temporal trend is also seen in Europe (73). Diabetic nephropathy is particularly common among the elderly and non-white populations, and is characterized by the presence of elevated urinary protein excretion in the absence of other renal disease (52). The major component of urinary protein is albumin. The first sign of renal involvement is microalbuminuria, which affects 20% to 40% of patients over a period of approximately 20 years since the initial onset of T2D (52). Treatment of microalbuminuria may prevent the development of overt nephropathy, which invariably progresses to chronic renal failure if left untreated (74).

The risk of nephropathy is partly determined by genetics. There appears to be familial clustering of nephropathy and high rates of hypertension and cardiovascular events among the relatives of those patients with T2D who have nephropathy (52). Among whites, the presence of the deletion polymorphism of the angiotensin-converting enzyme (ACE) gene has been shown to influence the rate of progression to nephropathy (52).

Associated risk factors of nephropathy include hypertension, elevated HbA1c values, increased cholesterol concentrations, smoking, advanced age, insulin resistance, male sex, non-white race, and possibly high dietary protein intake (75). Treatment to better control hypertension, blood glucose levels, and dyslipidemia could reduce diabetes-related kidney disease by up to 50% (75).

Neuropathy

Neuropathy is a common complication of diabetes affecting nearly 60% to 70% of people with the disease (51). The most common type of neuropathy is distal symmetric sensorimotor type, often called distal symmetric polyneuropathy (DSP) (51). DSP is often characterized by altered sensation, pain, and weakness, affecting the bilateral "stocking glove" pattern of the legs and arms (51; 57). With altered sensation, damage may not be detected until a secondary problem occurs, such as infection. DSP is present in 12% of persons at the time of diabetes diagnosis and in 25% after 25 years (57). Similar to other complications, the prevalence of neuropathy increases with age, diabetes duration, and poor control of glucose levels (51).

2.3.2.2 Macrovascular Complications

Macrovascular complications associated with diabetes include coronary heart disease, lower extremity arterial disease, and cerebrovascular disease (57). All of these complications are more prevalent in people with diabetes than in those who do not have the disease. Coronary heart disease is two to four times more common among persons with diabetes (55). Moreover, those with type 1 diabetes are at a ten-fold increased risk for developing coronary heart disease. The risk of stroke in people with diabetes was 2.5 compared to those without diabetes (56), and more than half of all lower limb amputations in the U.S. occur in people with diagnosed diabetes (54).

Coronary heart disease (CHD) is the number one cause of death among people with diabetes, causing nearly 65% of all deaths (55). In contrast to those people without diabetes, CHD appears earlier in life, and affects women almost as often as men (55). Based on NHIS data, the overall prevalence of CHD increases with age, with the effects seen in those less than 65 years of age. The results of the National Hospital Discharge Survey (69) demonstrated that

both men and women greater than 55 years of age, who were discharged with a diagnosis of diabetes, were more likely than those without diabetes to have at least one of all heart disease diagnoses, except cardiac dysrhythmia (55). Evidence from numerous population-based studies concluded that those with T2D had the greatest prevalence of myocardial infarction, ischemic ECGs, and coronary heart disease, while those with normal glucose tolerance had the lowest (55).

The risk factors of CHD and stroke in those people with T2D have been examined extensively (56). A number of studies have observed an association between CHD and glucose control; however, this remains an area of controversy (55; 56). Findings from the UKPDS revealed that there was a borderline significant 14.7% risk reduction in myocardial infarction in the intensive treatment group as compared to the conventional treatment group (4). However, given that T2D generally develops later in life, it is very difficult to separate the effects of glycemic control from age and duration of diabetes. Numerous epidemiologic studies have demonstrated that people with T2D have increased prevalence of hypertension and dyslipidemia (55; 57). Given the increased prevalence of these two disorders, combined with the general risk factors of for CHD, a person with T2D is at an increased risk for the development of CHD and both, hemorrhagic and non-hemorrhagic stroke (55; 56). This is due to the increased prevalence of hypertension which would result in hemorrhagic stroke, and hyperlipidemia which would result in non-hemorrhagic stroke, in those people with diabetes (56).

Peripheral vascular disease or LEAD (lower extremity arterial disease) includes conditions such as intermittent claudication, foot ulceration, and gangrene, which may lead to lower-level amputations (54). There is an increased prevalence in these conditions in those with diabetes as compared to those without diabetes. People with diabetes accounted for 51% of all

lower level amputations of the toe or foot (54). A number of the same risk factors for CHD and stroke are also risk factors for LEAD. Age, sex, hyperlipidemia, hypertension, and smoking have all been confirmed as significant risk factors for the development of LEAD (54).

Although there is a large amount of morbidity associated with diabetes, much of it can be prevented (6-8). When a team-approach to diabetes care is adopted, patient self-care behaviors, provider recommendations and adherence to national standards, community support, and the use of clinical information systems can work in tandem to prevent diabetes complications and to ultimately decrease diabetes-related morbidity and mortality (76; 77).

It is of utmost importance for the patient with diabetes to take the central role in their diabetes self-care plan by having regular check-ups, being aware of unusual symptoms like vision problems or numbness in their feet, self-monitoring their blood glucose regularly, controlling their weight and participating in regular exercise, seeking out diabetes and nutrition education, and seeing a diabetes specialist if necessary (78-82). With the patient at the helm of their self-care plan, the provider becomes a facilitator, making medication recommendations based on their lab values, and ensuring that the standards of medical care for persons with diabetes are being met (79; 82-86). Both patients and providers can benefit from community support for diabetes and the use of clinical information systems, which can automate lab results for providers and possibly provide patients with lab results with the click of a few buttons on their computer (77; 87). All of these factors will contribute to decreasing the prevalence and incidence of diabetes complications. However, if a structure is not in place in which the patient can be informed and activated and the provider cannot be prepared and proactive, diabetes-related morbidity and mortality will continue to rise (1; 39; 88).

3.0 DIABETES HEALTHCARE IN THE UNITED STATES

America is the "land of opportunity." It is the nation that is sought out for it's advanced technology, abundant resources, and quality healthcare. While the United States is among the world's most technologically advanced countries (89) and has the largest and most technologically powerful economy in the world (89), it is the current healthcare system that is in a state of flux, much to the dismay of the millions of healthcare consumers in this country. Healthcare consumers may believe that they are receiving the best possible care available to them, yet when this care is examined in detail, it becomes evident, based on sub-optimal delivery of processes and outcomes, that a gap exists between the healthcare that the public has and the care that it should have. Consumers of healthcare in this country are being affected by a healthcare system that is fragmented and in need of fundamental change. The U.S. is currently caught in a system that remains firmly rooted in acute and episodic care, resulting in consistently low quality healthcare (77), and not equipped to handle the epidemics of chronic disease that are sweeping the nation.

3.1 THE PARADIGM SHIFT

Chronic health conditions, such as diabetes, have been a public health concern since the 1920s when it was noted that chronic illnesses were replacing infectious diseases as the dominant healthcare challenge in the U.S. (90). During the 20th century, the prevalence of chronic illnesses continued to grow resulting in an epidemiologic transition where a long-term shift occurred in mortality and disease patterns (91). Noncommunicable diseases including diabetes and cardiovascular disease have replaced pandemics of infection. Today, one hundred million persons in the United States have at least one chronic illness, such as coronary heart disease, hypertension, asthma, and diabetes (92). Half of these individuals have more than one chronic

condition, and 88% of individuals aged 65 and older have one or more chronic conditions. Of this 88%, nearly one quarter has four or more conditions. Chronic illness accounts for three quarters of the nation's total health expenditures. This number is expected to rise at least 15% within the next five years and to at least 60% by the year 2050 (92).

Diabetes affects approximately 7% of the U.S. population, is the 6th leading cause of death by disease, and is growing in epidemic proportions. Diabetes takes an enormous toll in the United States by decreasing quality of life and causing death and disability, all at an enormous economic cost (1). An estimated $132 billion in direct medical costs and indirect medical expenditures are attributable to diabetes each year, as medical charges increase significantly for every 1% increase in HbA1c levels above 7% (93; 94). These costs are projected to increase with time to $156 billion dollars by 2010 and to $192 billion dollars by 2020 (95). Despite the high costs of diabetes and the significant improvement in outcomes with aggressive treatment, current treatment of diabetes frequently fails to meet desirable treatment goals and standards of care. This is the result of a fragmented healthcare system in which a gap exists between the treatment that a person with diabetes *is* getting and the treatment that a person with diabetes *should* be getting (96).

Due to its multi-faceted nature, diabetes requires a health system that promotes long-term management (97), not one in which care is provided episodically. Diabetes is not a disease that can be "fixed" at the doctor's office. Encompassing behavioral, psychosocial, and clinical factors, diabetes is one of the only chronic illnesses in which the patient manages the disease on a daily basis, outside of provider control (82). The patient is the primary person making the decisions regarding his or her own diabetes care and the patient is the person responsible for successful diabetes self-management. This concept is one that is still in its infancy stage in the

United States. Moreover, it is one that needs to be recognized and accepted by the healthcare system, providers, and patients (80-82; 98; 99).

Long-term management of diabetes requires successful organizational restructuring by the health system, reimbursement practices, and implementation of a multi-disciplinary team of health care professionals made up of physicians, nurses, certified diabetes educators, dietitians, pharmacists, and social workers, who incorporate patient self-management, and the use of management protocols, and computerized information systems (97). As the need for community-based acute and long-term care services has grown, the proportion of healthcare resources devoted to hospital care has declined. Moreover, there remains a paucity of clinical programs with the infrastructure to provide the full range of services needed by people with diabetes (100). Quality diabetes care is undoubtedly a shortcoming of the U.S. healthcare system.

Evaluation of quality is based on three main principles: structure, which includes the organization of the health system, process, which is the interaction between patients and providers, and finally, outcomes, which measure health status (100). When quality of diabetes care was examined using the Third National Health and Nutrition Examination Survey (NHANES III) (101) and the Behavioral Risk Factor Surveillance System (BRFSS) (102), it was found that none of the diabetes parameters reached the desired goals set forth by the American Diabetes Association (96). This lack of quality of care is likely the result of poor healthcare system organization. While the nation transitioned from a period of infectious disease outbreaks to chronic disease epidemics, the healthcare system did not transition with it, and remains caught an acute care model of healthcare delivery where care is fragmented and reactionary, not planned and coordinated (77; 87; 103).

3.2 QUALITY OF CARE

The Institute of Medicine defines quality as "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge." Given this definition, studies in the U.S. have repeatedly demonstrated poor quality for people with chronic illnesses, especially those persons with diabetes (96). There is a vast body of literature that establishing that several effective treatments and practices substantially reduce or prevent the burden that diabetes takes on individuals, families, and the healthcare system (104; 105); however, the level of care currently being delivered to people with diabetes is not adequate to produce health-related improvements (104; 106). This poor quality of care results in unmet patient needs and potential patient harm. In 1998, the Institute of Medicine's National Roundtable on Healthcare Quality documented three types of quality problems – overuse, underuse, and misuse, while the Advisory Commission on Consumer Protection and Quality reported that "the healthcare industry is plagued with over utilization of services, underutilization of services, and errors in health care practice." These quality problems do not occur because of failure or goodwill; they occur because of shortcomings in the ways care is organized (100).

There are four main underlying reasons for inadequate quality of care in the United States, which help explain the overuse, underuse, and misuse of healthcare. The growing complexity of healthcare science and technology, the increase in chronic conditions, a poorly organized delivery system, and constraints on exploiting the revolution in information technology contribute both independently and dependently to inadequate healthcare (100).

Healthcare science and technology is advancing at an extraordinary rate. The knowledge, skills, care interventions, devices, and drugs have advanced more rapidly than the U.S.

healthcare system's ability to deliver them safely, effectively, and efficiently (100), resulting in inadequate quality of care. This rate is unlikely to abate, as health technology is continuing to advance.

As a result of increased technology and medical science, people are living longer. Those aged 65 and older make up an increasingly large proportion of the U.S. population (100). The observed demographic changes have important implications for the organization of health care delivery, however, the U.S. healthcare system has yet to address these changes. A consequence of the aging population is an increase in the incidence and prevalence of chronic conditions, such as diabetes and heart disease (100). Chronic conditions are the leading cause of illness, disability, and death in the U.S. and affect nearly half of the U.S. population (77; 84-87; 90). The U.S. has recognized the growing rates of chronic illness, devoting the majority of health care resources to these conditions; however, devoting the majority of resources to chronic illness becomes complicated as nearly all persons affected by a chronic illness have a comorbid condition as well, as is the case with diabetes. People with diabetes are likely to be afflicted by blindness, kidney failure, amputations, and cardiovascular disease, which not only reduce the quality and length of life, but also takes a substantive economic toll on the healthcare system. Managing comorbid conditions in addition to chronic illness requires an effective collaborative process between patients, providers, and health systems (100).

The current health system is highly decentralized (100). It is complicated, as patients go through layers of bewildering processes and handoffs to seek the care they need. In the 1996 Picker Survey (107) patients reported that the U.S. healthcare system is a "nightmare to navigate" and is "expensive, unreliable, and impersonal." Ranked 37th in the world by the World Health Organization in overall health system performance (108), the U.S. health system has been

described as wasteful and unaccountable, failing to build on the strengths of the many health professionals involved in it (100). This issue is exemplified as the U.S. health system currently provides full coverage for gastric bypass surgery as a means to alleviate obesity, yet does not provide full coverage for a person with diabetes who wants to see a dietitian or a diabetes educator to learn how to eat right as a means of controlling their diabetes. It is only in those people with diabetes, who are on medicare, that one visit for diabetes education is covered (109-111).

In comparison to the highly ranked health systems of France, Italy, Spain, Oman, Austria, and Japan (108), the U.S. health system, which is increasingly afflicted by chronic conditions, like diabetes, needs to perform in such a way as to utilize available resources in order to provide quality care to those with chronic illness. The best health systems consistently rank high in WHOs five basic indicators of a good health system: overall level of population health measured by disability-adjusted life expectancy; health disparities within the population; health system responsiveness consisting of a combination of patient satisfaction and how well the system acts; distribution of responsiveness within the population or how well people of various socioeconomic status find that they are being served by the health system; and finally, the distribution of the health system's financial burden within the population. By utilizing available resources, the highest ranked health systems in the world reflect all of these attributes, as they are stewards for quality healthcare for their populations (112).

Finally, there remains a constraint on exploiting the revolution in information technology in the U.S. The advent of the Internet has been fundamental as it allows patients to search an estimated 10,000 health-related websites for information on diseases and treatments, health plans, providers, management of chronic illnesses, and health risks (100). The effect of the

Internet on the healthcare system may come in the form of the way in which services are organized. Individuals are becoming more empowered about their own health, seeking information from the Internet to take to their physician to get their opinion and judgment. Information technology does not stop at the use of the Internet to research information. The use of the web should be able to help both patients and providers gain better access to clinical evidence and serve as a training tool for clinicians. Information technology has the ability to automate clinical data, reduce errors by standardizing and automating decisions, and enhancing patient and provider communication through time-saving email communication and the availability of online test results (100).

While the revolution of information technology is at the forefront of chronic medical care, it must also be taken into consideration that most chronic care is provided in the primary care setting (83; 85; 86), where it becomes hit or miss as to whether information technology can even be a point of discussion. The U.S. health system is absolutely adamant about using information technology as a means to improve clinical care and communication; yet, it is reality that in a great number of primary care offices, there is no computer, let alone wireless devices or electronic medical records. Appointments are handwritten and filing cabinets are filled with paper charts. In underserved communities that are the focus of many health system initiatives and which are in need of the most resources, the focus should be placed on bringing offices up to date with their technology as a means to help their patients, not trying to exploit what the practice does not have (100).

3.3 ORGANIZATION OF HEALTHCARE

When healthcare is organized, there are basic concepts developed by the Institute of Medicine that should be followed. All of these can be directly applied to diabetes care and

management, especially in the primary care setting, where the majority of diabetes care is provided (85). Diabetes care should be evidence based, planned care, which follows the clinical guidelines set forth by the American Diabetes Association (113) and the Diabetes Quality Improvement Project (104). There should be a reorganization of practice, which uses a team approach that includes the use of ancillary professionals, such as certified diabetes educators and dietitians, with the patient as the most important member of the team (114). There should be particular attention paid to patient needs and access to clinical expertise, including education for, both, patients and providers, and access to specialists (76; 77; 115). Finally, supportive information systems should be in place, which involve patient registries, and provider feedback on preventive service utilization (76; 77; 100). However, as mentioned before, this is what the U.S. healthcare system *should* be providing for chronic illness care; it is not what it *is* providing. The U.S. healthcare system is providing care not based on evidence, but based on experience and training. Care is mainly driven by the physician, who may not believe that the patient is the primary decision maker in their diabetes management (83). There is limited access to diabetes specialists, due to insurance limitations, reluctance from the primary care provider to refer, fragmented access, and offices still exist in which there is no computer, which leads to sub-optimal patient tracking (76; 77; 100).

To combat this fragmented healthcare system, the Institute of Medicine (100) highlights ten simple rules for organization of the 21st century healthcare system, which will help to improve quality. Care should be based on continuous healing relationships; care is customized according to patient needs and values; the patient is the source of control; knowledge is shared and information flows freely; decisions are evidence based; safety is a system property; transparency is necessary; needs are anticipated; waste is continuously decreased; and

cooperation among clinicians is a priority. Three of these rules are directly applicable to diabetes care and management and need to be considered when re-organizing the current healthcare system. Care should be customized according to patient needs and values; the patient should be the source of control; and knowledge should be shared and information should flow freely (100). All of these factors are central to defragmenting the healthcare system to better accommodate a chronic illness like diabetes.

3.4 POTENTIAL SOLUTIONS

Much of the growing chronic disease burden on the U.S. healthcare system can be eliminated through more effective prevention and management (92). McGinnis and colleagues estimated that 50 percent of mortality from the ten leading causes of death is attributable to lifestyle behaviors that cause or complicate chronic illness (92). Finding strategies for preventing and managing these conditions will pose a major challenge for healthcare in the 21st century. However, with effective, well-tested models of chronic care management, which defragment the health system, and restructure it in a way in which care is evidence-based, population-based, and patient-centered, the health system can more effectively manage chronic conditions through primary and secondary prevention (92).

Numerous studies have been conducted in which successful, multi-faceted interventions were carried out in order to test the effect of restructuring the health system (116-121). The aims of these studies included increasing clinical expertise and decision support, improving patients' self-management, increasing the effectiveness of practice teams and interactions with patients, and having more accessible and useful clinical information (103). These changes reduced variation in care, encouraged patients to sustain participation in care programs, and encouraged

positive patient behavior and decision-making. Although research has demonstrated the efficacy of these treatments, the effectiveness has only begun to be tested (117).

Diabetes is a disease, which requires system restructuring in order for long-term management to be successful. Taking the above model of care, which is evidence and population based, and implementing it into primary care, where the benefit in real clinical practice can be tested, is one of the first steps in restructuring diabetes care in the United States (84-86; 114; 122; 123). This model, which incorporates the community, including resources and numerous public and private policies; the healthcare system, including its payment structures; and the provider organization encompassing an integrated delivery system, a small clinic, or a network of physician practices may meet the needs of people with diabetes, wherever they may live (85; 103).

4.0 THE CHRONIC CARE MODEL

Through years of clinical practice and research, Dr. Edward Wagner of the Group Health Cooperative of Puget Sound, Washington, witnessed first hand, the epidemic of chronic illness and the health system that could not handle it. This, more often than not, resulted in an uninformed, passive patient interacting with an unprepared, primary care practice team, which lead to a frustrating, inadequate encounter (85). It was through these experiences that Dr. Wagner developed the Chronic Care Model (76; 77; 84-86; 103; 124), (Appendix A) which is an entirely new way of thinking about and restructuring the U.S. healthcare system to meet the needs of the chronically ill.

The Chronic Care Model was developed for primary care patients with a chronic illness, and was derived from numerous efforts to improve chronic illness management. Because nearly 90% of the chronically ill are treated in the primary care setting, the Chronic Care Model constitutes a major rethinking of how primary care is delivered. Its purpose is to create a more informed activated patient and a prepared, proactive practice team working together in a partnership to improve functions and clinical outcomes. As the current health system is antiquated due to the temporal shift from infectious disease to chronic disease (91), the Chronic Care Model is based on this paradigm shift from the current model of heath care delivery that is problem-based to handle acute patient problems to a system that is prevention based to avoid long-term problems. The Chronic Care Model identifies and organizes the changes needed in the health care system, the practice, and the patient to improve outcomes (92). Although the model does not offer a quick and easy fix to the broken healthcare system, it is a multidimensional solution to a very complex problem (85).

Wagner and colleagues intended for the Chronic Care Model to be generic in nature, making it applicable to multiple chronic diseases and health care organizations (92). The model

is currently being implemented in more than 300 diverse healthcare systems to improve quality of care for asthma, congestive heart failure, depression, diabetes, and prevention of frailty in the elderly. It has also been demonstrated to work well across a variety of different organizations, including fee-for-service, Veteran's Administration, managed care, and community health settings (122).

Wagner and colleagues believe that chronic care takes place in three overlapping divisions: the entire community including resources and policies, the health care system including its payment structures, and provider organization (87). It is within these three divisions that the Chronic Care Model takes its shape. It identifies six essential elements of optimal chronic care: community resources and policies, health care organization, self-management support, delivery system design, decision support, and clinical information systems. These six essential elements form a blueprint for care that is evidence-based, population-based, and patient-centered (92). Based on the complex, multi-faceted nature of diabetes, the Chronic Care Model is an ideal model to implement to improve diabetes-related outcomes and to prevent diabetes complications (76; 77). All six elements of the Chronic Care Model find a home in diabetes. Whether it is providing diabetes education classes as self-management support, having "diabetes days" at the primary care provider's office as a means of redesigning the delivery system, or providing the primary care provider with information regarding his or her diabetes care to enhance the clinical information systems already in place, the Chronic Care Model is a heuristic model that identifies and organizes the changes needed to improve chronic illness care (92).

4.1 COMMUNITY (RESOURCES AND POLICIES)

Community resources and policies can support or expand a health system's care for people with chronic conditions. Often times, this concept is overlooked, as health systems do not make the most of the resources that are available to them. Partnerships with local senior centers, state departments of health, and/or national patient organizations can support and expand a health system's care for chronically ill patients. In general, these entities are able to provide care at a much more individualized level as compared to the health system. Whether it is a senior center providing exercise classes for the elderly or a national organization, such as the American Diabetes Association, advocating for an increase in research funding for children with type 2 diabetes, if the healthcare system looks outside its borders and forms powerful alliances and partnerships with programs and organizations in the community, it can enhance care for its patients.

4.1.1 Partnerships and Collaborations

Over the last two decades there has been an increase in the number of hospitals, medical schools, health clinics, and managed care organizations working with community partners to deliver relevant geographically and culturally appropriate diabetes care interventions (125-130). The message to partner with communities is not only a part of the Chronic Care Model, but it is also the consistent message of the World Health Organization (WHO) (131). The WHO's message to its member states is to assess the importance of diabetes in their countries and to develop population-based prevention and control strategies (131). Engaging community partners will generate public interest, discussion, ownership, and action around diabetes prevention and control (132).

Community development and partnerships are central to public health practice (133), yet they are two terms that lack conceptual clarity due to a shortage of general day-to-day use.

Community development can be defined as "the process of organizing and/or supporting community groups in identifying their health issues, planning and acting upon their strategies for social action/social change, and gaining increased self-reliance and decision-making power as a result of their activities." This definition contains five major components including nurturing relations with and among institutions and community groups that are more equitable in power sharing, supporting those whose living conditions provide them with less objective forms of power, developing community and support groups, using both community-based and community-development approaches to work, and developing community self-sufficiency and community self-reliance (133). The community is a trusted access point for reaching people with chronic conditions, their families, and their friends to support them in learning more about the chronic condition and gaining control over it. Because individuals are embedded withing social, political, and economic systems that shape behaviors and access to resources, it is necessary to develop and partner with communities to maintain health (132).

4.1.2 A Community-Based Response to Diabetes

Community diabetes interventions generally occur outside the typical clinical setting and attempt to reach persons diagnosed with diabetes, those at risk for diabetes, and the general public in non-traditional settings, such as schools, work sites, churches, campsites, and homes (134). Forming partnerships between healthcare providers, research institutions, local businesses, local stakeholders, and community partners may help to ensure that diabetes care is tailored to the unique needs and cultures of communities, such as literacy level, social class, and available resources (135), thus reducing the burden of diabetes in the community. For example, numerous research studies (136) have found improved recruitment and attendance at diabetes self-management education training in the community if there were partnerships with local churches,

community members, grocery stores, local businesses, and exercise facilities (131). These partnerships build confidence, competencies, and social connections (137-139) within individuals and within the community. With broad participation, community coalitions promote ownership by expanding resources and increasing commitment to sustain long-term health activities (137-139). Programs that grow out of a basis of community ownership are most likely to succeed (140) as the community has the opportunity to expand diabetes health promotion activities beyond individual lifestyle and influence social policy within the community (137-139). It is the community that in is the best position to increase the acceptance of diabetes-focused interventions, encourage adoption of healthy lifestyle behaviors, target environmental barriers, and reinforce the positive aspects of empowering individual people, families, workplaces, and neighborhoods (131).

Diabetes research in the community is typically aimed toward working with underserved communities, whose members experience limited access to resources and decision-making processes (132). The emphasis is on integrating knowledge into strategies to provide community and social change. If the potential for diabetes community-based research is recognized and capitalized upon, this type of research offers a means to reduce the gap between theory, research, and practice (132).

4.2 SELF-MANAGEMENT SUPPORT

Just as entities in the community must collaborate to form effective partnerships to enhance diabetes care and management, which may ultimately reduce the gap between theory, research, and practice, patients and providers must form partnerships with each other and within the community (114; 141; 142) to effectively care and manage diabetes. At the center of diabetes management is self-management (82; 109; 143-147), which encompasses the decisions and

behaviors that patients with chronic illness make, day to day, that affect their health. Diabetes control and outcomes depend largely on the effectiveness of self-management (136). However, effective self-management support means more than just telling patients what to do. It means the patient taking responsibility for their own health and acknowledging a central role in their care. Diabetes self-management support includes use of proven programs that provide basic diabetes information, emotional support for the person with diabetes and any family members or friends of that person, and strategies for living with diabetes, such as information regarding food choices at restaurants or various forms of physical activity (82; 109; 143-147). Using a collaborative approach, patients and their diabetes healthcare team, including physicians, certified diabetes educators, dietitians, social workers, and pharmacists work together to define problems, set priorities, establish goals, create treatment plans, and problem solve (114). Through the use of internal and community resources, on-going self-management support is viable and critical for the health of people with diabetes.

4.2.1 The Patients' Role in the Management of their Diabetes

Despite advances in diabetes research and technology, many people are still not achieving optimal outcomes, resulting in many devastating diabetes complications that lead to decreased quality of life and increased morbidity and mortality (82). However, as mentioned previously, these suboptimal outcomes are, in part, the result of a broken healthcare system in which a team approach to diabetes self-management support is not the standard practice. Traditional patient-provider relationships consisted (and still consist) of the patient's ability to adhere to the provider's therapeutic advice (82; 131). The model of diabetes management often used, assumes that the health provider's role is to tell the patient what to do and the patient's role is to comply with the recommendations (131). Self-management success is, generally, measured as the

patient's ability to adhere to a predetermined care program that may be suited to fit patients' diabetes, which may not be designed to fit their priorities, goals, resources, culture, and lifestyle (82). In this scenario, the provider attempts to solve the patient's problem without understanding the patient's personal experience, therefore leading to, both, a frustrated patient and a frustrated provider. Opportunities to develop action plans are missed and teachable moments are not capitalized upon.

4.2.2 Collaborative Care Management

As a large body of literature indicates (80-82; 98; 99; 131; 142), a major paradigm is emerging in which research recognizes the need for improved patient-provider relationships in which health decisions are made together (131). This paradigm is referred to as collaborative care management and is characterized by three fundamental, empowerment-based, aspects of chronic illness care: choices, control, and consequences (148). Patients with diabetes must self-manage their disease on a daily basis. The choices that they make each day have a much greater impact on their diabetes-related outcomes and on their lives, in general, than the choices that providers make for them. When the patient leaves the providers' office, they are in control, not the provider. They choose what recommendations they implement and which they disregard. They are directly responsible for the consequences of their choices and therefore are entitled to manage their diabetes in a way that best suits them (82). Collaborative care management is, essentially, a description of the patient-provider relationship and is care that strengthens and supports self-care in chronic illness while assuring that effective medical, preventive, and health maintenance interventions take place (124). It is set apart from other models of care in that patients are thought to have as much expertise in their diabetes care as their providers (84). An empowered patient will accept responsibility to manage his or her diabetes and is encouraged to

solve his or her own problems with information, not orders, from healthcare providers (84; 124). While physicians are the experts in medical care, the patient is the expert on how diabetes affects their lives. Studies based on strengthening the patient-provider relationship have consistently demonstrated positive outcomes, including greater patient satisfaction, adherence to treatment plans, higher self-reported health status, better emotional health, more symptom relief, and increased metabolic control of diabetes-related disease factors (80; 114; 149).

Based on the aforementioned positive characteristics of collaborative care management, it should be ready adopted by providers. However, this is not the norm of the U.S. healthcare system. Collaborative care is not the dominant approach in primary care (84; 124), where nearly 90% of all people with diabetes receive care (150). Gotler and colleagues found that participatory decision making, a crucial component of collaborative care, occurred in only one quarter of all visits to primary care physicians (151).

Although collaborative care management and self-management are conceptually similar, they are clinically separable (84). Because collaborative care alters the essence of the patient-provider relationship, it becomes daunting to implement it into all of primary care. Providing self-management education is more feasible, in that self-management skills can be taught over a relatively short time frame with the patient having the central role in their diabetes care and the provider understanding and supporting the self-management process (84). Diabetes self-management education (DSME) is used to give patients' effective problem-solving skills based on real-life experiences and to supplement collaborative care management (84; 131).

4.2.3 Diabetes Self-Management Education

Diabetes self-management education has been referred to as "the cornerstone of treatment for all persons with diabetes" by the Task Force to Revise the National Standards for Diabetes

Self-Management Education Programs (110; 136; 152; 153) and “the cornerstone to diabetes prevention and control” (110; 136; 154). DSME is the process of teaching individuals to manage their diabetes (118)(147) by providing them with the knowledge and skills needed to perform daily self-care, manage crises, and make lifestyle changes (131; 143) - strategies necessary for patients to effectively manage their diabetes and make informed decisions (82). The goal of DSME is to enable the patient to become the most knowledgeable and the most active participant in his or her diabetes care (143) by understanding the nature of the illness and its treatment, identifying emerging health problems in early, reversible stages (96), adhering to self-care behaviors (155), and making needed changes in health habits. More broadly, DSME assists patients in coping with the mental and physical demands of their illness, given their unique economic, cultural, and social circumstances.

DSME has been considered a crucial part of the clinical management of individuals with diabetes since the 1930s, based on the work of the Joslin Diabetes Center (152). In the 1960s and 1970s, typical diabetes education interventions/programs were usually hospital based and individualized for each patient. Education was most often provided at the patient’s bedside, usually on the morning of their discharge from the hospital (156). Because of this, the timing of the education was often times ill timed and insufficient (156). However, during the late 1970s and early 1980s, inpatient diabetes education programs were developed in which patients and family members were provided education by a team of diabetes health professionals. Nevertheless, with the evolvement of shorter lengths of hospital stay; these types of programs, eventually, were no longer able to provide the patient with adequate tools to manage the complexities of diabetes (156).

Through the years, DSME has evolved from sporadic instruction by physicians, nurses, and dietitians in physician offices and hospitals to more formal and comprehensive diabetes self-management education programs (143) taught by an entire team of healthcare professionals. The Diabetes Control and Complications Trial (DCCT) was crucial in the evolvement of these comprehensive education programs. Although not an a priori hypothesis, it was noted that as the study progressed, there was a need for dietitians and nurses to increase their involvement in management and education in order for patients to achieve HbA1c goals. The recognition and expansion of nurses and dietitians roles in DSME occurred as a result (68; 157).

The evolvement from piecemeal instruction in years past to the current, more comprehensive approach was not only prompted by a change in hospitalization procedures, but it was prompted by concerns about the variability in the quality of teaching and by the development of standards of diabetes education by the National Diabetes Advisory Board (158).

Since 1986, the American Diabetes Association (ADA) has offered recognition status for diabetes education programs that can meet these standards. Additionally, the ADA recommends annual assessment of self-management skills and knowledge of diabetes and encourages continued diabetes education (159). To add to the efforts by the ADA, in 1997, the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) initiated the National Diabetes Education Program (NDEP) to promote early diagnosis and to improve the treatment and outcomes for people with type 1 and type 2 diabetes (160). The NDEP's main focus is to promote optimal control of blood glucose, lipids, and blood pressure to help prevent devastating and costly micro and macrovascular complications (160). Based on the emergence of the importance of DSME over the past decade, one of the diabetes-related objectives of Healthy People 2010 is to increase the proportion of individuals with diabetes who receive

diabetes education from the 1998 level of 40% to 60% (147; 161). DSME has clearly become one of the top priorities of diabetes care and management.

The central goals of diabetes self-management education are to optimize metabolic control, prevent acute and chronic complications, and optimize quality of life, while keeping costs acceptable (147; 162). Modern DSME has been proven effective in producing, both, behavioral and biological improvements (143; 163). These goals can be accomplished through improving diabetes knowledge, problem solving skills, and skill performance through counseling and behavioral interventions. While, DSME has consistently been shown to improve health outcomes (155), there still remain significant knowledge and skill deficits in 50-80% of patients with diabetes (143), and glycemic control is achieved in less than half of individuals with type 2 diabetes (164). Research has demonstrated that DSME can improve self-management skills and adherence practices by affecting intermediate outcomes such as diabetes knowledge (e.g. basic procedures to manage hypoglycemia, role of insulin), psychological measures (e.g. self-efficacy, locus of control, problem solving, coping skills), and behavioral measures (blood glucose testing, physical activity, eating behaviors), which positively effect short-term metabolic outcomes, such as weight, body mass index, blood pressure, lipids, and blood glucose (131; 136; 165), and which in turn, lead to a decrease in diabetes-related complications. Muhlhauser and colleagues (166) demonstrated that patients with diabetes who do not receive DSME are four times more likely to develop a major complication of their diabetes.

The overarching goal of DSME is to enable the patient to become the most knowledgeable and the most active participant in his or her diabetes care, emphasizing the need for the individual with diabetes to manage their diabetes on a day-to-day basis (143). With the knowledge and skills of DSME in hand, the person with diabetes has the opportunity to change

the way in which they view diabetes, change the way in which they act regarding their diabetes, seek out needed materials and social support, recognize incentives to change diabetes-related behaviors, and develop new skills and take action in self-managing their disease (165; 167).

4.2.3.1 Access and Utility

Despite the increasing prevalence of diabetes worldwide combined with the vast amount of evidence that DSME has a positive effect on diabetes self-regulation in a variety of settings, very little research has been conducted to determine whether patients utilize or receive diabetes education services, how often they receive it, and whether it is effective in promoting self-regulation of the disease (168). In the little research that has been done, data have shown that over fifty percent of people with diabetes receive limited or no diabetes self-management education (143). Using data from the National Health Interview Survey (NHIS), Coonrod and colleagues found that 41% of people with type 1 diabetes, 51% of people with insulin treated type 2 diabetes, and 76% of people with non-insulin treated type 2 diabetes reported having never attended a diabetes related education class or program (169). Harris (170) followed up Coonrod's report with additional results of the NHIS in a review of medical care for people with diabetes. Harris found that two outcomes (self-monitoring of blood glucose at least once daily and having an annual dilated eye exam) occurred with substantially greater frequency for patients who had had diabetes education compared to those who had not, yet when NHIS data were analyzed, they indicated that only 35% of adults with diabetes in the U.S. ever attended a diabetes education class or program (170).

Of great concern is that those who are older, are of lower socioeconomic and educations levels, and are members of minority groups are the least likely to receive DSME (169; 171; 172), yet these are the groups in which the prevalence of diabetes is, generally, the highest. These

disparities are apparent due to the many personal, logistical, social, and economic barriers to both recommended self-management practices and to participation in DSME, which are almost all greater among minority populations (173-178).

There is good news to combat these many barriers, however, as recent research has shown that appropriately designed, developmentally and culturally appropriate programs are capable of reaching and assisting older adults and lower-income populations (176). There is also a substantial amount of research focusing on African American (179; 180), Latino (181), and Native American populations (182). These minority populations have, traditionally, been among the groups with very limited access to DSME and/or support; however, in recent years, major national programs are now addressing minority involvement as key objectives (160; 161; 183). The importance of this research is remarkable as the majority of the projected number of new cases of diabetes and the increased burden of diabetes in the coming years are expected to be in minority populations (2).

Another recent milestone in access and utility of DSME came in 2003 when the U.S. House of Representatives introduced a bill to increase access by obtaining Medicare reimbursement. The "Diabetes Self-Management Training Act of 2003" was introduced to seek "to improve access to diabetes self-management training by designating certified diabetes educators as certified providers of outpatient diabetes education services under part B on the Medicare program." Adding certified diabetes educators, as providers to the Medicare program, should, ideally, give diabetes patients access to the care they need (184).

It is possible that many of the aforementioned disparities have occurred due to the lack of a widely accepted, traditional model of access to DSME. Research in this area is limited as the only models available are broad frameworks of access to medical care. The most notable of

these frameworks came from Anderson and Aday (185; 186) in the 1960s and 1970s. In 1974, Anderson and Aday (186) developed a framework for describing access to medical care. In the Anderson and Aday framework, the determinants of access include 1) policy level features (financing of healthcare and workforce issues), 2) health delivery system features (resources and organizational factors) and 3) population features (predisposing factors, enabling factors, and need factors).

The Behavioral Model, focusing on the individual as the unit of analysis, suggests that people's use of health services is a function of their predisposition to use services, factors which enable or impede use, and their need for care (185). Combining both frameworks and applying them to access to DSME provides an extensive, comprehensive framework. A combination of these frameworks allows for demographic factors, social structure, health beliefs, genetic factors, personal health practices, psychological characteristics, community and personal resources, health systems features, and policy features to predict access and use of medical care (185; 186). These factors have all been demonstrated as barriers to access and utility of diabetes care (178; 187-190), and possibly, barriers to access and utility of DSME.

Using a comprehensive framework to understand access and utility to DSME for people with diabetes may provide the knowledge and information needed to develop targeted interventions in the populations most at need. Although not documented in the literature, aspects of the Chronic Care Model can be directly related back to the frameworks suggested by Anderson and Aday (185; 186). The self-management support section of the Chronic Care Model encompasses many of the aforementioned factors that may predict increased access and utility to medical care. For example, placing Certified Diabetes Educators, which are now able to bill for their services, at point of service in the primary care office, where most diabetes care is delivered, will increase

access and utility of DSME, which will likely lead to improved metabolic and behavioral outcomes.

4.2.3.2 Efficacy and Effectiveness

Measuring, both, efficacy and effectiveness is crucial in diabetes self-management. A large body of literature has developed on diabetes education and its efficacy; however, studies on the effectiveness of DSME remain sparse. There have been several important quantitative reviews demonstrating the positive effects of diabetes education (143; 166; 191-196); however educational techniques have developed over the last 15 years since these reviews were published, shifting from didactic education techniques to interventions involving patient empowerment, which includes participation and collaboration (147). Additionally, reviews on the effectiveness of diabetes education have traditionally been compilations of studies of heterogeneous quality (136), which fail to identify the most effective form of diabetes education for specific populations or outcomes (136).

Efficacy

To test the efficacy of an intervention is to test the impact of the intervention under highly controlled circumstances. For example, the Diabetes Prevention Program (6) was a highly efficacious trial as there were strict inclusion/exclusion criteria, incentives, and a wide variety of meeting places. The most efficacious studies have the highest internal validity. In the case of DSME, these would be the studies in which one could conclude with confidence that DSME caused the outcome in question (197).

Measuring the efficacy of DSME is quite difficult given that self-management education is frequently combined with diabetes treatment (143). For example, in studies that wish to examine the effect of DSME on a particular outcome, interpretation issues often arise due to possible

confounding relationships between the outcome of interest and other diabetes-related factors. Factors such as medication dosages, physical activity, and dietary habits all have the possibility of confounding the relationship between DSME and the outcome. Without a sound scientific study design and the proper statistical methodologies, these confounders make it difficult to assess DSME as a separate entity. Moreover, the difficulty in separating DSME from treatment is apparent in articles that address reductions in hospitalizations for diabetes-related problems as proof of efficacy of DSME (166; 192; 198). These articles lack a control group, which would provide a comparison between those people who received education and those who did not. Despite the obstacles in measuring the efficacy of DSME, there is a vast body of literature, which does so.

Norris et al. (147) evaluated the efficacy of DSME on glycemic control in adults with type 2 diabetes in a recent meta-analysis. The authors only included studies if they were randomized controlled trials that were published in the English language, tested the effect of self-management education on adults with type 2 diabetes, and reported extractable data on the effect of treatment on glycemic control. They chose to only include randomized controlled trials in the meta-analysis because this type of study design most often supports maximum validity and causal inference (147). Norris's goal was to examine the efficacy of DSME as broadly as possible; therefore interventions in all settings were included. To ensure maximum validity, studies were only included if the educational component of the intervention could be examined independently.

The meta-analysis by Norris and colleagues provided evidence of the efficacy of DSME for individuals with type 2 diabetes on glycemic control, and was able to delineate the factors, which contribute to its efficacy. It was found, on average, that DSME interventions decreased

glycohemoglobin by 0.76% more than the control group at immediate follow-up, by 0.26% at 1-3 months of follow-up, and by 0.26% at four or more months of follow-up. Further, it was found that duration of contact time between educator and patient was the only significant predictor of DSME effect, with approximately twenty-four hours of contact time needed for a 1% decrease in glycohemoglobin levels (147). Although Norris and colleagues found positive effects of DSME on glycohemoglobin levels, a number of studies had low internal validity. No study in this meta-analysis fulfilled the criteria for absence of selection, performance, attrition, and detection bias. Attrition was greater than 20% in nearly 1/3 of the studies (147).

Although the randomized controlled trial is the gold standard in assessing causal inference and ensuring maximum validity, other study designs have been used to evaluate the efficacy of DSME on glycemic control and other diabetes-related outcomes. Brown et al. (155) conducted a meta-analysis on the effects of educational interventions on knowledge, self-care behaviors, and metabolic control. Brown included study designs that used a control group and those involving a one-group pretest-posttest design. Also included in the meta-analysis were unpublished literature, the use of a checklist for quality assessment (155), a quality score (196), and the removal of outliers to achieve statistical homogeneity, a characteristic of most efficacy studies. Positive effect sizes were found for knowledge outcomes, dietary compliance, skill performance, metabolic control, psychological outcomes, and weight loss. In comparison to Norris' review, Brown found an effect size of 0.41 for glycohemolgobin and no difference in metabolic control by the total time spent with the educator. Padgett et al. (191) reviewed the effects of educational and psychosocial interventions on management of diabetes. The meta-analysis tested the effects of eight intervention types (didactic education, enhanced education, diet instruction, exercise instruction, self-monitoring instruction, social learning/behavior modification, counseling, and

relaxation training). The overall mean effect size was 0.51, indicating moderate but significant improvements for all intervention subjects; however, education approaches based on diet instruction and social learning/behavior modification were the most effective interventions (effect sizes = 0.68 and 0.57 respectively) (191).

While the studies reviewed in the aforementioned meta-analyses assessed the efficacy of DSME by testing the impact of an intervention, their generalizability is relatively low. Although the results are generalizable to adult populations, they are likely limited to clinic settings. For example, in the review by Norris, only four interventions were delivered outside of the medical clinic (147). Moving from the clinic to the community is a transition that research on the effectiveness of DSME is attempting to make. Engaging community resources through partnerships and coalitions and tailoring the efficacy tested interventions to more community-based populations may provide highly generalizable results depending on the effectiveness of the interventions.

Effectiveness

While there is demonstrated efficacy of DSME (147; 155; 191), many questions remain about DSME's effect on diabetes outcomes. Efficacy studies cannot easily generalize findings to other, particularly vulnerable populations (minority populations, older individuals with other comorbid conditions, socially and/or economically disadvantaged groups, and individuals at high risk for developing diabetes) and settings other than the specific population under study. This is issue that results is a major gap in our understanding of how to implement and sustain ideal diabetes care in the real world (9).

Unlike studies that test whether an intervention is efficacious, effectiveness studies test an intervention under less controlled circumstances (197). These types of studies maximize

external validity, which is the degree to which one can generalize to other times, places, or populations. The challenge of high quality effectiveness research is the balance between external and internal validity.

While these types of studies are the most crucial in moving diabetes care from "bench" to "bedside" and out of the "ivory tower" of research to ultimately reduce the gap between theory and practice, these types of studies are most often ridden with methodological errors, and face challenges in disseminating results (199). Effectiveness studies are much more difficult to carry out compared to efficacy studies. They often times require a multi-faceted intervention, sophisticated analyses, and expertise in translating the results of the study into the community. Unlike pharmacological studies, metabolic unit studies, or animal studies, educational researchers simply have less control over the conditions under which the interventions take place (199).

Norris et al. (136) conducted a systematic review of the effectiveness of DSME in type 2 diabetes. The authors reviewed 72 randomized controlled trials published since 1980 that tested various forms of DSME. After reviewing the studies, the authors concluded, "evidence supports the effectiveness of self-management training in type 2 diabetes, particularly in the short-term." The authors note that it is clear that DSME has evolved from primarily didactic interventions (focusing on the acquisition of knowledge and information) of the 1970s and 1980s into collaborative, more theoretically based empowerment models of the 1990s (136). In the studies that used a didactic approach, positive effects on knowledge were found, with mixed results for glycemic control and blood pressure, and no effect on weight. However, in the studies using a collaborative approach, positive effects on glycemic control were found in the short term and mixed results with follow-up greater than one year (136).

The authors state in the review that even the best studies often had flaws, limiting their power to determine the best practices (199). Many of the studies were subject to major confounding variables, which may have affected metabolic outcomes. For example, there were no considerations of the effect of medication changes when education interventions were not integrated with medical care. Norris and colleagues (136) also discussed the low internal validity of the studies under question. Although diabetes education studies always contain performance bias because of the inability to blind patients to the intervention, out of the 72 studies reviewed in Norris' systematic review, not one study was free of other biases (e.g. selection bias, attrition bias, detection bias). Additionally, internal validity was threatened by lack of blinding the assessor, infeasibility of blinding subjects, high attrition, contamination of the control group, unintended co-interventions, and deficits in the reliability and validity of the instruments used to measure knowledge, self-care, and dietary habits (136). Other methodological problems were also inherent in a great number of the studies reviewed, including inadequate descriptions of the study intervention and participants and exclusion of discussion on the representativeness of the study population. Generalizability was also frequently limited by the volunteer nature of the participants. The behavioral theories on which the interventions were based were only documented in a few studies. Finally, the authors expressed a concern that the researchers may not have measured the most important outcomes as most of the studies reviewed focus on knowledge and glycemic control, excluding the more holistic outcomes of quality of life, patient functioning and longevity (136; 200-203).

While there are some well-designed and executed studies that support the effectiveness of DSME for patients with type 2 diabetes (mainly in the short term), there still remains a paucity of research of high methodological quality in diverse populations and settings. These types of

studies are crucial in order to assess the effectiveness of DSME on sustained glycemic control, cardiovascular disease risk factors, micro and macrovascular disease, and quality of life (136).

4.2.4 Self-Care Behaviors

Effective self-management of diabetes is not just based on simple adherence to a prescribed regimen. It also requires active behavioral involvement of patients on a day-to-day basis – namely in the form of self-care practices and behaviors (204). However, behavioral involvement will not be successful if an individual's self-efficacy (confidence in his or her ability to perform specific tasks required to reach desired diabetes-related goals) is low. A sufficient sense of self-efficacy is crucial for individuals to effectively cope with the complex demands of a diabetes self-management plan (making healthy food choices, staying physically active, self-monitoring blood glucose, taking prescribed medications, talking regularly to the diabetes management team to problem solve, reduce risks for complications and cope with lifestyle changes) (204). Being successful at overcoming many of the aforementioned challenges, that individuals with diabetes face, depends largely upon self-efficacy, as these beliefs are specific to behaviors and situations in which they occur. Self-efficacy beliefs affect the courses of action people choose to take, the amount of effort they choose to invest, how long they will persevere, their resilience to adversity, and what they ultimately accomplish (74; 204). Self-efficacy as a predictor of self-care behaviors in people with diabetes is well-documented in the literature (163; 205-207). It has been shown to be associated with self-reported adherence in adults (70; 206; 208-212) and adolescents (213; 214), as well as glycemic control (212; 215; 216) and better perceived general health, mental health, and social functioning (70). Because self-efficacy is a dynamic, changeable belief, an increase in the sense of self-efficacy may result in increased motivation for self-care behaviors (204).

Adding to the complexity of self-management from a research perspective is that evidence does not clearly support the effectiveness of DSME on measures of outcome performance. As noted by Norris and colleagues, researchers may not be measuring the most important outcomes, as most of the DSME studies reviewed focus on knowledge and glycemic control, excluding the more holistic outcomes of quality of life, patient functioning, longevity, and ultimately, sustained behavior change (136). Without a specified set of outcome measures, diabetes educators cannot determine their effectiveness with individuals and populations, compare their performance with established benchmarks, or establish the unique contribution of DSME in the overall context of diabetes care (71). To overcome this problem, the American Association of Diabetes Educators just recently (2003) adopted behavior change as the outcome of DSME (71).

In order to assess behavior change, a predetermined set of behaviors had to be developed in order for diabetes educators to gather evidence to support their practices and modify their interventions in response to this evidence (71). To address this need, the American Association of Diabetes Educators (AADE) developed the AADE 7 Self-Care Behaviors, which provide diabetes educators with a standard outline to use when counseling people with diabetes. The AADE 7 is designed to give diabetes educators a way to measure change in patient behaviors, determine effectiveness of programs at both the practice and individual patient levels, establish benchmarks for comparisons, and provide a way to measure the economic and health impacts of DSME (217). The AADE 7 focuses around seven key behaviors that promote successful self-management, including 1) healthy eating habits, 2) being physically active, 3) monitoring health status, 4) taking medications, 5) problem solving, 6) healthy coping, and 7) risk reduction. These 7 self-care behaviors are specifically designed to fit in with the National Standards for Diabetes

Self-Management Education requirements (217). Appendix B outlines the AADE 7 Self –Care Behaviors.

Application of the seven core self-care outcomes/performance measures to evaluate effectiveness of DSME provide the educator and the clinician with the ability to understand what is working and what is not in the patient's quest to make behavior changes in the self-management of their diabetes. As Norris and colleagues (136) noted, the majority of the DSME studies reviewed did not mention or expand on the behavioral theories on which the interventions were based. Without a strong conceptual framework of behavioral theory as a basis for an intervention, evaluating the effectiveness of DSME as a means to change behavior is suspect. The AADE 7 is rooted in the behavioral theories/models of self-efficacy [224], stages of change [248], and the health belief model [235]. Through the continued use of these seven outcomes/performance measures, the establishment of a unique core of knowledge about specific patient-focused interventions will allow DSME to be recognized as an effective and essential therapeutic intervention in the care of people with diabetes (71).

4.2.5 Behavioral Theory in Diabetes Self-Management Education Research

Diabetes is one of the most psychologically and behaviorally demanding of all chronic illnesses (218). One of the central roles of DSME is to help patients facilitate a behavior change in order to achieve improvements in both metabolic and behavioral outcomes. Consequently, effective DSME programs are ones, which the intervention is based on a strong conceptual framework of behavioral theory, laying the roadmap for delivery. As the literature indicates, the majority of DSME research and practice is based on theory (78), however, most of the time the theory that guides the research study or program has to be inferred, which consequently prohibits DSME research from evolving into a coherent, sound, and progressive body of knowledge (78)

and limits the translation of the intervention into the clinical setting. This leads to a poor understanding of the role of theory in DSME research (219). Many see theory as an intangible conceptual theme with little relevance. However, the use of behavioral theory in practice may convince the skeptics that DSME works as an essential therapeutic intervention.

The basic theory underlying DSME is that diabetes patient education is a necessary component of care and that some methods of education are more effective than others (78). However, there is a paucity of articulated (theory that has been made explicit so that it can be understood by someone other than the one who is offering the theory) and elaborated (articulated theory that has been discussed, debated, and used in research) theory in the published literature on DSME (78). Of the 76 studies that were reviewed by a panel of diabetes educators for the AADE Educational and Behavioral Research Summit, 88% lacked a theoretical framework (220). Moreover, the use of behavioral theory in clinical practice has, historically, not been demonstrated in the literature; however, the utility is beginning to be recognized by certified diabetes educators (79). It is therefore critical to examine behavioral theory in the broad sense, and how it is related to DSME more specifically, to help ensure that diabetes educators and researchers will adopt sound behavioral theory as a basis for their interventions (78). Although the DCCT (5) was not a study of the effect of DSME on metabolic control, it is an excellent demonstration of the role of behavioral science in diabetes care, which was not based on a sound behavioral theory. The DCCT's chief finding, that patients who were able to maintain glucose at near-normal levels had significantly less diabetic retinopathy, neuropathy, and nephropathy, was greatly due to the study's interventionists helping participants adhere to the complex and demanding treatment regimen (5). Although the DCCT effectively addressed behavioral issues, it lacked a strong conceptual framework of behavioral theory and did not adequately define or

monitor the methods for addressing the many behavioral issues involved (5). Because of this, the study did not address the critical questions of what motivational variables predict long-term glucose control and how health care providers can promote such motivation in patients with diabetes, many of whom are not as motivationally prepared as those selected in the DCCT (336). Consequently, generalization and translation of the DCCT's success is now limited (163; 200; 221).

In the general sense, theory is defined as a plausible story that makes narrative or causal sense out of a series of phenomena (222). However, more specifically, behavioral theory has the underlying assumption that human beings are capable of making choices, and hence the role of behavioral theory is to help educators and researchers understand the relationships among the setting and factors that influence patients' choices (222). The following behavioral theories/models are sound conceptual frameworks, which have been tested, both, generally, and in diabetes. All of these theories/models have the potential to be a framework for DSME interventions. Each of these theories/models poses a framework for which interventions combine with various patient states or traits to produce behavioral outcomes (223).

4.2.5.1 Self-Efficacy

The concept of self-efficacy arose out of the Social Learning Theory (later relabeled as Social Cognitive Theory), developed by Albert Bandura, which emphasizes the importance of observing and modeling the behaviors, attitudes, and emotional reactions of others (224). As stated by Bandura, "Learning would be exceedingly laborious, not to mention hazardous, if people had to rely solely on the effects of their own actions to inform them what to do. Fortunately, most human behavior is learned observationally through modeling: from observing others one forms an idea of how new behaviors are performed, and on later occasions this coded

information serves as a guide for action" (225). Social learning theory explains human behavior in terms of continuous reciprocal interaction between cognitive, behavioral, and environmental influences, spanning both cognitive and behavioral frameworks (226). Through years of studying and experimenting with Social Learning Theory, Bandura became aware that a key element was missing, not only from the prevalent learning theories of the day, but also from his own theory. In 1977, with the publication of "Self-efficacy: Toward a Unifying Theory of Behavioral Change," he identified the important piece of that missing element—self-beliefs.

Perceived self-efficacy is defined as people's beliefs about their capabilities to produce designated levels of performance that exercise influence over events that affect their lives (224). It is the internal state that individuals experience as "competence" to perform certain desired tasks or behaviors (226). These beliefs determine how people feel, think, motivate themselves and behave. A strong sense of self-efficacy enhances human accomplishment and personal well being in a variety of ways. People with high self-efficacy approach difficult tasks as challenges to be mastered rather than threats to be avoided. They set challenging goals and maintain a strong commitment to them. They heighten and sustain their efforts in the face of failure. They attribute failure to insufficient effort, knowledge, or skills and approach threatening situations with assurance that they can exercise control over them. Such an efficacious outlook produces personal accomplishments, reduces stress and lowers vulnerability to depression (224; 225). Self-efficacy is one of the major components of nearly all behavioral theories/models and is the underlying framework for a number of the theories presented here. Discussed below is a brief, but descriptive summary of the concept of self-efficacy in, both, general terms and when applied to diabetes self-management education. Because diabetes self-management is largely dependent on behavioral factors within the individual, a high degree of self-efficacy is of utmost importance

in a patient with diabetes and has been proven crucial for successful completion of self-care behaviors (227).

Sources of Influence

People's beliefs about their efficacy are developed through four major sources of influence: mastery of experiences, vicarious experiences provided by social models, social persuasion, and modification of self-beliefs to reduce stress reactions and alter negative emotional states (224). The most effective way of creating a strong sense of self-efficacy is through mastery of experiences. Successes build a robust belief in one's personal efficacy, however failures tend to undermine it. After people with a high degree of self-efficacy are convinced that they have what it takes to succeed, they persevere in the face of adversity and quickly rebound from setbacks. In relating this source of influence to people with diabetes, it has been observed by both researchers and diabetes educators that when goals are accomplished in the diabetes plan, the patient is more motivated and has a renewed sense of accomplishment. This renewed sense of accomplishment and confidence drives them to take on additional goals. Even if the "road blocks of life" stand in their way, such as personal illness or financial hardship, their self-efficacy allows them to persevere.

The second source of influence for strengthening self-beliefs of efficacy is through vicarious experiences provided by social models. Observing the success of peers raises the observers' beliefs that they too possess the capabilities to master comparable activities and succeed. People tend to seek models that possess the competencies to which they aspire. These models then transmit knowledge and teach observers effective skills and strategies for managing environmental demands. A relatively new concept in DSME is the use of lay health coaches or peer coaches to help people with diabetes succeed in their management plans. In an article by

Joseph et al. (228), peer coaches who were known to be successfully managing their diabetes were paired with individuals who were struggling with behavior change associated with managing diabetes. Coaches met initially with participants in a face-to-face meeting for one hour and talked with them once a week for 10 to 15 minutes for the next 8 weeks. The initial interview and subsequent phone conversations focused on the person's problems and efforts at behavior change. At the end of the study, participants reported that coaching was personal, useful in disease management, and helpful in their quest to establish and adhere to routines of care. Participants also reported making progress toward changing their behavior related to diet, exercise, and blood glucose monitoring (228). Modeling their behavior after others who faced similar challenges helped in improving their sense of self-efficacy and consequently their ability to make a behavior change.

Social persuasion is the third way of strengthening self-efficacy. People who are persuaded verbally that they possess the capabilities to master given activities are likely to put forth greater effort and sustain it rather than harboring self-doubt and dwelling on personal deficiencies. Successful efficacy builders structure situations that bring success and avoid placing people in situations prematurely where they are likely to fail. Certified diabetes educators (CDEs) are an example of individuals who use social persuasion to strengthen self-efficacy in the quest to make a behavior change. DSME that is patient focused has been shown to be successful in helping patients to make a behavior change, which is often dependent on an increased sense of self-efficacy (120).

Finally, people rely greatly on their emotional states in judging their capabilities. Positive mood enhances perceived self-efficacy, while negative mood diminishes it (224). In the case of diabetes, where depression is twice as prevalent than in the general population (229), emotional

states make a big difference in self-management. Positive emotional states help in increasing self-efficacious feelings and behaviors, while negative emotional states often deteriorate these feelings and behaviors. For example, if a patient is suffering from an episode of depression, their self-efficacy is diminished and in turn, their confidence in their abilities to manage their diabetes deteriorates.

Psychological Processes

Self-efficacy beliefs produce diverse effects (e.g. increased confidence, motivation, competence, coping abilities) in the individual. These effects come from four major psychological processes: cognitive, motivational, affective, and selection. The effects of self-efficacy beliefs on cognitive processes take a variety of forms, as much of human behavior is regulated by the goals which a person values. The stronger the perceived self-efficacy, the higher the goal challenges people set for themselves and the firmer their commitment to them (224; 225).

Self-efficacy also plays a key role in the self-regulation of motivation. Beliefs of self-efficacy determine the goals people set for themselves, how much effort they expend, how long they persevere in the face of difficulties, and their resilience to failures. People who harbor self-doubts about their capabilities tend to slacken their efforts or give up quickly when faced with obstacles and failures. However, those with a strong belief in their capabilities exert greater effort when they fail and persevere until they accomplish what they set out to do (225). A central feature of DSME is the patient-generated action plan, a set of behaviors to achieve a goal (i.e. weight loss) that is developed by the patient and nurtured by the healthcare provider (84). Rather than prescribing specific behavior changes, providers assist patients in making management choices and achieving success in reaching self-selected goals (149). Action plans

should be realistic, proposing behavior that the patient is confident that they can accomplish. Self-efficacy theory holds that the successful achievement of an action plan is more important that the action plan itself because the patient, not the healthcare provider, develops the plan. The main purpose of an action plan is to give the patient the confidence in managing their diabetes. This newly gained confidence has the potential to then fuel the internal motivation needed to carry the action plan forward beyond the initial phase, so that the patient can revise it and tailor it to their needs (149).

People's beliefs in their coping capabilities affect how much stress and depression they experience in threatening or difficult situations, as well as their level of motivation. People who believe that they can exercise control of difficult situations may not experience negative thought patterns, unlike those who believe that they cannot manage difficult situations often resulting in high anxiety. These individuals magnify the severity of the situation and dwell on their coping deficiencies, leading to anxiety and often times depression. A low sense of self-efficacy to exercise control over pensive thought contributes to the occurrence, duration and recurrence of depressive episodes (224). There have been numerous studies (230-233) examining correlates and predictors of depression in people with diabetes. The majority of research in this area has found that the various comorbidities of diabetes are amongst the strongest correlates and predictors of depression. In the case where a person with diabetes has low self-efficacy, the complexity of managing comorbidities impacts successful management of their diabetes, which may also lead to a depressive episode. Their negative thought patterns, often times apathetic in nature, deteriorate any confidence they have in themselves to manage their disease. This cycle may then repeat itself as the disease progresses until the patient's low self-efficacy, combined with depression, eventually leads to total lack of concern and interest about their diabetes.

Finally, beliefs of personal efficacy can shape the course that people take by influencing the types of activities and environments they choose. Individuals are a product of their environment. By the choices they make, people cultivate different competencies, interests, and social networks in turn, determine their life courses (224).

High levels of self-efficacy have been considered to be adaptive because they stimulate higher goal setting and perseverance, thus surpassing their usual level of accomplishment. In a study involving patients with type 1 diabetes, those patients with more positive efficacy experiences used more adaptive coping and reported better mental health than patients holding a less optimistic view (234). Although self-efficacy is not the only explanatory factor in behavior change, it adds substantially to our understanding of diabetes self-care behavior.

4.2.5.2 Health Belief Model

The Health Belief Model (HBM), derived from psychological theories, is one of the most widely used conceptual frameworks for understanding health behavior. The HBM was first developed in the 1950s by social psychologists Godfrey Hochbaum, Irwin Rosenstock, and Stephen Kegels working in the U.S. Public Health Services (235). The model was developed in response to the failure of a free tuberculosis health-screening program. When few adults attended the free screening, program organizers began investigating why more adults did not attend. Hochbaum, however, began to study what motivated the few who did attend. He quickly learned that their perceived risk of disease and perceived benefits of action were crucial factors in their motivation (235). The HBM underscores the importance of individual's perceived risk and perceived seriousness as part of their health beliefs and determines the likelihood of adopting preventive health behaviors (236). The more an individual perceives him or herself to be at a

particular health risk and considers this risk to be serious and important, the more likely it is that he or she will make the necessary changes to prevent health problems from occurring.

The HBM hypothesizes that behavior depends mainly on the value placed by an individual on a particular goal, and the individual's estimate of the likelihood that a given action will achieve that goal (213)Originally formulated to explain preventive health actions (i.e. seat belt use, condom use, medical compliance), the HBM was later applied to prescribed therapies and sick-role behaviors (237). As the model matured, the nature of events underlying beliefs about health problems was extended to include diagnosed conditions, such as diabetes (238).

The HBM assumes that health is valued and that cues for action are prevalent (235). The model is based on the understanding that a person will take a health-related action (i.e., self monitor their blood sugar) if that person: 1) feels that a negative health condition (i.e., hypoglycemia) can be avoided, 2) has a positive expectation that by taking a recommended action, he or she will avoid a negative health condition (i.e., self monitoring well help them know when they might be getting hypoglycemic), and 3) believes that he or she can successfully take a recommended health action (i.e., he or she can self monitor their blood sugar comfortably and with confidence) (237).

There are six major dimensions to the HBM that can be applied to both, type 1 and type 2 diabetes. Initially there were only 4 dimensions. However, because self-efficacy was found to fit conceptually within the HBM framework and to be a strong predictor of health behaviors, an expanded HBM that incorporates readiness to change and self-efficacy was developed to provide a more powerful approach to understanding health-related behavior (237). The Expanded Health Belief Model (EHBM) has become the most frequently used Social Cognition Model to predict

health behaviors (239). Similar to the HBM, it suggests that behavior is influenced by an individual's beliefs and attitudes related to health outcomes (239). It addresses individual perceptions (perceived susceptibility/severity), mediating/moderating factors (knowledge, psychosocial variables, demographic variables, adherence, and motivational cues) and the likelihood of action (perceived benefits and barriers, self-efficacy, and intention). The six dimensions of the EHBM, as it relates to diabetes, are perceived susceptibility and severity of diabetes and its short and long-term complications, perceived benefits of and barriers to the treatment and self-management of the disease, strategies to activate readiness to make a behavior change based on motivational cues, and lastly, the patients' confidence in their ability to successfully attain those goals (237). According to the model, individuals with diabetes will most likely adhere to the treatment plan if they have a motive and if they hold the following four beliefs to be true: they are susceptible to problems due to diabetes, diabetes could have a serious, negative impact on their lives, adherence to professional recommendations will be beneficial in reducing the threat of diabetes comorbidities, and the difficulties associated with following the health recommendations are outweighed by the benefits (240).

The utility of the HBM in DSME is evident as the model provides a useful framework of psychological variables that are predictors of patient adherence, and may therefore serve as a logical basis for interventions (241). Cerkoney and Hart found that, in a group of people taking insulin for their diabetes, there was a positive correlation between the patient's adherence to guidelines and his or her belief model score (242). Although Cerkoney and Hart's findings were of great importance, to date, there has not been a substantial amount of literature on using HBM as a basis for DSME interventions and/or diabetes care, especially in adults with type 2 diabetes. As mentioned earlier, nearly all diabetes education interventions are based on a theory. The lack

of literature in this area may be the result of educators and researchers failing to include and describe the theoretical framework on which their intervention was based, not that the HBM is not being used in DSME. The research in this area, although limited, has demonstrated the same findings in a variety of populations. Perceived severity of the disease tends to be strongly correlated with metabolic control (243; 244), while perceived barriers tend to be strongly correlated with worse self-care behaviors (245). Increased self-efficacy has been shown to be correlated with more frequent blood glucose monitoring, less frequent missed doses, less binge eating, and closer adherence to an ideal diet (245). There has been quite a bit more research conducted on the use of the HBM in individuals with type 1 diabetes, where adherence to a treatment plan (i.e. insulin use) is of critical importance. Charron-Prochownik and colleagues (237) examined the use of the HBM in terms of understanding young children's health beliefs and diabetes regimen adherence (237). They found that overall, both children and their parents reported moderate to very strong health beliefs (e.g. diabetes is severe) while barriers to management were perceived as low to moderate as predicted by the HBM. Also, both children and parents reported high degrees of self-efficacy, as they felt very confident in being able to assist in performing diabetes self-care behaviors and carrying out the diabetes treatment plan. Children's perception of the severity of their illness, barriers to treatment and self-efficacy were found to be significantly correlated with observable adherence or metabolic control (237). In a second study conducted by Charron-Prochownik and colleagues (239), the objective was to identify significant correlates among constructs of the Expanded Health Belief Model (EHBM) with reproductive behaviors and metabolic control in teens with type 1 diabetes. It was found that being told by a healthcare professional to seek out preconception counseling was a motivational cue that triggered an action step. Several major constructs of the EHBM were

significantly correlated with beneficial reproductive health behaviors and metabolic control (239).

While the HBM and EHBM are the most widely used models to predict health behaviors, they do have limitations. One of the problems that has plagued the HBM and EHBM is that different questions are used in different studies to determine the same beliefs; consequently, it is difficult both to design appropriate tests of the HBM/EHBM and to compare results across studies. Another reason why research does not always support the HBM/EHBM is that factors other than health beliefs also heavily influence health behavior practices. These factors may include societal influences, cultural factors, socioeconomic status, and previous experiences. While the relationship between one's beliefs and their health behavior has been proven strong, it is the totality of one's life that will best predict behavioral practices.

4.2.5.3 Transtheoretical Model

The Transtheoretical Model (TTM) or "Stages of Change" was developed by James Prochaska as an integrated framework for understanding how individuals and populations progress toward adopting and maintaining health behavior change for optimal health. It is the most widely used stage model in health psychology (246). The model has its roots in psychotherapy for smoking cessation and was developed in 1979 after Prochaska completed a comparative analysis of eighteen therapy systems and a critical review of three hundred therapy outcome studies. From the analysis and review, Prochaska found that the same common processes were involved in making and sustaining a behavior change (226). The TTM is based on the premise that people are at different stages of motivational readiness for engaging in health

behaviors and that intervention approaches are most useful when they are matched to a person's stage of change (247).

The core constructs of the TTM include stages of change (the most widely used construct), the processes of change, the pros and cons of changing, self-efficacy, and temptation. The TTM separates behavior change into five discrete stages that are defined in terms of a person's past behavior and his or her plans for future action. Investigators usually assign people to stages on the basis of their responses to questions concerning their prior behavior and current behavioral intentions (246). Behavior changes are assumed to occur over a period of time. Thus, the stage construct is an important part of the TTM because it represents the temporal dimension of time (226). The precontemplation stage is defined as a time when people are not seriously thinking about changing their behavior during the next six months. Many individuals in this stage are unaware or under aware of their problems tending to avoid reading, talking, or thinking about their high-risk behaviors (226; 248). The second stage, contemplation, occurs when people are aware that a problem exists and are seriously thinking about a behavior change but have not yet made a commitment to take an action. They are more open to feedback and information about the problem behavior than those in the precontemplation stage (226; 248). The third stage is called preparation and combines intention and behavioral criteria. Individuals in this stage are intending to take action in the next month and have successfully taken action in the past year (226; 248). In this step, the person has taken some small steps toward action, such as buying necessary clothes for exercising or cutting back on the fat grams they consume, but they have not reached an effective criterion for successful action. Individuals in this stage are recruited for weight loss and exercise programs. Action is the stage in which people have made specific overt modifications in their life-styles within the past six months. Since action is observable, behavior

change often has been equated with action (226; 248). But in the TTM, action is only one of the five stages. Not all modifications of behavior are considered as action in this model. Action is attainment of a criterion that scientists and professionals agree is sufficient to reduce risks for disease (226; 248). For example, for nutrition, there is some consensus that less than 30% of calories should be consumed from fat. The action stage is also the stage where vigilance against relapse is critical (226; 248). Relapse, or "recycling" is considered a natural part of the change process and not a failure, as movement through the stages is not necessarily a linear process. If those making changes continue with their new pattern of behavior, they will move into the fifth stage, maintenance. Maintenance is the stage in which people are working to prevent relapse but they do not apply change processes as frequently as do people in action (226; 248). People in this stage have changed their problem behavior for at least six months and are increasingly more confident that they can continue their changes. They are less tempted to relapse (revert to an earlier stage), as their change has become a habit, and increasingly more confident that they can continue their behavior change. The final stage is termination (226; 248). This stage is defined as the time when the individuals who have changed have zero temptation to return to their old behavior and they have 100% self-efficacy. This is a stage that few people reach with certain behaviors, like alcoholism. Since this may not be a practical goal for the majority of people, it has been given less attention in research (226).

The second major construct of the TTM is the processes of change (248; 249). The processes of change are the covert and overt activities that people use to progress through the stages. Processes of change provide important guides for intervention programs, since the processes are the independent variables that people need to apply, or be engaged in, to move from stage to stage (248). Ten processes have received the most empirical support in our research to date. The

first five (consciousness raising, dramatic relief, self-reevaluation, environmental reevaluation, and social liberation) are classified as experiential processes and are used primarily for the early stage transitions to increase intention and motivation (249). The last five (helping relationships, counter conditioning, reinforcement management, self-liberation) are labeled behavioral processes and are used primarily for later stage transitions where behavior change is getting underway and needing to be maintained (249). Research has suggested that change is best achieved by appropriate matching of processes with stages of change (250). A description of the ten processes of change is listed in Table A1.

The third construct of the TTM, decisional balance, refers to the pros and cons of behavioral change (248; 249). An individual's decision to move from one stage to the next is based on the relative importance (pro), or the lack thereof (con), of the behavior change. In most circumstances, the pros of health behavior are low in the early stages and increase across the stages of change, and the cons of health behavior are high in the early stage and decrease across the stages.

The fourth and final construct of the TTM is self-efficacy/temptations (248; 249). The self-efficacy construct represents the situation specific confidence that people have that they can cope with high-risk situations without relapsing to their unhealthy or high-risk habit. This construct was adapted from Bandura's self-efficacy theory (225) and is represented either by a temptation measure or a self-efficacy construct. Situational temptation is, in effect, the opposite of self-efficacy and the same set of items can be used to measure both, using different response formats. The Situational Self-efficacy Measure reflects the confidence of the individual **not** to engage in a specific behavior across a series of difficult situations. Both the self-efficacy and temptation

measures have the same structure (227), as the most common types of tempting situations are negative affects or emotional distress, positive social situations, and craving. Research has shown a specific pattern of changes in self-confidence and temptations across the stages of change. People report greater temptations and less confidence in the early stages and this pattern then reverses itself in the later stages where people feel less temptation and more confidence (251). Thus, when matching an intervention to a person's stage of change, it is also important to be aware of their self-confidence and temptations in different situations.

The application of the TTM in diabetes care was introduced in 1993 (252). Since then, several studies (253-257)and a large-scale clinical trial (258) have been conducted helping to move the TTM from theory to practice. A large-scale cross-sectional study of the stages of change applied to diabetes care behaviors (diet, exercise, medication use, and self-monitoring of blood glucose) was conducted in 1997 (256). This study focused on validating the use of the TTM in diabetes and developing psychometrically sound measurement tools. A sub study of this project focused on the stages of change for smokers in a sample of people with either type 1 or type 2 diabetes (257). The study found that of those people who smoked, more people with type 2 diabetes were in the maintenance stage (72.5% vs. 44.5%) while there were no differences in stage across type of diabetes for those who were current smokers. Further, when comparing those people who received advice from their providers, regarding smoking cessation, to those who did not receive advice, 57.8% of people who received advice were in precontemplation, 35.1% were in contemplation, and 7.1% were in the maintenance stage. In comparison, more than 85% of those who reportedly had not received provider advice regarding smoking cessation were in the precontemplation stage, 10% in contemplation, and 2% in maintenance (257). While this study

does have limitations (i.e. small sample size, limited statistical testing) it emphasizes the necessity for tailoring advice and providing stage-matched interventions (247; 257).

More recently, researchers have examined the stages of change in relation to metabolic control after a DSME intervention was delivered (253; 254). Kavookjian (254) found that although a patient may become ready for action towards self-care, a decrease in HbA1c levels might change more slowly. Peterson et al. (253) found that patients in the preparation and action stages achieved a significantly larger reduction in HbA1c levels in a shorter time than patients in the precontemplation and contemplation stages. The authors concluded that stages of change was significantly associated with clinical improvement in HbA1c levels at three months after an educational intervention, and these significant differences in clinical improvement between groups were sustained for at least 12 months. However, it should be noted that although study patients had significant reductions in HbA1c levels, none achieved an HbA1c level of ≤ 8% or less (253).

Jones et al. (258) conducted a recent, large-scale clinical trial (The Diabetes Stages of Change (DiSC) Study) to compare usual diabetes care with an intervention developed from the TTM, called Pathways to Change (PTC). The PTC intervention consisted of stage-matched personalized assessment reports, self-help manuals, newsletters, and individual phone counseling designed to improve readiness for self-monitoring of blood glucose, healthy eating, and/or smoking cessation (258). The authors' objective was to determine whether the intervention would result in greater readiness to change, greater increases in diabetes self-care behaviors and improved metabolic control. The authors found that those receiving the intervention were more likely to progress in the stage sequence for the respective self-care behaviors than those receiving

usual diabetes care (258). The authors concluded that the PTC intervention has the potential for positively impacting the health of a broad population of individuals with diabetes, not just the minority who are ready for change (258). Vallis et al. (259) conducted a follow-up sub-study of the DiSC study on stages of change for healthy eating. The authors' goals of this study were to identify diabetes-related characteristics of individuals at different stages of readiness to change to healthy, low-fat eating. Results demonstrated an increase in healthy eating as participants moved from the preaction to the action stages: percent of calories from fat was lower and the number of daily servings of fruits/vegetables was higher, supporting the staging algorithm used in the TTM. Vallis et al. (259) also found that those participants in the action stage, and especially in the maintenance stage, were more likely to have received diabetes education within the last year, had a better quality of life, and not to smoke (259).

Although only a fair amount of research has been published on the application of the TTM in diabetes, additional large-scale trials examining stage-matched approaches in people with diabetes are in progress (256). The trials will continue to examine stage-matched intervention programs for multiple diabetes and related health behaviors compared with usual care approaches. Researchers will continue to develop additional written stage-based self-help materials, such as handbooks and newsletters; stage-matched telephone counseling approaches; and expert system-generated individualized feedback reports for people with diabetes (247). By becoming aware of diabetes-related characteristics of readiness to change, educators and researchers can predict the likelihood of change. However, a strong body of evidence is accumulating supporting the adoption of new stage models of behavior change due to the problems that are emerging with the methods that the TTM uses to measure the central construct of stages of change (260).

While the TTM is one of the most highly regarded models of health behavior change, it too has its limitations. In recent years, the TTM has been critiqued rather extensively (225; 246; 260; 261) and has been shown to suffer from conceptual and empirical limitations, including problems of stage definition, measurement, and discreteness (234). Sequential transition across the stages has not been established due to the lack of longitudinal studies of the TTM (no longitudinal studies have documented progression through all five stages of change (261), and there is little evidence that therapeutic interventions must be matched to a stage in order to facilitate a behavior change (262). A basic problem with the model involves how the stages of change are defined and measured. Sutton (260) has noted that, in some cases, the staging algorithms are logically unsound. For example, in the commonly used staging algorithm developed by DiClemente et al., someone in the preparation stage of quitting smoking must have unsuccessfully tried to quit for 24 hours in the past year. This means that smokers cannot reach the preparation stage the first time they try to quit. Moreover, the time frames used to define the different stages (e.g. planning to change in the next 6 months (contemplation) vs. in the next month (preparation)) are arbitrary. Any variation in the time limits shifts the composition of the stages (246).

In addition to using staging algorithms to measure stages of change, multidimensional questionnaires, in which an individual receives a subscale score for each stage have been used. An example of this type of questionnaire is the University of Rhode Island Change Assessment Scale (URICA) also known as the "Stages of Change Questionnaire." When different types of behaviors have been studied using these types of measures, inconsistencies in the definitions of the stages have occurred. For example, in the URICA, an individual in the action stage must be

working on the problem, where as in other studies that use a staging algorithm, an individual in the action stage must have ceased the problem behavior within the past six months (262).

Another limitation of the TTM is that most participants do not fit neatly into one stage of change or process of change, but instead they may respond to items on questionnaires representing at least two different, sometimes nonadjacent, stages (i.e. precontemplation-action) or processes. Researchers have tried to remedy this problem by measuring an individual's readiness to change using a continuous measure in place of an algorithm that forces each individual into a stage. The problem exists, however, when the participants' readiness to change is measured on a continuum but the concept of stages is retained (262). If individuals are in more than one stage at a time, the fundamental requirement of a stage theory is no longer met (225). The ten processes of change have also come under a considerable amount of scrutiny in the literature. Psychological change is dynamic, featuring reciprocally interacting cognitive, behavioral, and environmental influences (225). According to this theory, it is the knowledge of these mechanisms that should most effectively determine the selection and use of interventions, not descriptive categories. Ryan and Deci (263) state:

> "One does not have to progress through each stage of internalization with respect to a particular regulation; indeed, one can initially adopt a new behavioral regulation at any point along this continuum depending on prior experiences and situational factors…there is no necessary "sequence."

4.2.5.4 Self-Determination Theory

Self-determination theory (SDT) is a macro-theory of human motivation concerned with the development and functioning of personality within social contexts. The theory focuses on the degree to which human behaviors are self-determined - that is, the degree to which people

endorse their actions at the highest level of reflection and engage in the actions with a full sense of choice (263-265).

SDT evolved over the past three decades as a set of four mini-theories that share the concept of basic needs (263; 266). Each mini-theory was developed to explain a set of motivationally based phenomena that emerged from laboratory and field research focused on different issues. Cognitive evaluation theory addresses the effects of social contexts on intrinsic motivation (264). Organismic integration theory addresses the concept of internalization especially with respect to the development of extrinsic motivation (264). Causality orientations theory describes individual differences in people's tendencies toward self-determined behavior and toward orienting to the environment in ways that support their self-determination (264). And basic needs theory elaborates the concept of basic needs and its relation to psychological health and well-being. Together these mini-theories constitute SDT (264).

Within SDT, the components for healthy development and functioning are specified using the concept of basic psychological needs, which are innate, universal, and essential for health and well-being. Basic psychological needs are a natural aspect of human beings that apply to all people, regardless of gender, group, or culture. To the extent that the needs are continually satisfied, people will function effectively and develop in a healthy way, but to the extent that they are dissatisfied, people will show evidence of ill-being or non-optimal functioning (222; 264) Ryan and Deci (263) identified these psychological needs as the need for competence, relatedness, and autonomy. These needs are essential for facilitating optimal functioning, growth, and integration (263). Thus, the objective of SDT is the investigation of people’s inherent growth tendencies and their innate psychological needs that are the basis of their self-

motivation and personality integration, as well as the conditions that foster those positive processes (263).

SDT provides an example of how a theoretical analysis of motivation improves upon the Transtheoretical Model. For example, lack of motivation to make a behavior change can be due to a number of reasons, such as the person not valuing the activity, low self-efficacy, or the belief that change will not yield a desirable outcome. Different underlying reasons for lack of motivation at any point in the process of changing a behavior may require different interventions. Self-determination theory also considers not only the level of motivation but also the degree to which the motivation is extrinsic or intrinsic (263). The theory proposes a continuum of motivation ranging from external regulation to intrinsic motivation, reflecting different degrees of autonomy or self-determination. The greater the person's autonomy or intrinsic motivation is, the greater the person's likelihood of learning and sustaining a behavioral change (263). SDT also considers the extent to which significant others in a person's social context are autonomy supportive, which means that significant others understand the person's choices, and provide relevant information. According to the theory, a person will develop and maintain an increased level of autonomous motivation to the extent that significant others are autonomy supportive (264).

Applying Self-Determination Theory to Diabetes

In the past, research that examined psychosocial issues and patient-provider relationships in diabetes care mainly focused on adherence and compliance. However, a large body of work has gone far beyond the issues of adherence and compliance and the implications of these terms in diabetes care. Anderson (267) suggests that the use of the constructs of "compliance" and

"adherence" are counter-productive because they both construe the problem to be the patient's behavior. Anderson followed up with this concept in developing the Empowerment Approach to Diabetes Education (80-82) which is a patient-centered, collaborative approach tailored to match the fundamental realities of diabetes care (252). Glagow et al. (268) also criticized the concepts of compliance and adherence based on their lack of utility, sending the wrong message to patients and to healthcare professionals (221) as adherence and compliance behaviors are multi-dimensional, not a single unitary concept.

During the past five years, SDT, an additional alternative approach to compliance and adherence, emerged in the diabetes literature. The application of STD to diabetes is somewhat different than the application of the Health Belief Model or the Transtheoretical Model. SDT views motivation as psychological energy that is directed toward particular goals (269). Studies, which use STD, hypothesize that people with diabetes have greater motivation if their health care provider supports their autonomy, competence, and relatedness. They also test the hypothesis that if a patient feels more autonomous and competent, they will have better glycemic control and better quality of life (269). To date, Williams et al. (269-271) and Senecal et al. (208) are the only research groups studying concepts of self-determination theory in relation self-care behavior and to DSME. They use the term "autonomy motivation" to refer to the psychological process that drives patient behavior change and the term "autonomy support" to refer to actions by healthcare professional that enhance patient autonomy motivation (221; 271). Individuals tend to feel more competent when they are autonomously motivated and that autonomy support enhances felt competence and autonomous motivation (271).

In the first Williams et al. study (271), the objective was to explore factors that were hypothesized to relate to the patient becoming more motivated for long-term glucose control,

building on the results of the DCCT. Patients who perceived their health care providers to be more autonomy-supportive (provides choices, listens and acknowledges patient perspective, and provides clear rationale for behavior change) improved their glycemic control over 12 months (8.4 vs. 8.1, $p<0.01$, 8.4 vs. 8.0, $p<0.01$) and they reported greater autonomous regulation of their treatment regimen in comparison to those who did not perceive their provider as autonomy supportive (271). An increase in perceived competence accounted for the significant decrease in HbA1c levels ($\beta = -0.31$, $p<0.001$) (271). The authors concluded that when the health care climate is rich with provision of choice, information about the problem, acknowledgement of patients' emotions and minimal pressure to behave in particular ways, patients might display improved metabolic outcomes.

The second Williams et al. study (269), a randomized trial of patient activation versus passive education, examined whether using the patient-activation approach introduced in the Expanding Patient Involvement in are (EPIC) trials might also prompt providers to be more autonomy supportive. If patients are taught to take greater initiative during their provider visits, the providers might in turn be more supportive of the patients' autonomy for self-management (270). Thus, patients experiencing the activation intervention may have more internalization of autonomy and competence. Williams et al. concluded that change in perceived competence was found to predict diabetes self-care behaviors and maintenance of change in glycemic control over the period of six months to 12 months. In addition, perceived autonomy support predicted change in autonomous motivation and was a marginal predictor of change in perceived competence (269).

The third and final study, by Senecal et al. (208), examined constructs drawn from SDT in relation to dietary self-care and life satisfaction among people with diabetes. Results

demonstrated that both self-efficacy and autonomous self-regulation were associated with adherence (β = 0.54 and 0.21, respectively) and with life satisfaction (βs = 0.15 and 0.34, respectively). Further analyses confirmed that self-efficacy was significantly more associated with adherence, where as autonomous self-regulation was significantly more associated with life satisfaction. Based on the model, the authors concluded that interventions for dietary self-care and life satisfaction in people with diabetes should focus on increasing self-efficacy and autonomous self-regulation (208).

While the literature on Self-Determination Theory and diabetes remains sparse, it is growing as SDT gains more popularity in diabetes research. The patient empowerment approach to diabetes education (described in the next section), developed by Anderson, is in fact rooted in Self-Determination Theory and has been prevalent in the diabetes literature since the early 1990s. Multiple studies using the empowerment approach have been conducted and published over the past decade, as empowerment has become an important concept in diabetes education, despite the changes that have occurred in our culture, healthcare system, and health practices (81).

4.2.5.5 Empowerment

Empowerment is a vision or a philosophy. It is not thought of as a theory or a model. Anderson and Funnell (81) define empowerment as "the discovery and development of one's inherent capacity to be responsible for one's own life." People are empowered when they have sufficient knowledge to make rational decisions, sufficient control and resources to implement their decisions, and sufficient experience to evaluate the effectiveness of those choices (81). Empowerment is not a new concept as it has been used in other educational contexts for many years. It has its underpinnings in the work of educators and psychologists who have worked

primarily with socially disadvantaged populations (98). Anderson and Funnell (79) chose empowerment to describe their philosophy of diabetes education because it is based on the assumption that to be healthy, people with diabetes must be able to bring about changes not only in their personal behavior, but also in their social situations and the organizations that influence their lives (98). The empowerment approach reflects Anderson and Funnell's belief in patient autonomy and the right and responsibility of patients to make their own choices, concepts that are deeply rooted in Self-Determination Theory and self-motivation (81). Empowerment is not a tool that is applied to patients at an appropriate "stage" in their illness. The vision of empowerment guides each encounter with patients at every stage of their illness.

Historically, most diabetes educators accepted compliance/adherence as an appropriate goal for diabetes education (267). It was the standard used to evaluate patient behaviors and the success or failure of a diabetes educator (81). Because of this "do or die" role that the educator had to play, they were becoming increasingly burned out from being held responsible for accomplishing the impossible – motivating and changing others. Because of this frustration, the Michigan Diabetes Research and Training Center developed a statement about Anderson and Funnell's vision of diabetes education. It was through this process that the empowerment approach to diabetes education was initiated.

Empowerment is quite different from the traditional medical model of diabetes education, which often resembles a paternalistic relationship. The healthcare provider is seemingly the adult who reprimands his/her disobedient child for not adhering and complying with his/her recommendations for self-care and ultimately thinks that when it comes to his/her patients' diabetes, they know best (99). Practicing within the empowerment philosophy requires the much-needed paradigm shift from provider-centered care, as exemplified above, to patient-centered

collaborative care. The goal of diabetes education, within the empowerment approach, is to enable patients to make informed choices, not to get them to comply with or adhere to provider-selected goals (81). Behavioral strategies are not applied to patients to get them to change, as they are in the models/theories mentioned previously. Instead, these strategies are taught to patients who use them to change behaviors on their own. When a diabetes educator adopts the empowerment approach, their role is no longer to change their patients' behavior, but to inspire, inform, support, and facilitate their efforts to identify and achieve their own goals (81).

Recognition and viability of the empowerment approach has grown tremendously over the past decade, from a philosophy that was only acknowledged by a few diabetes educators to being an integral part of the diabetes education organization. Since the first article on diabetes and empowerment was published in 1991, there have been 79 articles published on this subject, including randomized controlled clinical trials of diabetes education using the empowerment approach (80). Several of these studies have documented that the empowerment approach and similar approaches (collaborative care and problem-directed education) are effective and that patients do achieve outcomes that are both personally and metabolically desired despite not being directed to do so (76; 136; 147). These studies have reported that patients are able to identify goals that are important to them and achieve behavioral changes that facilitate meaningful improvements in outcomes (81). Because these changes are identified as something important to the patient, they are more likely to be sustained than changes recommended by others.

As stated previously, our healthcare system is based on an acute, medical care model that often fails to adequately account for the individual patient, creating a distance rather than collaboration between patients and providers (117; 124; 142; 171; 272; 273). In order to

effectively implement the empowerment approach, patients need patient-centered education designed to promote informed decision making, and providers need to practice in ways that support patient efforts to become effective self-managers (82). If we wait for the healthcare system to value and foster patient-centered care, we may be waiting a long time. System-specific strategies can be implemented by practices to promote patient-empowerment and self-management (117). These efforts include creating patient-centered practices and providing active, ongoing self-management support using a team approach to diabetes care. Adopting the empowerment approach to diabetes education does not enable educators or healthcare providers to directly change patient behavior per se, but it does allow them to adapt their own practices while establishing and equal partnership with patients and creating relationships that nurture, sustain, and satisfy both the patient and the provider (81).

Theory is a tool that can significantly enhance the ability of the person using it to achieve certain, quantifiable objectives and improvement in behavioral and psychological/psychosocial outcomes (80; 207; 274-277). However, because theory is only a tool, the vision and skills of the person using it will always dominate. Linking theory to behavior and health outcomes not only helps move diabetes care forward, but also has the potential to enhance care for other chronic conditions (269). General theories of behavior (e.g. self-efficacy, self-determination theory) apply to practitioners as well as patients in understanding how practitioners can change their own behavior with respect to counseling their patient. Examining the effect of these practitioner level variables on patient and system level outcomes is still in its infancy. However, current and future research is beginning to tackle this concept.

4.3 DELIVERY SYSTEM DESIGN

Improving the health of people with chronic illness requires transforming a system that is essentially reactive – responding mainly when a person is sick – to one that is proactive and focused on keeping a person as healthy as possible (76). For diabetes, it is essential to assure the delivery of effective, efficient clinical care and self- management support. This requires not only determining what care is needed, but also spelling out roles and tasks to ensure that the patient gets care using structured, planned team approach interactions, and making sure that all healthcare providers are delivering patient-centered, up-to-date information about the patient's healthcare plan. These changes require utilizing a team of healthcare professionals (e.g. physicians, nurses, dietitians, diabetes educators, social workers, pharmacists) who have the knowledge and time to carry out the range of tasks required to manage diabetes (278). Making follow-up a part of standard procedure is also critical, so patients are not left on their own once they leave the doctor's office (76; 77). Health literacy and cultural sensitivity are also important concepts in diabetes care as providers are increasingly being called upon to respond effectively to the diverse cultural and linguistic needs of patients due to the racial/ethnic and socio-economic variation in diabetes (37). In a well-designed delivery system, using the aforementioned components, providers plan visits well in advance, based on patient needs and self-management goals. Effective management of chronic illness requires more than simply adding interventions to an existing system focused on acute care. Successful chronic illness programs, by contrast, maintain regular contact and prevent losses to follow-up with their patients, collect critical data on health and disease status regularly, meet educational and psychosocial needs, and respond appropriately to clinical needs (76).

4.3.1 Practice Redesign in Western Europe

With the transition of disease from acute to chronic, the responsibility for the care of people with diabetes has shifted away from hospitals to primary care (117; 279; 280). Efforts to redesign chronic illness care range along a continuum of intensity of care to enhance primary care at one end to providing care by specialists at the other. In the middle of the continuum are models that add specialized personnel to primary care teams (76). This restructuring of primary care was observed several years ago in Western European nations when the care of chronically ill patients was gravitating from primary care to hospital-based clinics run by specialists (76; 77). Concerns about cost and fragmentation of care began efforts in several countries to improve the management of chronic illnesses in primary care and to return care to the general practitioner (76). Finnerty et al. (281) improved hypertensive care for inner city residents by reorienting clinic operations to make them more responsive to the needs of hypertensive patients through the use of health aides, appointment reminders, and easier access to services. Additionally, the British Chronic Care Clinic (282; 283) or "mini-clinic" also changed the orientation and design of primary care practices, but in a periodic way. The mini-clinic is a block of time, integrated into the provider's practice that is devoted to and organized for the care of patients with a particular condition, like diabetes. After being identified through disease registries maintained by the practice, patients are invited to attend the clinic. The practice redesign using mini-clinics included specially designed visits with the primary care practice team at regular intervals, a planned set of assessments, visits with various health professionals, a group meeting, and systematic follow-up (282; 283). The widespread adoption of mini-clinics received national recognition in 1990, when they became reimbursable through the National Health Service (76).

The Swedish National Board of Health and Welfare developed primary care based diabetes programs as a more traditional approach to redesigning their practices. These programs placed special emphasis on diabetes training and education. A study of this program demonstrated that provider education alone did not increase compliance to guidelines (284). Further research revealed that most practices did not have the capacity to even consider new approaches to care, much less plan their incorporation into a busy practice (284). A solution was reached when an effort at encouraging practice team meetings and redesigning practice systems to improve adherence with guidelines and patient self-management behavior was implemented (77).

Finally, a structured teaching and treatment program for patients with diabetes was developed in Germany to improve primary care for chronic illness (285). These programs emphasized group patient education conducted by the practice and an extensive provider education effort, along with financial incentives. These multi-session education programs received by both patients and providers resulted in a significant weight reduction and improved disease control (166; 285).

4.3.2 Adoption of the Mini-Clinic/Group Visit in the U.S.

In recent years, the adoption of diabetes mini-clinics/group visits by researchers and practitioners in the U.S. has emerged. The use of mini-clinics or group visits for patients with chronic illnesses has recently been linked to better metabolic control (272; 286), reduced hospitalization (287), improved knowledge (286), better quality of life (272; 286), and improved process measures indicating better follow-up of patients (272; 288). Beck and colleagues (287) studied “group consultations” for older patients in a randomized trial and found that such patients were more satisfied, more up to date in preventive care, and used health services less often than comparison patients. Wagner et al. (272) evaluated the impact of primary care group visits on the

process and outcome of care for patients with diabetes. He found that in comparison with control patients who received usual care, the intervention group received significantly more recommended preventive procedures and helpful patient education (272). Further, intervention patients had slightly more primary care visits, but significantly fewer specialty and emergency room visits. Consistent positive associations between the number of group visits attended and patient satisfaction and A1c levels were observed (272). Group consultations or visits may provide the most efficient vehicle for the delivery of team care and subsequently better quality of care for people with diabetes.

Only recently have U.S. researchers acknowledged the need for practice redesign. During the transition period from acute to chronic disease, primary care practices in the U.S. should have modeled themselves after the European approaches by redesigning their systems in order to accommodate their patients with diabetes and other chronic illnesses. Implementation of a number of specialized personnel (e.g. CDEs) as part of the primary care practice team should have occurred (278). The delegation of key tasks to appropriate members of the practice team, especially non-physicians, is the central feature of successful programs and is an important element of team care planning (114). Adding to the compelling evidence of practice redesign and the association with improvement in metabolic control in people with diabetes, studies have demonstrated that if regular contact with patients is guaranteed (an element that could be implemented by a CDE), the standard of diabetes care in primary care can be improved (289).

4.3.3 Multi-faceted Diabetes Care Interventions

Several guidelines and diabetes self-management programs have been developed nationally and locally to try to improve diabetes care in the community. However, studies have shown that compliance with diabetes clinical practice recommendations is sub-optimal in

primary care (106) and that a large proportion of patients with diabetes remain at high risk for complications (32) – an effect of an inadequate practice design. Consequently, a wide range of interventions aimed at improving diabetes care and achieving better metabolic control for patients with diabetes have been studied (117). It is through these interventions that we can begin to understand the best way of narrowing the gap between what is known to be effective in diabetes care and the care that is currently provided in order to redesign primary care practices to enhance care for people with diabetes.

Renders et al. (117) conducted a systematic review of controlled trials evaluating the effectiveness of interventions targeted at health care professionals who care for nonhospitalized patients with type 1 or type 2 diabetes in primary care, outpatient, or community settings. The interventions were aimed at improving the processes of care or patients outcomes for patients with diabetes. Studies were only included if they were randomized or quasi-randomized trials randomized by patient, healthcare professional, or practice, interrupted time series, or nonrandomized studies controlled at a second site with data before and after the intervention and appropriate choice of control site (117). Interventions were classified as professional, financial, organizational, or any combination of these. Studies that implemented only patient-oriented interventions were excluded, as these studies do not help to determine the most effective ways to deliver diabetes care.

A total of 41 heterogeneous studies met the inclusion criteria and in all of the studies, the intervention strategies were multi-faceted (i.e. intervening at the more than one level of care). The majority of the studies were interventions based on local and national clinical practice guidelines and in nearly all studies included, postgraduate education was part of the multi-faceted intervention (117). Renders et al. found that combining patient education, a nurse, or

both with arrangements for follow-up or multiple professional interventions led to improvements in patient outcomes as well as the processes of care (117). Nurses, and more specifically, certified diabetes educators, can communicate with, both, the patient and the physician, to help facilitate patient education, and even assume some of the responsibilities of the physician.

Although the studies reviewed were able to provide some information as to what is effective in diabetes care compared to the care that is currently provided, all studies evaluated had methodological limitations ranging from inadequate concealment allocation to randomization errors in which patients or providers were randomized within a clinic or practice, thereby making them prone to contamination (117). Measurements varied between intervention and control groups and in some studies, blinding was only partly adequate. High dropout rates were also prevalent, which reduced the study's power to detect significant differences if they truly existed. In 25 of the studies reviewed, the follow-up period was less than one year, therefore making it unclear as to whether these multi-faceted interventions can be sustained in the long-term (117). Finally, reported outcomes were corrected for clustering (an essential component of analysis of multi-faceted interventions) at the health care professional or practice level in only one study.

Renders et al. concluded, based on their systematic review, that organization in practice, such as enhancing the role of the nurse or implementing central computer systems that improve the delivery of complex packages of care, are likely to have an impact on the provision of care for diabetes, along with a wide range of other conditions, especially in the short-term (117). However, due to the many limitations that plagued the studies under review, solid conclusions are limited, as more research on the long-term effectiveness of multi-faceted interventions, which may improve process and clinical outcomes, is needed.

4.4 DECISION SUPPORT

It is crucial to promote diabetes clinical care that is consistent with scientific evidence and patient preferences. Treatment decisions need to be based on explicit, proven guidelines supported by clinical research, such as the American Diabetes Association Standards of Care (113), the Diabetes Quality Improvement Project (DQIP) measures (104; 290), the American Association of Clinical Endocrinologist's (AACE) Medical Guidelines for the Management of Diabetes Mellitus (291), and/or the National Standards for Diabetes Self-Management Education (111) (discussed previously) in order to demonstrate if quality care is being delivered. Guidelines should also be discussed with patients, so they can understand the principles behind their care. For example, patients should understand the goal levels for their diabetes care and why they are getting (or not getting) the appropriate treatment.

4.4.1 Clinical Guidelines

In the late 1980s and early 1990s, several organizations developed performance measures and guidelines for diabetes care, but the result was that providers were often required to collect and report many different, often times conflicting, measures, depending on their care delivery system (104). It was, therefore, recognized that a national consensus on measures could enhance this process and provide a method for assessing care within and across health care settings while providing a meaningful mechanism for quality improvement (104). Consequently, national performance measures and care guidelines were developed to provide a unified set of diabetes-specific performance and outcome measures that serve as benchmarks for quality-of-care measurement (115; 290). These measures and guidelines provide standards for optimal diabetes care, allowing for a comparison of providers, health systems, and insurers, not only to measure quality of care, but also to identify targets for quality improvement efforts (115). These

measures or benchmarks should be integrated into daily practice through a delivery system allowing expertise to be integrated through timely reminders, feedback, standing orders and other methods that increase their visibility at the time that clinical decisions are made.

4.4.1.1 ADA Standards of Care

The American Diabetes Association Standards of Medical Care (113; 159; 292) are intended to provide clinicians, patients, researchers, payers, and other interested individuals with the components of diabetes care, treatment goals, and tools to evaluate quality of care (292). The standards of care define basic medical care for people with diabetes. While individual patient factors may require modification of these standards, the ADA has chosen targets that are evidence-based and desirable for most patients with diabetes. The standards are not intended to replace more extensive evaluation and diabetes management as needed (113; 292).

The standards of care are based on a complete review of the relevant literature by a diverse group of experts in diabetes care. After weighing the quality of evidence from rigorous double blind clinical trials, recommendations are drafted, reviewed, and submitted for approval to the ADA Expert Committee. The recommendations included are diagnostic and therapeutic actions that are known or believed to favorably affect health outcomes of patients with diabetes (292). The standards of diabetes care seek to provide 1) physicians and other health care professionals who treat people with diabetes with a means to set treatment goals, assess the quality of diabetes treatment provided, identify areas where more attention or self-management training is needed, and define timely and necessary referral patterns to appropriate specialists; and 2) provide people with diabetes a means to assess the quality of medical care they receive, develop expectations for their role in the medical treatment, and compare their treatment outcomes to standard goals (113).

4.4.1.2 Diabetes Quality Improvement Project (DQIP)

The DQIP was founded in 1997 through a partnership between the Center for Medicare and Medicaid Services (CMS), the National Committee for Quality Assurance (NCQA), the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), and the American Diabetes Association (ADA)(104; 290). The operations group was created of public and private sector organizations and agencies to provide general direction, and a Technical Expert Panel (TEP) was formed to develop quality performance measures. The Operations Group included the American Diabetes Association, the Foundation for Accountability in Health Care (FACCT), CMS, NCQA, the American Academy of Family Physicians-American Society of Internal Medicine (ACP-ASIM), the Centers for Disease Control and Prevention (CDC), and the Veterans Health Administration (VHA) (104). The goal was to establish a single, unified set of diabetes-specific performance measures for diabetes care quality improvement and accountability in the United States. The objective was to develop new performance measures that have the capability of retrospectively assessing the level of care delivered across the entire population with diabetes, in contrast to the ADA Standards of Care, which recommend the desired level of care for a single patient (104). In order to meet the criteria for a performance measure, the measure had to include 1) a strong evidence base; 2) feasibility, reliability, and sustainability for uniform application across health systems; and 3) variability across populations so that improve can be monitored (104). To ensure that these measures comprehensively represented diabetes management, endocrinologists, internists, family physicians, dietitians, educators, nurses, epidemiologists, and experts in performance measurement were included on the expert panel, as well as individuals from large group practices, managed care plans, and federal healthcare agencies (104).

Two classes of performance measures were developed. Accountability measures include credible evidence linking process measures to important clinical outcomes and the degree to which clinical outcomes could be modified (i.e. they could be improved) by the efforts and interventions of health care systems (104). The feasibility of these measures includes whether the measure could be collected accurately, reliably, and at a reasonable cost, and variability across health care settings ensured that there would be opportunity for improvement (104). The second class of performance measures are referred to as quality improvement measures, as these met the evidence base applied to the accountability measures but could not be measured across different health care settings (104). DQIP represents the first widely adopted, comprehensive performance measurement standards, not just for diabetes but for any single chronic disease (104; 290).

4.4.1.3 AACE Medical Guidelines for the Management of Diabetes Mellitus

In 1994, the American Association of Clinical Endocrinologists (AACE) developed a system of intensive diabetes self-management. This system is the core of the AACE Medical Guidelines for the Management of Diabetes Mellitus. The AACE guidelines differ from the ADA Standards of Care and DQIP in that a key component of the AACE system of care is a patient-provider contract, which maintains the importance of the patient-provider relationship and the patients' participation in their own care (291). The system includes concepts of care, the responsibilities of the patient and physician, and the appropriate intervals of follow-up assessment. Also included is the timing of required laboratory testing, determined by evidence-based and consensus clinical experience (291).

4.4.2 Personalized Provider Education

The most common approach to increasing provider expertise has been continuing medical education in a variety of forms. Another aspect of decision support, that is critical in diabetes care, is to ensure that those who make treatment decisions receive ongoing training to stay current with the latest evidence, using new models of provider education such as tutorials (293), academic detailing (294), consultation conferences (195) and related interventions, that improve upon traditional continuing medical education (76). There is a general agreement in the literature that conventional didactic lecture approaches have no enduring effects on practice style (295). However, new, more personalized approaches to provider education have been proven effective (195; 293; 294). For example, when using academic detailing for educating providers on diabetes-management, a diabetes specialist visits a provider in his/her office to provide a 15 to 20 minute educational intervention on a specific topic (76; 294). The purpose of academic detailing is to provide complete and objective information based on best available evidence. Further, providers can receive continuing education credits for the time they spend with the detailer (76; 294). These more "hands-on" approaches have demonstrated an impact among physicians and serve as a template for providing more personalized, hands-on methods of physician education.

4.4.3 Integration of Specialist Expertise into Primary Care

While the aforementioned provider education strategies have been proven effective, they cannot meet the ongoing needs for expertise in the management of specific patients. Evidence has demonstrated that quality diabetes care, as measured by processes and outcomes that is delivered by specialists is better than that delivered by generalists (115). Zgibor and Orchard (115) reported that those people receiving care from diabetes specialists were more likely to receive diabetes education, to be treated with intensive insulin therapy (> 2 injections/day), and

to receive an eye exam compared to those receiving generalist care. Further, in subjects less than 18 years of age, lower rates of proliferative retinopathy were observed in those receiving a higher proportion of their diabetes duration in specialist care, along with lower incidences of neuropathy, overt nephropathy, and coronary artery disease (115). However, despite these better outcomes, not all people with diabetes need to be treated by a specialist. Specialist care requires conventional referral or consultation, which remains the dominant source of expert assistance in diabetes care and management. Referrals have the potential of fragmenting care, not increasing the skills of the referring physician, and ultimately, contributing to increased costs (405). As most people with diabetes receive care in the primary care setting, health insurers often view primary care as a more cost effective source of care than specialists (296). Over the years, primary care providers have been viewed as coordinators of care and a channel to the specialist. For many patients with diabetes, the primary care provider is the person who determines whether they "need" specialist care (83; 297). This 'gatekeeper' phenomenon results in patient and provider confusion and lack of continuity of care (115). Therefore, implementing the constructs of specialist care into primary care may be a more cost effective method for delivery of diabetes care.

Although the need for more expertise plays a role, the evidence suggests that the system effects are even greater (77). The Medical Outcomes Study (298) showed that usual specialist primary care for diabetes and hypertension was not substantially better than usual generalist care in the same communities, and neither system was optimal (298). Recent studies have suggested that specialist run diabetes clinics achieve better outcomes than usual generalist care (278; 299; 300). They reorganize care specifically to meet the clinical, educational, and psychosocial needs of people with diabetes. Therefore, alternatives to referrals for conventional specialist care have

been and need to be explored, namely, a reorganization of care which integrates specialist expertise into primary care.

Collaborative care (discussed previously) is one of the strategies that makes specialist expertise available in primary care as specialists and generalists manage patients together in the primary care setting (301). The integration of specialist expertise into primary care is crucial due to the complexity of diabetes care and management. When primary care providers were surveyed regarding delivery of diabetes care, they reported that they did not feel adequately trained or prepared, and may not be able to focus on the psychosocial and educational needs of their patients (302). They also viewed diabetes as a difficult disease to treat in comparison to other chronic illnesses, due to its complexity and required coordination of care (302). Therefore, translating the patterns of care delivered by specialists and other specialty providers (e.g. diabetes educators) to generalists in the primary care setting is critical as the current primary care model in unlikely to be adequate for patients with diabetes. Moreover, because diabetes specialists or specialty care teams are more focused on the care of patients with diabetes, the integration into primary care may ultimately improve long term outcomes (115; 303).

A prime example of reorganization of care focusing on the generalist-specialist interaction, is the work of the Group Health Cooperative, which relies on a three-tiered system of diabetes care consisting of an expert team (diabetologist and nurse specialist), who spend most of their time in the primary care setting supporting local experts (generalist physicians with a particular interest in diabetes and certified diabetes educators), educating generalist providers, and seeing difficult patients, jointly, with the primary care teams (123; 194). Such a model that distributes

expertise may prove to be far more cost effective for diabetes than the more conventional specialty care or specialty referral models (76).

Adding to the evidence that diabetes care and coordination needs to be reorganized are the recent studies that have suggested that specialist run diabetes clinics achieve better outcomes than usual generalist care (115; 280; 304). Such clinics, including those in the DCCT (5) involve much more than specialized physicians (300). As discussed previously, nurse case management was an integral part of intensive therapy in the DCCT (68) and has been proven to be effective in reducing smoking and cholesterol levels after acute myocardial infarctions (68). The success of the DCCT relied heavily on the use of case managers who worked closely with patients on the lifestyle and medication changes required to achieve glycemic control (300).

A simple method of translating specialist expertise into primary care is through the use of a case manager. Therefore, a number of researchers (218; 278; 305; 306) have begun to examine the effect of a nurse case management or disease management model of care on patient outcomes. Aubert et al. (278) conducted a 12-month randomized, controlled trial, comparing a nurse case management model of diabetes care with usual diabetes management in the primary care setting (278). Patients in the nurse case management group had a decrease in mean A1c levels of 1.7% compared to those in the usual care group who had a decrease of 0.6%. Additionally, self-reported health status improved in the nurse case management group (278). Taylor et al. (305) evaluated the efficacy of a nurse-care management system designed to improve outcomes in patients with complicated diabetes through a randomized controlled trial (305). In this study, conducted at Kaiser Permanente Medical Center, patients with longstanding diabetes, one or more major medical comorbid conditions, and an A1c > 10% were randomized

to either a special intervention, consisting of meeting with a nurse care manager, group sessions, and telephone calls, or usual care for one year. At one year, mean reductions in A1c (intervention group: 1.14% vs. usual care: 0.35%), total cholesterol (intervention group: 20.6 vs. usual care: 11.5), and LDL cholesterol (intervention group: 19.4 vs. usual care: 6.5) were significantly greater for the intervention group compared to the usual care group (158). Additionally, significantly more patients in the intervention group met the goals for A1c (<7.5%) than patients in usual care. However, there were no significant differences in any of the psychosocial variables or in the number of physician visits between groups (305). Finally, Clarke et al. (218) reported on a survey of self-reported data from 750 participants in a comprehensive diabetes management program. Their underlying assumption was that if patients had regular, personal contact with nurses and ancillary health professionals, lifestyle behavior changes would be able to be facilitated and sustained (218). Results showed strong perceptions of positive behavior change over a broad range of medical and lifestyle treatment areas associated with effective management of diabetes. These results suggest that diabetes disease management programs are effective approaches to help patients accomplish critical lifestyle behaviors (218).

The aforementioned disease management programs all have common features, which aid in their successes. All of the programs address the critical role that patients play in managing their diabetes by assuring that case managers are trained educators with ready access to a defined set of high-quality educational offerings (300). Also, the delivery of care is redesigned to give patients more time with the case manager, access to a broader array of resources and expertise, and closer follow-up. Explicit guidelines and regular communication with specialists are also integral to the disease management programs, and collection and organization of relevant data for individual patients and populations support population-based care, reminders, and feedback

(300). Through the use of these multi-faceted approaches to diabetes care, coordination of care is improved, better outcomes are achieved and, effective systems are built.

4.5 CLINICAL INFORMATION SYSTEMS

Effective chronic illness care is virtually impossible without information systems that assure ready access to key data on individual patients as well as populations of patients (307). A comprehensive clinical information system for tracking and monitoring interventions as well as patient, practice, or population-based outcomes is a critical component of effective chronic disease management (307; 308). Clinical information systems can enhance the care of individual patients by providing timely reminders about needed services and summarized data to track and plan care. At the practice population level, they identify groups of patients needing additional care as well as facilitate performance monitoring and quality improvement efforts (307).

Information systems do not have to be elaborate, although increasingly they are becoming electronic (308). In the absence of specialist or specialty group expertise, computer decision support systems may meet some of the day-to-day needs for expert advice (76). Computerized information has three important roles: 1) as registries for planning individual care and conducting population-based care; 2) as reminder systems that help primary care teams comply with practice guidelines; and 3) as feedback to physicians, showing how each is performing on chronic illness measures such as A1c and lipid levels (76; 77; 85; 307; 308).

4.5.1 Registries

Information systems should include disease registries that include information about patients, their care, and their outcomes, as this is an essential ingredient of all population-based strategies to improve chronic illness care, more specifically, diabetes care (76; 77; 308). The use

of a registry gives healthcare providers the ability to track, monitor, and provide feedback on interventions and outcomes (308). Without the use of a registry, providers are forced to be responsive to patients, waiting for them to present for care, rather than inviting or reminding patients to participate in care in accord with a predetermined plan of care. Health care teams that have access to a registry can call in patients with specific needs, deliver planned care, receive feedback on their performance, and implement reminder systems (307).

The use of registries plays an important role in both physician reminder systems and feedback. For example, the registry may feed into a reminder pop-up message on the electronic medical record, which flags laboratory work or exams not performed according to schedule (85). For individual patients, registries can be used to print reminder sheets for each visit, while as a population tool, they can electronically risk stratify a practice population to identify patients with elevated laboratory values or those requiring a referral to a specialist (85).

4.5.2 Reminder Systems

There is documentation in the literature that simple, integrated computer-based clinical reminder systems are consistently effective in promoting recommended preventive procedures and behaviors in patients (76; 77; 85; 307-310). Shea et al. (311) conducted a meta-analysis of 16 randomized controlled trials to evaluate computer-based clinical reminder systems for preventive care in the ambulatory setting. Computer reminders improved preventive practices compared with the control condition for vaccinations, breast cancer screening, colorectal screening, and cardiovascular risk reduction, but not cervical screening or other preventive care, such as dental screening and breast and testicular self-exam (311). While reminders for diabetes-related conditions were not included in this meta-analysis, many of the aspects of the cardiovascular risk reduction reminders include services that should be provided to people with

diabetes, such as blood pressure checks and hypertension follow-up, dietary assessment and counseling, and cholesterol screening (311).

A more sophisticated system for patients with diabetes might track A1c and lipid values, self-management goals, blood pressure levels and documentation of screening for eye, foot, and renal complications ((308). Toth-Pal (445) and Balas et al (309) conducted studies to evaluate the effects of a program for computer generated physician reminders specific to diabetes. Both studies proved that computer generated reminder systems were effective in increasing laboratory and manual screening tests (444), prompting follow-up procedures (309), and computerized insulin therapy adjustment using home glucose records (309; 310). Finally, a real world application of a system that focuses on provider reminders to enhance diabetes care is the Diabetes Electronic Management System (DEMS). DEMS is a chronic disease management system for patients with diabetes (312). All members of the diabetes team including physicians, nurses, dietitians, clinical assistants and diabetes educators use it at the point of care. Because it is designed for ease of navigation, automatically generated reports, quality audits, aids to compliance with good care guidelines, alerts, advisories, prompts, and warnings that guide the healthcare provider, it is a quality system that can be implemented into several aspects of chronic illness care. DEMS now contains data on over 34,000 patients and is in daily use at multiple sites worldwide (312).

4.5.3 Physician Feedback

Registries also facilitate the provision of feedback to the practice (76). Several rigorous studies have shown variable impacts of feedback (306). It is logical that healthcare professionals would modify their practice if given feedback that their clinical practice was inconsistent with that of peers or accepted guidelines (313); however, provider feedback has not been found to be

consistently effective. Jamtvedt et al. (313) recently conducted a systematic review to assess the effects of feedback on the practice of healthcare professionals and patient outcomes. Of 85 studies included in the review, the one factor that appeared to predict the effectiveness of feedback across studies was baseline non-compliance with recommended practice (313). The authors concluded that while feedback can be effective in improving professional practice, the effects are generally small to moderate. This variability may be explained by the differences in the study populations (e.g. residents may be more responsive to feedback than mature physicians) or by the context in which the feedback was given (e.g. personal communication from an expert is more powerful than receiving feedback in the mail). Three diabetes specific studies (119; 314; 315) demonstrated this same variability. In studies evaluating the impact of provider feedback on the processes and intermediate outcomes of care, provider feedback modestly improved outcomes in patients with diabetes. Although feedback has mostly been studied in isolation, as the only clinical improvement strategy being tested, it may have much greater utility when used in the context of more comprehensive approaches to improving outcomes in chronic illness care (76).

The six components of the chronic care model are interdependent, building on one another (85). Exercise programs and peer support groups are community resources that help patients with diabetes acquire self-management skills. Redesigning the ways in which care is delivered in the system through the use of a diabetes care team, based in primary care, is essential to teach self-management because physicians do not have the time or may not be properly trained to deal with the complex management and coordination of care that diabetes requires (85). For diabetes registries to be successful, redesigning delivery systems is necessary so that members of the diabetes team are responsible for working with the registry. Clinical

practice guidelines, like the ADA Standards of Care or DQIP, provide evidence upon which physician feedback data and reminder systems are based. Finally, these elements of the CCM are unlikely to be maintained without an organizational environment featuring innovative leadership (85).

A combination of all of the aforementioned elements of the CCM should produce an informed, activated patient interacting with a prepared, proactive practice team, resulting in high-quality, satisfying encounters and improved outcomes (85).

5.0 DIABETES TRANSLATION

The Chronic Care Model provides a sound, encompassing methodology for improving the quality of healthcare for people with diabetes and more generally, people with any chronic illness. As reviewed previously, several systematic reviews were conducted on different aspects of the CCM. These reviews provide the best evidence of the efficacy and effectiveness of different strategies to ensure changes in practice and to improve diabetes care (316). However, there has been a failure to use efficacious treatments as recommended, often causing a breakdown at the patient, healthcare provider and system levels (317; 318). The process of repairing these problems is laden with challenges. These challenges require a more comprehensive, applied research that strives to translate available knowledge and operationalize it in clinical and public health practice.

Translational research provides a bridge between efficacy trials and clinical and public health practice (317) with the goal being to facilitate optimal healthcare for as many people as possible rather than ideal healthcare for a few, therefore, making it conducive to developing effective public health policy. Translational research attempts to measure a variety of real-world attributes of interventions shown to be efficacious in idealized settings. It focuses on real world health care delivery problems including impact of interventions on diverse populations, generalizability and transferability of findings (9; 317; 319; 320). It also concentrates on effectiveness and its influence on processes and outcomes and the sustainability of long-term implementation in real-world settings, with the goal being efficiency, equity, and facilitation of optimal health and health care for as many people as possible (9).

Traditional basic science/epidemiology offers a means of characterizing a problem, while efficacy and clinical trials research is aimed at understanding the solution to these problems. While, clinical trials are increasingly becoming more effectiveness-oriented, they are still

typically limited to narrow populations, specific settings, or one specific intervention (317). Many of these studies also lack sustainability over time, generalizability, and transferability to the majority of people in diverse settings (9; 317). It is through translational research, using studies better informed by theory and current knowledge, that solutions to problems can be implemented into real-world settings (317; 321).

Translation occurs in two continuous phases (322). The first is "bench to bedside" i.e. from laboratory research to clinical research applications (9). This phase applies basic scientific discoveries to human health care under controlled circumstances. The second translational phase is from the clinical research setting to real-world practice (9). It promotes the adoption of promising clinical research by a community-based healthcare system under uncontrolled and often uncontrollable circumstances (320). Often times, clinical trials include highly selected populations with particularly intensive treatment protocols conducted by expert research teams. The challenge is determining how to translate findings from this ideal setting to the frequently less than optimal situations that face typical physicians, who care for diverse communities with limited resources and face several competing demands (9; 321; 323; 324). Stark national figures demonstrate these challenges and emphasize that much more needs to be understood regarding how to implement and sustain evidence-based diabetes care in the real world. Particular attention needs to be paid to external validity and the applicability of programs and results in different settings; identification and understanding of barriers and facilitators to diabetes translation; a movement from an acute-care paradigm to a multi-faceted chronic-care model that is population based, proactive, and patient centered; an understanding of vulnerable, understudied populations; diabetes translational interventions that document whether patient outcomes improved in non-clinical settings; sustainability of these organizational interventions;

economic studies of translation including cost-effectiveness analysis; and public health and public policy efforts are all areas that are crucial and are a priority for this type of research (9; 93; 95; 317; 319; 320; 325).

Some of the aforementioned challenges are beginning to be studied. Several promising interventions to optimize implementation of efficacious diabetes treatments are available (278; 306; 326-330). However, many of these interventions need to be more formally tested in larger randomized or quasi-experimental trials using outcomes of special interest to patients (i.e. patient satisfaction and quality of life) (331) and to policymakers (i.e. cost-effectiveness). Further, there is a lack of knowledge about the long-term impact on health outcomes, quality of life and cost of strategies aimed at improving diabetes care at the patient provider, and system levels (202; 203; 319; 332). The Translating Research Into Action for Diabetes (TRIAD) study is an ongoing, observational, multi-center cohort study and is the first of its kind to examine many of these major issues (311; 319; 333).

Glasgow and colleagues (200; 334; 335) have developed the RE-AIM approach to diabetes translation to help researchers, program developers, and evaluators understand and address key translation issues (Appendix C) (200; 334; 335). RE-AIM is a model for evaluating public health interventions that assess five dimensions: reach into the community, its effectiveness, the extent of its adoption, its implementation, and its maintenance by individuals and healthcare sites (269). These dimensions occur at multiple levels (e.g. patient, provider, organization, community) and interact to determine the pubic health or population-based impact of a program or policy, serving as a solid framework for program planning (334; 335).

“Reach” assesses the infiltration of a program into its intended target audience. It is composed of the participation rate among eligible people and the representativeness of these

participants. Development of more broadly applicable, generalizable interventions is the goal of this category (335). "Effectiveness" includes changes on the dependent variable(s) or intervention targets and also impact on quality of life and economic outcomes, including any adverse consequences. Research needed in this area includes demonstration of the broader impacts (not just A1c levels and diabetes knowledge) of interventions (335). Significant progress has been made in defining the evidence-based patient-oriented treatment outcomes for self-management to target (269; 336). Closing the gap between scientific knowledge from previous diabetes research and the care that patients currently receive, requires the incorporation of these outcomes into current patient-centered DSME interventions and assessments (269; 337). "Adoption" is similar to "Reach," however; it is assessed at multiple levels (i.e. patient, provider, organization) (335). "Implementation" includes the extent to which different components of an intervention are delivered as intended and the level of intervention delivery across staff (335). And finally, "maintenance" encompasses all levels of the intervention. At the individual level, it is the long-term effects of an intervention on both targeted outcomes and quality of life. At the organizational level, maintenance refers to the extent to which an intervention is sustained over time (335). RE-AIM is an example of what is needed to make coordinated and substantial changes in diabetes care. Changes made by individuals, providers, health systems, and finally, policy makers will be necessary to accelerate translation of research into practice (200). Failure to adequately evaluate programs on all five dimensions of RE-AIM may lead to a waste of resources, discontinuities between stages of research, and failure to improve public health (200).

Based on the summary of evidence provided in the literature, there is an increased need for more major translational research, using standardized methods in multiple settings across populations and systems, to move toward optimal population care for diseases like diabetes

(317). The Institute of Medicine (100) has argued that new systems of care and new ways of thinking are needed to tackle complex diseases like diabetes. Therefore, it is critical that translational research be designed in a way that understands the system as a whole and not simply its parts (319). Continued research in this area, which encompasses a variety of fields such as epidemiology, health services research, psychology, sociology, health policy, and economics (205; 319), is necessary if we are to realize the potential of landmark trials, such as the DCCT (5), UKPDS (4), and DPP (6), and prevent the enormous aggregate burden of diabetes on our society.

6.0 CONCLUSION

Diabetes is a chronic disease with complex causes, manifestations, complications, and management. The sixth leading cause of death by disease, it affects a vast proportion of people of varying ages, races/ethnicities, income levels, and geographic settings. The disease imposes huge public health and economic burdens despite the availability of numerous efficacious treatments. This is due in part to the sub optimal application of these treatments in practice, resulting from a fragmented health care system, which has not transitioned from a problem-based system, to a prevention-based system of care. Studies of the level of diabetes care provided in the real world, and especially in primary care practices where the vast majority of patients are seen, consistently show that performance levels fall short of what is recommended. Simple process measures, such as ordering an A1c or lipid profile, are performed far less frequently than recommended and adherence to behaviorally oriented aspects of optimal diabetes management, are performed even less often.

To combat the current, fragmented health care system, system change approaches, which are population-based, cost-effective, proactive, and patient-centered, are critical in order to improve the delivery of care for people with diabetes. The Chronic Care Model has been widely adopted by a variety of health care systems and includes six key, multidisciplinary elements that characterize good chronic illness care. The elements of the model combine to create a more informed, activated patient, and a prepared, proactive practice team that work together in a partnership to improve clinical and behavioral outcomes.

A wider application of system change strategies in the community and health system settings, based on scientific findings, represents an essential tool to improve the quality of care and the quality of life for all persons with diabetes and to reduce health disparities. Diabetes translational research has the capabilities of accelerating the transfer of new scientific knowledge

into clinical and public health practice. More research is needed to develop effective public health approaches to motivate and sustain the required changes, on the part of the health care provider, the patient, and the health system, needed to improve diabetes care and management.

7.0 METHODS

7.1 OBJECTIVE AND SPECIFIC AIMS

With the results of landmark studies, like the DCCT (5), UKPDS (4), and DPP (6), it is clear that positive outcomes can be achieved through both drug therapy and behavioral change. However, for the full potential of these studies to be achieved, a bridge between these trials and the "real-world" must be created to allow for the translation of the aforementioned findings into the community and its health care system.

Although these landmark studies have proven the efficacy of their tested treatments, there has thus far, been less than optimal use of these treatments as recommended, outside of the research setting, reflecting a breakdown at the patient, healthcare provider and system levels (317; 318). A more comprehensive, applied research, based on chronic illness care that aims to translate available knowledge and operationalize it in clinical and public health practice is needed. This research needs to be formally tested in randomized or quasi-experimental trials using outcomes of special interest to patients (i.e. patient satisfaction and quality of life) (331) and to policymakers (i.e. cost-effectiveness) in order to determine the effectiveness of such interventions.

This study proposes to improve health outcomes in people with diabetes who receive care in the primary care setting, through implementation of a model of care focused on provider education, patient empowerment and enhancement of the patient-provider partnership. As a part of this investigation, we aim to:

1. Examine the effect of a diabetes education intervention, based on the Chronic Care Model for both patients and providers on patient clinical outcomes (HbA1c, Non-HDL-c, and blood pressure), behavioral outcomes (self-monitoring of blood glucose), and psychological/psychosocial outcomes (quality of well-being and empowerment) at 12 months

following the education intervention, overall, and across three study groups. We hypothesize that:

a. Implementation of the Chronic Care Model intervention results in better glycemic, blood pressure and lipid control, while increasing self-care behaviors, empowerment scores and quality of well-being in those who receive the intervention compared to those who do not.

2. Determine which patient characteristics, including demographic, psychological/psychosocial, healthcare delivery and clinical factors, alone or in tandem, predict improvements in clinical outcomes (HbA1c, Non-HDL-c, and blood pressure) at 12 months following the intervention both overall, and between three the study groups. We hypothesize that:

a. Psychological/psychosocial factors will contribute to the observed improvements in clinical outcomes (HbA1c, Non-HDL-c, and blood pressure) independent of medication treatment intensification, overall and between the three study groups.

3. Determine which patient factors predict returning for a 36-month follow-up visit. Additionally, determine if the improvements in clinical outcomes (HbA1c, Non-HDL-c, and blood pressure) and behavioral outcomes (self-monitoring of blood glucose) observed at 12 month follow-up are sustained at 36 months follow-up, overall, and between the three study groups, and if so, what factors predict and contribute to the sustained improvements. We hypothesize that:

a. Psychological/psychosocial factors will predict returning for a 36-month follow-up visit.
b. Improvements in clinical (HbA1c, Non-HDLc, systolic blood pressure, diastolic blood pressure), behavioral (self monitoring of blood glucose), and psychological

(quality of well-being) outcomes will be sustained in the group, which received the Chronic Care Model Intervention. Psychological/psychosocial factors will predict and largely contribute to the sustained improvements in clinical outcomes (HbA1c, Non-HDL-c, and blood pressure).

7.2 STUDY DESIGN

7.2.1 Overview

This study was a multi-level, non-blinded, cluster design, randomized controlled trial that took place in an underserved suburb of Pittsburgh, Pennsylvania between 1999 and 2003. The study was divided into four phases: Phase I: cross-sectional chart review; Phase II: intervention and 12-month follow-up; Phase III: repeat chart review, and Phase IV: 36-month follow-up visit. The study design and timeline are listed in Figure 8.1 and Table A2 respectively. All phases of the study took place in the study community. Implementation of each element of the Chronic Care Model into each respective group and phase of the study is outlined in Table 8.1.

7.2.2 Phase I: Cross-Sectional Chart Review

The chart audit was conducted to establish benchmarks for adherence to the ADA standards of care and to determine generalizability of the clinical trial population. General, family, or internal medicine practices with admitting privileges to the local community hospital were considered eligible. Based on hospital staff rosters, there were 24 eligible primary care practices in the study community. These practices were free standing practices in the community whose patients were insured by a variety of carriers. Letters were sent to all providers in the eligible practices inviting them to participate in the study. Eleven practices, representing 24 providers (21 physicians, 2 nurse practitioner/physician assistants, and 1 behaviorist), chose to participate in the first phase of the study. Seven of the practices were group practices (more than

one physician) where four were internal medicine practices and three were general practice. Three of the solo practitioners were internists while the remainder was a general practitioner. In the group practices, all practitioners participated. All practitioners agreed to participate in the chart audit.

The study's principle investigator trained two chart reviewers. Training was performed using a standard chart review protocol (Appendix D). Training consisted of both trainer and trainee reviewing the same charts over a three-day period (approximately 20 charts). After each chart was reviewed by both, discrepancies were noted and the chart was reviewed to adjudicate discrepancies. If greater than 5% of responses were discrepant, chart audit procedures were reviewed.

All medical charts with a diagnosis of diabetes during or prior to calendar year 1999 were audited. These charts were identified through ICD-9 codes, problem lists, and lab results. A diagnosis of diabetes was confirmed by the presence of 2 or more fasting glucose readings >126mg/dl, or two random glucoses >200mg/dl, or an HbA1c >7%, or use of a diabetes medication. A total of 762 charts from eleven primary care practices were audited at baseline (October 2000 to January 2002) using the Assessment of Diabetes Care chart review form (Appendix E).

7.2.3 Phase II: Interventions

Upon completion of the chart audit phase of the study, providers provided informed consent and practices were randomized into one of the three study arms shown in Figure 1. The initial block randomization procedure was undertaken, with the number of people with diabetes in each practice as the blocking factor. The three largest size practices were used as the first block, then the three next largest sized practices in the subsequent block. Minimization was used

for the assignment of the next three practices. Three practices were randomized to receive the Chronic Care Model intervention, which included patient and provider diabetes education (CCM); three practices were randomized to receive only provider education (PROV); and five practices were randomized to receive usual care (UC), which consisted of the subjects' regular diabetes care throughout the study period. No treatment was withheld as part of the study protocol.

7.2.3.1 Provider Interventions

Patient and Provider Diabetes Education Group (CCM) & Provider Diabetes Education Group (PROV)

First, the intervention that was implemented into CCM and PROV consisted of physicians attending one problem-based learning education session. The session emphasized patient problem solving and goal setting as well as diabetes management. An endocrinologist and a CDE lead the physicians through a series of patient cases. Second, all providers received their chart audit results in the form of a report. The reports examined adherence to recommended process and outcome variables in comparison to their peers in the community and to the American Diabetes Association Standards of Care. The reports were reviewed by the CDE in the CCM and PROV groups using academic detailing. The CDE visited the providers in their offices and provided a 15 to 20 minute educational intervention on the results of their practice's chart audit. An example of the report is provided in Appendix F.

Patient and Provider Diabetes Education Group (CCM)

Those providers randomized to CCM were encouraged to redesign the process in which they saw patients with diabetes for routine visits. This was requested for two reasons: 1) a CDE would be made available to them on a day of their choosing; thus, in order to maximize the time,

office staff were encouraged to schedule routine visits on these days, and 2) these "diabetes days" were designed with the idea that the provider would be more focused on diabetes for that particular day. Providers were encouraged to refer patients to the CDE for point of service education whenever possible.

All Providers (CCM, PROV, UC)

The following decision support items were given to all of the providers regardless of study group:

- American Diabetes Association Standards of Medical Care for People with Diabetes
- Flow sheets that incorporated the ADA guidelines
- A packet of posters and information from the Pennsylvania KeyPRO and the Lower Extremity Amputation Prevention Program to assist in complying with the ADA Standards of Care, foot screening, and tracking of patient testing and results

7.2.3.2 Patient Intervention (CCM)

Recruitment

Recruitment of participants began in September 2001. The 762 patients, from the chart audit, made up the pool of patients eligible for recruitment into the randomized controlled trial. The physician practices mailed letters to their patients with diabetes, inviting them to participate in phase II of the study, which was the randomized controlled trial. One hundred nineteen subjects, 30 from the CCM arm, 38 from the PROV arm, and 51 from the UC arm, chose to participate. Recruitment ended in June 2002. Subjects were followed-up at one-year post entry into the study (October 2002 – March 2003). One hundred and seven participants provided follow-up data, two of who provided no clinical data. Response rate was 90% (Figure 8.1). Due to

IRB regulations, no further contact could be made by investigators to increase levels of recruitment

Intervention

Patients receiving care from those providers randomized to the main intervention group were invited to participate in six Diabetes Self-Management Eraining (DSME) sessions held weekly followed by monthly support groups held until the time of their one year follow-up visit. The curriculum was based on the University of Michigan DSME curriculum. This included the required diabetes education content areas that are set forth in the American Diabetes Association (ADA) Standards for DSME (109). The participants received a notebook that contained the session materials for each of the six University of Michigan empowerment-based sessions. Each person's notebook contained their personal information that was procured at the baseline clinic visit including height, weight, BMI, lipid values, blood pressure and HbA1c on the Diabetes Risk Profile (Appendix G). To help the participant understand the "normal" values for each of these measures, there was additional information that described the standard for each measure. Information was provided about actions that might be taken to impact the patient's measure or value. All of the meetings followed in a similar manner. Classes started with an open-ended question and the discussion and questions followed. The CDE kept a check-off list of the DSME content areas required by the ADA. As content areas were discussed, examples were provided, questions were answered, and visual aids were presented. Once the topic was checked off, it was not closed for discussion. Topics often were discussed week after week as participants gathered more information and digested it during the week. The participants were given unlimited time to ask questions and discuss issues. Most of the discussion moved naturally to comments, questions or further discussion about diabetes. This format facilitated fulfillment of required

content areas without following an outline or formula in a didactic manner. Greater than 75% of the participants attended at least three-fourths of the six classes.

Support groups were formed when the participants completed the DSME program part of the educational intervention and were held each month for six months. Each month there was a different topic or a guest speaker who presented information about diabetes. The topics included, but were not limited to foot care for diabetes, a cooking class focused on healthy eating and recipe modification, alternative treatments for diabetes and problem solving skills. Over half of the participants attended at least two-thirds of the available support groups.

Measures

After providing informed consent at a baseline visit, all participants had their height, weight, and blood pressure measured according to standard protocol (Appendix H). Subjects had a blood draw for measurement of lipids and HbA1c and provided a urine sample to test for microalbumin (Micral Strips). At this baseline visit, all subjects participated in a one-hour discussion with the certified diabetes educator (CDE) and completed the following self-reported questionnaires which have all been validated and tested in adult populations with diabetes: a modified version of the University of Michigan Diabetes Research and Training Center's Diabetes Care Profile (338), Diabetes Empowerment Scale (80), Diabetes Knowledge Test (339), the World Health Organization (Ten) Well-Being index (277), and the Barriers to Diabetes Care instrument (340). All subjects were given a card to send for "Take Control of Your Diabetes" from the National Diabetes Education Program. All measures were collected at baseline and 12-follow-up (Table A3). At 12-month follow-up, subjects were mailed their questionnaires ahead of time and asked to bring them to their 12-month follow-up visit. Baseline and 12-month follow-up surveys are listed in Appendices I and J, respectively.

Modified Diabetes Care Profile (DCP)

The Diabetes Care Profile is a self-administered questionnaire that assesses social and psychological factors related to diabetes and its treatment. The modified version of the DCP contains scales that assess patients' self-reported diabetes healthcare utilization, diabetes self-care, medication use, and comorbidities. The DCP also contains questions concerning demographic information (338). The DCP was chosen as part of the University of Michigan Diabetes Research and Training Center's available survey instruments. The DCP has been previously validated in people with diabetes in community settings.

Diabetes Empowerment Scale

The Diabetes Empowerment Scale (DES), a 30–item psychosocial self-efficacy scale developed specifically for empowerment-based diabetes patient DSME, contains 3 subscales addressing patients' management of the psychosocial aspects of diabetes care, patients' dissatisfaction and readiness to change, and the patients' readiness to set and achieve diabetes related goals. Scale scores range from 1 – 5, with one indicating the lowest empowerment score, and 5 indicating the highest empowerment score (80). The DES is the only instrument of its kind that measures patient empowerment.

Diabetes Knowledge Test

The 23-item Diabetes Knowledge Test (DKT) represents a test of general diabetes knowledge. The first 14 items are appropriate for people who do not use insulin, while the entire 23-item questionnaire was administered to people who do use insulin. Questions address understanding of key diabetes content topics like, medication effects, monitoring and nutrition (339). The DKT was chosen as part of the University of Michigan Diabetes Research and

Training Center's available survey instruments. The DKT has been previously validated in people with diabetes in community settings.

World Health Organization (Ten) Well-Being Index

The WHO (Ten) Well-Being Index combines negative and positive aspects of well-being in a single uni-dimensional scale. Its advantage lies in its ability to show overall change along the continuum of well-being, thus facilitating comparisons between patient groups and treatments. Scores range from 0 – 30, with 0 indicating the lowest quality of well-being, and 30 indicating the highest quality of well-being (277). The WHO 10 was chosen because it is a self-administered questionnaire that assesses perceived current well-being and provides an overall indicator of mental health over the past 2 weeks. The questions are designed to minimize the possibility of wrongly attributing a symptom of poorly controlled diabetes to the presence of anxiety or depression, and they are short and easy to understand.

Barriers to Diabetes Care Instrument (BDC)

The BDC is a three question qualitative survey, which identifies thirty specific patient-identified barriers to care. Each of these barriers to care, themselves, comprises a range of issues. The thirty barrier categories are grouped into five different aspects: 1) psychological (including beliefs held by the individual); 2) their current general and specific knowledge of their situation; 3) their internal physical barriers to care; 4) community barriers to care; 5) psycho-social barriers to care (340). The BDC was chosen because of its ability to qualitatively collect barriers data. Further, it has been validated in various community settings and a variety of underserved and multi-ethnic populations.

Laboratory Measures

Due to the need for convenient scheduling and room availability for research clinics, non-fasting blood samples were collected at both baseline and follow-up assessments on study participants. We used the DCA 2000® to measure the percent concentration of hemoglobin A1c in the blood. This assay is based on a latex immuno-agglutination inhibition methodology. The Cholestech LDX System® was used to combine enzymatic methodologies and solid-phase technology to measure total cholesterol, HDL cholesterol, and triglycerides. The coefficients of variation are listed in Table A5. We used Non-HDLc (total cholesterol – HDLc) instead of LDL cholesterol, as the participants were not required to fast prior to the blood draws. Microalbuminuria was measured using Chemtrip Micral® test strips. After one minute, the intensity of color produced on the test strip is directly proportional to the albumin content of the urine. The accuracy of the Chemstrip Micral® test strips is displayed in Table A5.

7.2.4 Phase III: Repeat Chart Review

A 28% random sample of 219 charts of the original 762 charts were identified by study I.D. and were audited at 12-month follow-up to determine if changes occurred in practice patterns and clinical outcomes over the course of the study. 219 charts provided sufficient power to detect differences in practice patterns and clinical outcomes from baseline to 12-month follow-up if they truly existed. The Assessment of Diabetes Care repeat chart review form is listed in Appendix K.

7.2.5 Phase IV: Second Follow-up Visit

Subjects, who provided data at the 12-month follow-up, were contacted for a 36-month follow-up (October 2004-May 2005) assessment. Subjects were sent a letter in the mail, by the research staff, inviting them to participate in a second follow-up assessment. A copy of the

questionnaire was also included in the mailing for subjects to fill out before coming in for the 2nd follow-up assessment. During the assessment, all clinical measures were repeated. In addition to the measures outlined above, subjects completed the Diabetes Empowerment Scale Short-Form (341) in place of the Diabetes Empowerment Scale (80), the Summary of Diabetes Self-Care Activities measure (207), the Problem Areas in Diabetes Survey (PAID) (342), and the Assessment of Diabetes-Related Distress (DDS) (275) (Table A3). The 36-month follow-up questionnaire is listed in Appendix L. The additional measures were chosen because of their ability to assess the behavioral, psychological, and psychosocial aspects of diabetes care and management, not previously addressed in the baseline and 12-month follow-up questionnaires. All of the measures have been previously validated.

7.2.5.1 Additional 36-Month Follow-up Measures

Diabetes Empowerment Scale Short Form (DES-SF)

The DES-SF is an eight-item measure that allows for a brief, overall assessment of diabetes-related psychosocial self-efficacy. It was developed from the above 30-item Diabetes Empowerment Scale. Scores range from 1 – 5, with one indicating the lowest empowerment score, and 5 indicating the highest empowerment score (341).

Summary of Diabetes Self-Care Activities Measure (SCSCA)

The SDSCA measure is a 25-item self-report questionnaire of diabetes self-management that includes items assessing the following aspects of the diabetes regimen: general diet, specific diet, exercise, blood-glucose testing, foot care, and smoking. Respondents report on the frequency with which they performed the aforementioned, various activities over the previous seven days (207).

Problem Areas in Diabetes Survey (PAID)

The PAID survey is a measure of psychosocial adjustment, specific to diabetes. It is a 20-item questionnaire in which each item represents a unique area of diabetes-related psychosocial distress. Each item is rated on a six-point Likert scale, reflecting the degree to which the item is perceived as currently problematic. A total scale score, hypothesized to reflect the overall level of diabetes-related emotional distress, is computed by summing the total item responses (342).

Diabetes Distress Scale (DDS)

The DDS provides an assessment of diabetes-related emotional distress. It contains 28 items and on four distress-related scales: emotional burden subscale, physician-related distress subscale, regimen-related distress subscale, and diabetes-related interpersonal distress (275).

7.3 STUDY OUTCOMES

The primary outcomes of the clinical trial included reduction in HbA1c, Non-HDL, and blood pressure levels. Secondary outcomes for the study were improvements in quality of well-being, diabetes knowledge, empowerment, and self-care behaviors.

7.4 STATISTICAL ANALYSES

The statistical analyses for all specific aims incorporate both descriptive and inferential techniques. The methodological design of the study incorporated a hierarchical approach (patients clustered within physician practices), so this was considered in the statistical analyses. Prior to testing any hypotheses, the distribution of and descriptive statistics for all variables of interest were performed to determine distribution, mean, median, and other characteristics necessary to determine appropriate statistical analyses to be performed. Measures of central tendency (e.g. proportions, means, standard deviations, medians, etc.) were used for all

descriptive analyses. Implementation of the Chronic Care Model into each respective group and phase of the study is outlined in Table 8.1.

Specific Aim 1:

In univariate analyses, paired t-tests for continuous data and McNemar's test for categorical data were used to determine within group differences between baseline and 12-month follow-up. In order to examine differences between the three arms of the study, a combined between and within group analysis of variance was performed for each outcome of interest. Following any significant findings, statistical modeling was employed to investigate whether there were any differential effects on outcomes due to process or demographic differences. Stepwise linear or logistic regression was then used as a screening mechanism to identify if differences existed, before the incorporation of multi-level modeling into the statistical analyses. Generalized linear modeling was used to analyze the change in outcome values from baseline to 12-month follow-up. The main goal of the use of generalized linear modeling was to adjust for the possible effect of the clustering of patients within provider practices to determine if the observed between group differences were truly due to the intervention. The effect of practice group was adjusted for the clustering of patients within practice, age, and insulin use in all models. Baseline values of the dependent variable were adjusted for if significant differences occurred between baseline and follow-up values.

Specific Aim 2

Based on the results of specific aim 1, prediction models were constructed to determine which patient characteristics predict the change in metabolic outcomes observed at 12-month follow-up. After a series of univariate analyses, which examined correlations and associations with the outcomes of interest, nested forward linear regression was used to build the best fitting

models for change in HbA1c, Non-HDL-c, and systolic and diastolic blood pressure. The effect of the clustering of patients within provider practices was forced into all models, along with age and insulin use. Significant variables (demographic, psychological/psychosocial, healthcare delivery, behavioral) from the univariate analyses were entered into the models one at a time based on their level of significance (most significant variables entering first). An adjusted R^2 was used to determine the amount of variability accounted for in each model. Once the best fitting models were determined, multi-level models were then incorporated into the analyses to investigate the possible effect of the clustering of patients within provider practices. Generalized linear modeling was used to analyze data from baseline to 12-month follow-up.

Specific Aim 3

The analyses for specific aim 3 will build on the analyses for specific aims 1 and 2. Once again, the distribution of and descriptive statistics for all variables of interest will be performed to determine distribution, mean, median, and other characteristics necessary to determine appropriate statistical analyses to be performed. Measures of central tendency (e.g. proportions, means, standard deviations, medians, etc.) will be used for all descriptive analyses. Paired t-tests for continuous data and McNemar's test for categorical data will be used to determine within group differences between 12-month follow-up and 24-month follow-up. In order to examine differences between the three arms of the study, a combined between and within group analysis of variance will be performed for each outcome of interest. Following any significant findings, statistical modeling will be employed to investigate whether there were any differential effects on outcomes due to process or demographic differences. Stepwise linear regression will then be used as a screening mechanism to identify if differences existed, before the incorporation of multi-level modeling into the statistical analyses. Generalized linear

modeling will be used to analyze the change in outcome values from 12-month follow-up to 24-month follow-up in order to adjust for the possible effect of the clustering of patients within provider practices. The effect of practice group will be adjusted for the clustering of patients within practice, age, and insulin use in all models.

If the results from specific aim 1 could be sustained at 36-month post follow-up, we will examine which patient characteristics contribute to the sustained improvements. This will be accomplished by repeating the analyses performed for specific aim 2.

7.5 POWER AND SAMPLE SIZE

In initial sample size calculations for this study, we estimated that with 70 people in each of the three intervention arms we will have the ability to detect a 1.3 unit difference in HbA1c, a 17 mg/dl difference in LDL cholesterol, and an 8.4 mmHg difference in systolic blood pressure (80% power, non-directional alpha=0.05) if differences truly exist between the intervention group and usual care. However, because our participation rate was lower than expected (CCM: n=30, PROV: n=38, UC: n=51), our ability to detect significant differences, if they truly existed was minimized. Power calculations for continuous variables are summarized in tables A6 and A7. Table A6 represents the within group power analyses for the observed differences in the study's primary and secondary outcomes in the CCM and UC groups from baseline to 12-month follow-up. Between group power analyses to detect clinically significant differences in the primary outcomes between the CCM and UC groups are represented in Table A8.

8.0 MANUSCRIPT 1:

TRANSLATING THE CHRONIC CARE MODEL INTO THE COMMUNITY: RESULTS FROM A RANDOMIZED CONTROLLED TRIAL OF A MULTIFACETED DIABETES CARE INTERVENTION

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8.1. ABSTRACT

Objective – To determine if using the Chronic Care Model (CCM) in an underserved community leads to improved clinical and behavioral outcomes for people with diabetes.

Research Design and Methods - This multi-level, cluster design, randomized controlled trial examined the effectiveness of a CCM-based intervention in an underserved, urban community. Eleven primary care practices, along with their patients, were randomized to 3 groups: CCM Intervention (n=30 patients), provider education only (PROV) (n=38), and usual care (UC) (n=51).

Results – A marked decline in A1c was observed in the CCM group (-0.6%, p=0.008) but not in the other groups. The magnitude of the association remained strong after adjustment for clustering (p=0.01). The same pattern was observed for a decline in Non-HDL-c and for the proportion of participants who self-monitor blood glucose (SMBG) in the CCM group (Non-HDL-c: -10.4 mg/dl, p=0.24; SMBG: +22.2%, p<0.0001) with statistically significant between group differences in improvement (Non-HDL-c: p=0.05; SMBG: p=0.03) after adjustment. The CCM group also showed improvement in HDL-c (+5.5 mg/dl, p=0.0004), diabetes knowledge test scores (+6.7%, p=0.07), and empowerment scores (+2, p=0.02).

Conclusions - These results suggest that implementing the CCM in the community is effective in improving clinical and behavioral outcomes in patients with diabetes.

8.2 INTRODUCTION

Diabetes affects approximately 7% of the U.S. population, and has reached epidemic proportions (1). Diabetes represents a significant public health burden worldwide by decreasing quality of life and causing death and disability, at great economic cost (2). Though quality diabetes care is essential to prevent long-term complications, care often falls below recommended standards regardless of health care setting or patient population, emphasizing the necessity for system change (3-6).

The Chronic Care Model (CCM) (3; 4; 7; 8) is a multi-faceted framework for enhancing health care delivery. The model is based on a paradigm shift from the current model of dealing with acute care issues, to a system that is prevention based (3; 5; 7-9). The premise of the model is that quality diabetes care is not delivered in isolation and can be enhanced by community resources, self-management support, delivery system redesign, decision support, clinical information systems, and organizational support working in tandem to enhance patient-provider interactions (3; 4; 7-13). Currently, few efforts exist to implement multifaceted approaches to improve quality of care in diabetes, despite studies that demonstrate their proven effectiveness (3; 4; 11; 14; 15).

The objective of the current study was to determine the effectiveness of an intervention based on the CCM in primary care settings. We hypothesized that patient clinical (glycemic, blood pressure, and lipid control), behavioral (self-monitoring blood glucose (SMBG)), psychological/psychosocial (quality of well-being (QWB) and empowerment scores), and diabetes knowledge outcomes would improve in patients who received the CCM intervention compared to those who did not.

8.3 METHODS

This study was a multi-level, non-blinded, cluster design, randomized controlled trial (RCT) that took place in an underserved, urban suburb of Pittsburgh, Pennsylvania between 1999 and 2003. The target community was a former home to the steel industry and a victim of industrial downsizing, with increased rates of unemployment and an out-migration of the young and more affluent. This resulted in an elderly community, in a socio-economically depressed area, with a high prevalence of chronic diseases. The study was carried out in three phases: Phase I: cross-sectional chart review to determine baseline patterns of care; Phase II: randomization and provision of the intervention with 12-month follow-up including clinical assessment; and Phase III: repeat chart review to catalog post intervention patterns of care. The study design is outlined in Figure 8.1. Details of implementation of the CCM are outlined in Table 8.1.

Study population

Phase 1: Cross-Sectional Chart Review

A chart audit was conducted to establish benchmarks for adherence to the American Diabetes Association (ADA) Standards of Care (16) and to determine the generalizabilty of the population randomized in the RCT. Twenty-four general, family, and internal medicine practices, encompassing 42 providers, with admitting privileges to the local community hospital were eligible for the study. These practices were free standing practices in the community whose patients were insured by a variety of carriers. Letters were sent to all providers in these practices inviting them to participate. Eleven practices, representing 24 providers (21 physicians, 2 nurse practitioners/physician assistants, and 1 behaviorist) participated in the baseline chart audit (Phase I). One hundred percent of providers within each of the practices participated. Participating providers were slightly younger and had significantly less time practicing in comparison to the providers who chose not to participate (46 years of age vs. 51 years of age,

p=0.08 and 17.1 years vs. 27.3 years, p<0.0001 respectively). Additionally, of the providers who chose to participate, 82.6% were from a group practice, in comparison to those who did not participate, in which 42.1% were from a group practice. There were no differences by board certification (participating providers vs. non-participating providers: internal medicine: 60.9% vs. 47.4%; family practice: 30.4% vs. 42.1%, p=0.85). One of the participating providers was an endocrinologist but also served as a primary care provider. All participating providers gave informed consent.

Medical charts that included a confirmed diagnosis of diabetes by ICD-9 codes (250.**), problem lists (type of diabetes), and lab results (≥ 2 fasting glucose readings >126mg/dl, or 2 random glucoses >200mg/dl, or HbA1c >7%, or use of diabetes medication) during or prior to calendar year 1999 were audited by a trained chart reviewer. Charts for 762 patients met the diagnosis criteria and were audited.

Phase II: Interventions

Upon completion of the chart audit, practices were randomized into one of three study groups (Figure 1). An initial block randomization procedure was undertaken with practice size (determined by the number of people with diabetes in each practice) as the blocking factor. The randomization resulted in three practices receiving the CCM intervention; three practices receiving only provider education (PROV), and five practices receiving usual care (UC).

CCM Intervention (Patient and Provider Diabetes Education Group)

The CCM intervention involved patient and provider education, as well as the provision of other CCM elements in the community (Table 1). Provider-based diabetes education was offered to all providers via attendance at one problem-based learning (PBL) session (Table 1). Additionally, providers randomized to the CCM intervention were encouraged to redesign the

process in which they saw patients with diabetes for routine visits (Table 1). A CDE was placed in the practices on provider specified “diabetes days” and was available to all patients with diabetes and to the providers for consultation. The CDE remained in the practices for 6 months.

Patients receiving care from providers randomized to the CCM intervention were invited to participate in six diabetes self-management educatin (DSME) sessions, which were facilitated by a certified diabetes educator (CDE), and held weekly, followed by monthly support groups held until the time of their one-year follow-up visit. The curriculum for the sessions was based on the University of Michigan DSME curriculum (17). This included the required diabetes education content areas set forth in the ADA Standards for DSME (18). At the first session, subjects received their clinical data results along with information about self-care behaviors that could be taken to influence their results. All of the subsequent DSME sessions were structured in a similar manner and were based on the empowerment approach to diabetes education (19). Classes started with an open-ended question and discussion. DSME content areas were discussed, examples were provided and questions were answered throughout the session. Topics were often re-discussed as participants gathered more information and considered it during the week. Greater than 75% of the participants attended at least three-fourths of the six classes.

Monthly support groups were formed when the participants completed the classes. Support group topics included foot care, a cooking class focused on healthy eating and recipe modification, alternative treatments, and problem solving skills. Over half of the participants attended at least two-thirds of the available support groups.

Provider Education Only Group (PROV)

This intervention consisted of the providers attending one PBL session (Table 1). All providers in the CCM and PROV groups received their chart audit results. The reports were

reviewed by the CDE using academic detailing (20). In contrast to those providers in the CCM intervention group, the CDE was not placed in these practices but was made available to these providers for consultation during a 6-month period of the study.

Usual Care (UC)

Providers in the UC group were mailed their practice's chart audit report and decision support items.

Recruitment of participants began in September 2001 when the consented providers mailed letters, written for them by study investigators, to their patients with diabetes, inviting them to participate in the study. Patients were instructed to contact study staff for appointment scheduling and to answer any questions they may have had. The 762 patients, identified from the chart audit, made up the pool of eligible subjects. One hundred and nineteen subjects, 30 from the CCM group, 38 from the PROV group, and 51 from the UC group, chose to participate. Recruitment ended in June 2002. To determine if the RCT population was a representative sample of the chart audit population, RCT participants were compared to chart audit subjects. No significant differences were observed in any demographic characteristics [age: RCT: 67.6 years, 95% CI: (65.6, 69.6) vs. chart audit: 65 years, 95% CI: (63.9, 66.1); diabetes duration: RCT: 11.9 years, 95% CI: (9.9, 13.9) vs. chart audit: 9.3 years, 95% CI: (8.6, 10); % male: RCT: 50.4, 95% CI (40.8, 58.4) vs. chart audit: 46.9, 95% CI (35.7, 58.1); % non-white: RCT: 8.4, 95% CI (3.4, 13.3) vs. chart audit: 8.2, 95% CI (7.2, 9.2).

Measures

After providing informed consent at baseline, all participants had height, weight, and blood pressure measured according to standard protocol. Subjects also had a non-fasting blood draw for lipids and HbA1c and provided a urine sample to test for microalbuminuria. Following

testing, all subjects participated in a one-hour question and answer session with a CDE at which time they completed a series of questionnaires (outlined below), which have all been validated and tested in adult populations with type 2 diabetes. These measures were also collected at 12-month follow-up. One hundred and seven participants had follow-up data. Two provided no clinical data. The final follow-up response rate was 90%.

Survey Instruments

Modified Diabetes Care Profile (DCP)

The modified DCP is a self-administered questionnaire that contains scales that assess patients' diabetes healthcare utilization, diabetes self-care, medication use, and comorbidities (21). Sections of the original DCP (21) that did not directly relate to our study objectives were removed (i.e. social and personal factors, attitudes toward diabetes, diet adherence, monitoring barriers and understanding management practice, exercise barriers, long-term care benefits).

Diabetes Empowerment Scale (DES)

The DES, a 30–item psychosocial self-efficacy scale developed specifically for empowerment-based DSME, contains 3 subscales addressing patients' management of the psychosocial aspects of diabetes care, dissatisfaction and readiness to change, and readiness to set and achieve diabetes related goals. (22).

Diabetes Knowledge Test (DKT)

The 23-item DKT represents a test of general diabetes knowledge. Questions address understanding of medication effects, SMBG, and nutrition (23).

World Health Organization (Ten) Quality of Well-Being Index (WHO-QWB10)

The WHO-QWB10 includes negative and positive aspects of well-being in a single uni-dimensional scale. (24)

Laboratory Methods

HbA1c was determined with the DCA 2000® analyzer (25). The Cholestech LDX System® (26) was used to measure total cholesterol, HDL-c, and triglycerides. Non-HDL-c was calculated (total cholesterol – HDL-c). Microalbuminuria was measured using Chemstrip Micral® test strips.

Study Outcomes

The primary outcomes of the RCT included reduction in HbA1c, non-HDL-c, and blood pressure levels. Secondary outcomes for the study were improvements in QWB, diabetes knowledge, empowerment, and the frequency of SMBG.

The University of Pittsburgh Institutional Review Board approved the study protocols and all patients gave informed consent.

Analyses

Analyses and results presented in this report will focus on the RCT. Changes in provider practice patterns will be examined in a forthcoming report.

In univariate analyses, paired t-tests for continuous data and McNemar's test for categorical data were used to determine within group differences between baseline and 12-month follow-up. In order to examine differences between the three study groups, a combined between and within group analysis of variance was performed for each outcome of interest. Stepwise linear or logistic regression was then used as a screening mechanism to identify if differences existed between the outcome and process/demographic characteristics, before the incorporation of multi-level modeling. Mixed modeling (27) was used to analyze the change in outcome values from baseline to 12-month follow-up between study groups. The effect of study group was adjusted for the clustering of patients within provider practices, age, and insulin use in all

models. Baseline values of the dependent variable were adjusted for if significant differences occurred between baseline and follow-up values (28).

8.4 RESULTS

Demographic characteristics of the 119 subjects, participating in the RCT, are shown in Table 8.2 by study group. Demographic characteristics were similar across groups, with the exception of age, where subjects were older in the CCM group (CCM: 69.7, PROV: 64.4, UC: 68.6, p=0.04).

Analysis of the change in clinical outcomes among subjects from baseline to follow-up was conducted on the 105 subjects who had complete laboratory data at both time points (Table 8.3). A1c values declined significantly in the CCM group, with no change in the other groups (CCM: 7.6% to 7%, p=0.008, PROV: 7.3 % to 7.3%, p=0.92, UC: 6.9 to 6.8%, p=0.15). When the effect of group was adjusted for the clustering of patients within practices, age, insulin use, and baseline A1c value, the magnitude of the association remained strong (p=0.01). The same pattern of results was observed for non-HDL-c (CCM: 153.7 mg/dl to 143.3 mg/dl, p=0.24, PROV: 170.9 mg/dl to 168.8 mg/dl, p=0.79, UC: 147.3 mg/dl to 148.7 mg/dl, p=0.78) with a statistically significant between group difference in improvement (p=0.05) after adjustment in the multivariate models (Table 8.3). There was no intervention effect on blood pressure levels. We further adjusted for treatment intensification (medication dosage increase and/or medication class change) with no change in interpretation.

The change in psychological/psychosocial and behavioral outcomes among subjects was also examined. Results are detailed in Table 8.3. After adjustment for the clustering of patients within practices, age, insulin use, and baseline values, there were no statistically significant between group intervention effects on the DKT, WHO-QWB10, and DES scores. Within group

differences in the aforementioned outcomes, though, were observed. Subjects in the CCM group demonstrated improvement in DKT scores (55.2% to 61.9%, p=0.07) and mean total DES scores (3.8 to 4.0, p=0.02). WHO-QWB10 scores decreased significantly in the PROV group (19 vs. 17.2, p=0.02). Lastly, there were statistically significant within and between group differences in the frequency of SMBG. Frequency of SMBG increased significantly in the CCM group, with no change in the other groups (CCM: 77.8% to 100%, p<0.0001, PROV: 84.4 % to 90.6%, p=0.16, UC: 81.3% to 81.3%%, p=1.000). When the effect of group was adjusted for the clustering of patients within practices, age, insulin use, and baseline SMBG, the magnitude of the association remained strong (p=0.03).

8.5 CONCLUSION

This pilot study found that a CCM-based intervention was effective in improving clinical, behavioral, psychological/psychosocial, and diabetes knowledge outcomes in patients with diabetes. The CCM group, which received both patient and provider education demonstrated significantly improved HbA1c levels, non-HDL-c levels, and rates of SMBG compared to the other study groups. Moreover, clinical outcomes improved even after adjusting for treatment intensification. In addition, within the CCM group, improvements in HDL-c levels, diabetes knowledge, and empowerment scores were observed. These results are important, as they demonstrate that a multi-faceted intervention can improve diabetes outcomes in an underserved, urban community.

These data confirm the majority of findings of others, which noted improvements in process and outcome measures related to DSME interventions. In a systematic review on the effectiveness of DSME in type 2 diabetes, studies that used a collaborative approach, as we did, demonstrated positive effects on glycemic control in the short term (29). While, the positive

synergistic effect of combining patient education with various provider interventions has previously been shown in a range of settings, and among those with type 1 and type 2 diabetes (29), there have also been negative studies of patient-centered interventions and quality improvement projects. Just recently, O'Connor et al (30) and Gerber et al (31) conducted well-designed interventions, but produced null results in, both, clinical and behavioral outcomes.

Had we not block randomized our practices and adjusted for the clustering of patients within practices, our data would have been at risk for contamination or over estimation of the effect size. Indeed, most multi-faceted studies to date (29) have included inadequate concealment allocation and randomization errors, thereby making them prone to contamination.

Our pilot intervention differs from previous efforts in that we implemented the entire CCM as a multi-faceted intervention. There is a paucity of literature regarding implementation of the entire CCM in diabetes care. We have therefore not attempted to dissect out the efficacy of individual components of our intervention. Rather, we have implemented the entire CCM as our multi-faceted intervention. With the exception of a Danish study (32), in which representative general practices significantly improved long term control of diabetes through a variety of educational interventions, there have not been other published RCTs to our knowledge, implementing a combination of interventions to improve quality of care for people with diabetes. In contrast to the Danish study (32) and our current study, most studies choose to implement one aspect of the CCM (33). Bodenheimer, et al (33) conducted a systematic review of studies of diabetes care programs featuring the four main elements of the CCM (self management support, decision support, delivery system design, and clinical information systems). Each study was classified on the basis of whether it detected significant improvements in the processes of care, patient outcomes, or both, based on the number of elements that were implemented. Patient

outcomes improved in the 5 studies that implemented the 4 main elements of the CCM, however, outcomes also improved in the majority of studies that did not implement all 4 elements. Although specific elements of the CCM can not be teased out of the aforementioned studies or our study as essential to improvement, Bodenheimer et al note that 19 of 20 interventions that included a self-management component, improved a process or outcome of care (8; 33).

In conducting translational research, circumstances and environments are not "controllable," like efficacy-based research (34); therefore, limitations exist. For example, the baseline A1c values were quite low for an underserved community. Thus, there was potential for a floor effect. One way to elucidate whether there was a floor effect is to follow the subjects longitudinally to observe if the improvements could be sustained. This issue will be presented in a forthcoming report. Along those same lines, the UC group started the study with lower mean HbA1c levels than the CCM group. This was taken into consideration when we adjusted for the differences in baseline values in the multivariate models. Additionally, our RCT was underpowered to detect significant differences in the primary and secondary outcomes due to our small sample size, which was largely due to regulatory constraints. The university institutional review board did not permit us to contact patients directly. Therefore, it was the responsibility of the provider practices to recruit patients into the trial using predetermined recruitment methods developed by the study investigators. In initial sample sizes calculations, we estimated that 70 people in each of the three study groups would provide sufficient power to determine if differences truly existed between the intervention group and usual care. It is possible that Type II error may have affected the results observed. Thus, if there were improvements in other outcomes, we may have been unable to detect them.

We have demonstrated in this pilot study that outcomes for people with diabetes in an underserved, urban community can be improved by implementing the CCM (3; 4; 7; 8). As a result of this study, the University of Pittsburgh Medical Center (UPMC) health system has redesigned the way in which diabetes care is delivered (35). CDEs now use the empowerment approach (24) to deliver DSME at point of service in several primary care practices throughout western Pennsylvania (35). Additionally, recent efforts have been aimed at acquiring reimbursement for CDEs. As of November 2005, CDEs who deliver DSME at point of service can now bill for their services in the UPMC health system. Our community partnerships, population-based sample of participants, flexible patient-centered approach to DSME, and primary care practice redesign suggest that this model for improving diabetes care in the community is feasible and effective and could be applied to other chronic illnesses. Future large-scale research studies are needed to demonstrate the effectiveness of this approach.

We would like to acknowledge the University of Michigan DRTC, the Lions District 14B and 14E, the local hospital foundation, and the UPMC Division of Community Health Services.

Table 8.1 Implementation of the Chronic Care Model

Element	Study Group	Phase	Activity
Community (Resources and Policies)	CCM, PROV, UC	I-III	Community partnerships and collaborations were made between the University of Pittsburgh and leaders in the local community, including physicians, the community hospital foundation, and the Lion's Clubs.
Self-Management Support	CCM	Phase II	Patients receiving care from those providers randomized to CCM were invited to participate in six DSME sessions, which were facilitated by a certified diabetes educator (CDE), and held weekly, followed by monthly support groups. Curriculum included the required diabetes education content areas set forth by the ADA ((15). The empowerment approach to diabetes education was used (22).
Delivery System Design	CCM	Phase II	Providers randomized to CCM were encouraged to redesign the process in which they saw patients with diabetes for routine visits A CDE was made available to them on a day of their choosing Office staff were encouraged to schedule routine visits on these days These "diabetes days" were designed with the idea that the provider would be more focused on diabetes for that particular day Providers were encouraged to refer patients to the CDE for point of service education whenever possible.
Decision Support	CCM, PROV, UC	Phase II	One PBL session was held for providers. An endocrinologist presented cases and lead the providers through a series of diabetes management questions. A CDE demonstrated patient-focused problem solving and goal setting strategies. All providers received a benchmarking report, comparing their adherence to recommended process and outcome variables from the chart audit with that among their peers in the community and to the ADA Standards of Care (15). This was

Table 8.1 continued

			subsequently explained using academic detailing (20]. The following decision support items were given to all providers regardless of study group: ADA Standards of Care for People with Diabetes Flow sheets that incorporated ADA guidelines A packet of posters and information from Pennsylvania KeyPRO and the Lower Extremity Amputation Prevention Program to assist in complying with the ADA standards of care (15), and tracking of patient testing and results.
Clinical Information Systems	CCM, PROV, UC	Phase I	The majority of provider offices did not have a computer, let alone an electronic medical record, a baseline chart audits was conducted to establish benchmarks for adherence to the ADA standards of care (15) and to enhance provider feedback.
Organizational Support	CCM, PROV, UC	I-III	The Principle Investigator met with each of the providers who agreed to take part in the study to determine provider needs. This was done to enhance provider "buy in" and acknowledge chronic care as a priority. Additionally, funding was obtained from the local community hospital foundation and from the parent hospital system.

Table 8.2 Baseline Demographic Characteristics of the Clinical Trial Population by Study Group

	CCM (n=30)	**PROV (n=38)**	**UC (n=51)**	**p-value**
Age	69.7 (10.7)	64.4 (8.9)	68.6 (8.6)	0.04
Age at diagnosis	60.0 (12.4)	53.1 (12.4)	55.8 (12.6)	0.09
Duration (years)	10.3 (8.4)	11.5 (9.0)	13.1 (10.9)	0.46
Gender (% male)	50.0 (15)	39.5 (15)	58.8 (30)	0.2
Race (% non-white)	13.3 (4)	2.6 (1)	9.8 (5)	0.26
Education (% < high school education)	50.0 (15)	57.9 (22)	60.8 (31)	0.63
Income (% < $20,000/year)	44.4 (12)	52.8 (19)	44.4 (20)	0.72
Insulin use (%)	26.7 (8)	42.1 (16)	25.5 (13)	0.2
Microvascular complication (%)	28.6 (26)	18.3 (13)	23.3 (17)	0.31
Macrovascular complication (%)	20.6 (67)	18.0 (32)	19.6 (49)	0.79
Any complication (%)	63.8 (88)	47.7 (42)	57 (61)	0.06

* Results are mean (S.D.) or %(n)

Table 8.3 Changes in Clinical and Behavioral Outcomes across Study Groups Following the Chronic Care Model Intervention

	CCM (n=27)			PROV (n=32)			UC (n=46)			Adjusted p-value*
	Baseline	Follow up	p-value†	Baseline	Follow up	p-value†	Baseline	Follow up	p-value†	
A1c (%)	7.6	7.0	0.008	7.3	7.3	0.92	6.9	6.8	0.15	0.01
Non-HDL mg/dL	153.7	143.3	0.24	170.9	168.8	0.75	147.3	148.7	0.78	0.05
HDL mg/dL	39	44.5	0.0004	48.4	49.7	0.23	43.8	47.4	0.02	0.52
Systolic Blood Pressure mmHg	142.5	141.8	0.84	142.2	140.5	0.62	146.7	143.3	0.3	0.43
Diastolic Blood Pressure mmHg	73.4	73.7	0.84	77.5	75.6	0.26	76.1	76	0.96	0.43
Diabetes Knowledge Test Score (%)	55.2	61.9	0.07	68.8	67.3	0.35	69.2	70	0.48	0.88
WHO-10 Quality of Well-Being Index Total Score (Range 0-30)	21.3	20	0.33	19	17.2	0.02	20.3	19.8	0.37	0.17
Empowerment Scale Score (Range 1-5)	3.8	4.0	0.02	4.0	3.9	0.72	3.9	3.9	0.92	0.75
Self-Monitor Blood Glucose (%)	77.8	100	<0.0001	84.4	90.6	0.16	81.3	81.3	1.000	0.03

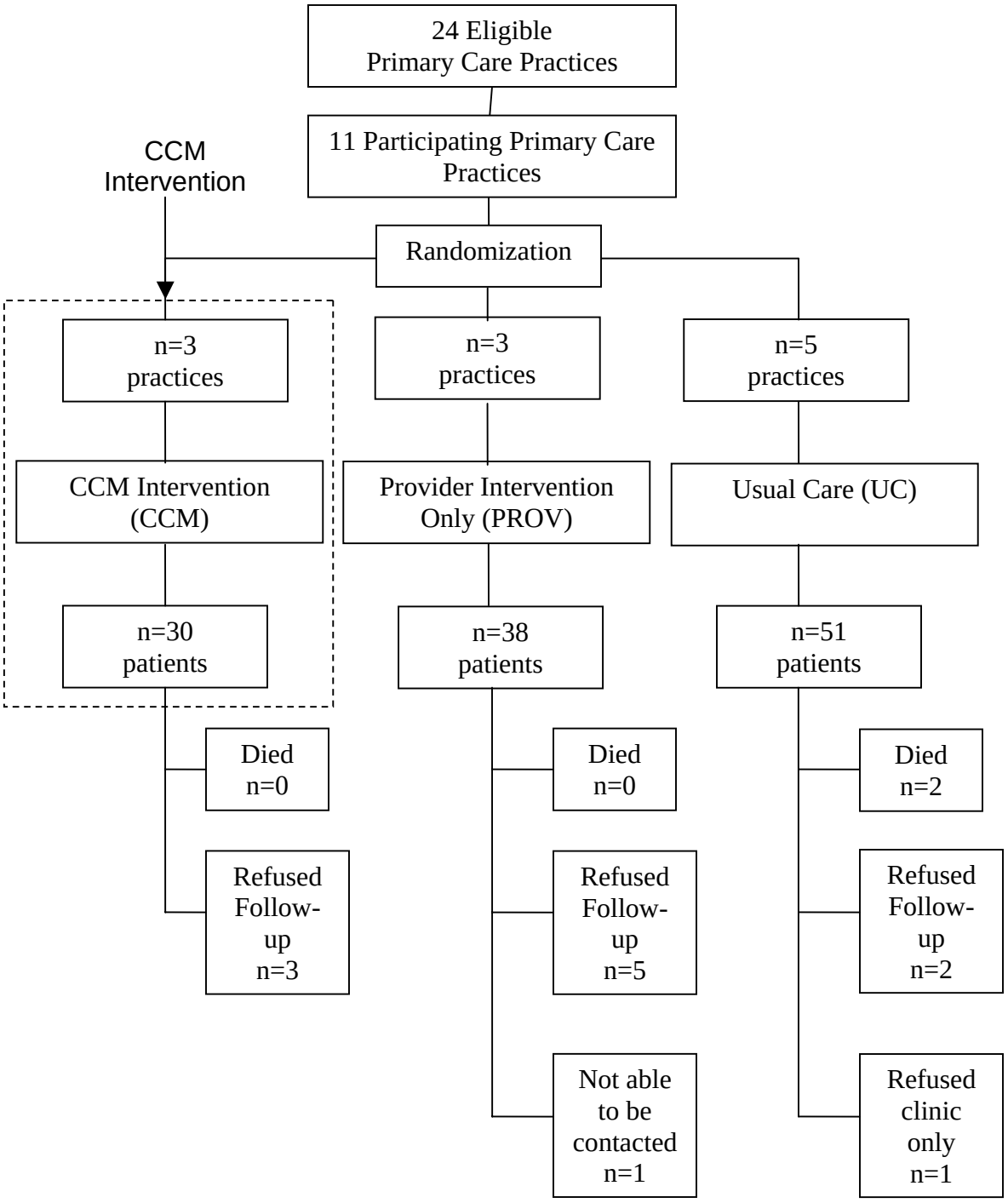

Figure 8.1 Study Design

*Group practices (more than one physician): n=7; Internal medicine practices: n=4;
General medical practices: n=3; Three solo practitioners were internists; One was a general practitioner

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9.0 MANUSCRIPT 2:

THE IMPACT OF INDIVIVUDAL LEVEL FACTORS ON THE IMPROVEMENT OF THE ABCS OF DIABETES: RESULTS OF A RANDOMIZED CONTROLLED TRIAL OF A MULTI-FACETED DIABETES CARE INTERVENTION

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9.1 ABSTRACT

Objective: To assess what individual level factors are associated with improvements in the ABCs (HbA1c, blood pressure, lipids) of diabetes following a multi-faceted diabetes care intervention.

Research Design and Methods: This multi-level, cluster design, randomized controlled trial examined the effectiveness of a Chronic Care Model (CCM)-based intervention in an underserved, urban community. Eleven primary care practices, along with their patients, were randomized to 3 groups: CCM Intervention (n=30 patients), provider education only (PROV) (n=38), and usual care (UC) (n=51). A series of multivariate generalized linear models, adjusting for the clustering, were constructed to determine what factors independently contribute to improvement in the ABCs.

Results*:* Greater improvements in HbA1c were experienced among subjects with higher HbA1cs at baseline (β=0.58, p<0.0001), who were older (β=0.02, p=0.02), who had higher scores on the WHO 10 Quality of Well-Being Subscale 1 (β=0.07, p=0.05), and who were in the CCM intervention group (β=0.6, p=0.04). Higher baseline blood pressure values (SBP: β=0.54, p<0.0001; DBP: β=0.59, p<0.0001) and insulin use (SBP: β=8.8, p=0.05; DBP: β=2.8, p=0.09) were associated with greater improvements in SBP and DBP. Additionally, not having retinopathy (β=-7.9, p=0.04) and having a high socio-economic position (β=6.7, p=0.09) were associated with improvements in SBP, while male gender (β=3.8, p=0.04), older age (β=0.21, p=0.03) and low scores on the Diabetes Empowerment Subscale: Setting and Achieving Diabetes Related Goals (β=-2.9, p=0.04) were associated with improvements in DBP. A similar pattern was observed for improvements in Non-HDLc. Subjects with higher Non-HDLcs at baseline (β=0.36, p<0.0001), who were currently taking insulin (β=14.7, p=0.07) and who were less

likely to be dissatisfied with their diabetes care and ready to make a change (β=-13.9, p=0.08) experienced larger improvements in their Non-HDLc levels. Interpretation remained unchanged for all outcomes after adjustment for medication treatment intensification.

Conclusion: These results suggest that a variety of individual-level factors are related to improvements in the ABCs of diabetes. Indeed, we demonstrated that psychosocial and psychological factors accounted for a greater amount of the variation in the ABCs of diabetes than clinical factors, and are important in contributing to improvement.

9.2 INTRODUCTION

Diabetes has reached epidemic proportions and continues to grow as one of the most significant public health problems of our time (1). Individuals with diabetes are at increased risk for vascular disease, including microvascular complications (eg, retinopathy, neuropathy, and nephropathy), macrovascular complications (eg, coronary heart disease and stroke) and lower extremity arterial disease (2-5). Over the past 15 years, evidence has demonstrated that control of HbA1c, blood pressure, and cholesterol (the ABCs of diabetes) can significantly delay or prevent these complications (6-9), which have major clinical, social, and economic implications (1). Unfortunately, the translation of this evidence into practice remains difficult. Consequently, diabetes care often falls below the recommended standards of care regardless of the healthcare setting or patient population, emphasizing the need for system change (10-12).

Due to its multi-faceted nature, diabetes requires a health system that promotes long-term management (13; 14), not one in which care is provided episodically. Unlike acute illnesses, diabetes encompasses behavioral, psychosocial, psychological, environmental, and clinical factors, all of which play a role in diabetes related quality of life, morbidity, and mortality. Moreover, what distinguishes diabetes from other chronic illnesses is that it is one of the few diseases in which the patient manages the majority of the disease on a daily basis, outside of provider control (15). Therefore, an entire host of individual level factors may influence a patient's control of their ABCs.

The Chronic Care Model (CCM) is a multi-faceted framework for enhancing healthcare delivery (11; 13; 14; 16). The model is based on a paradigm shift from the current model of health care dealing with acute care issues, to a system that is prevention based (11; 13; 17; 18).

One strategy for improving care in patients with diabetes is the use of multi-faceted diabetes care interventions, which aim to improve care on multiple levels, including the patient, provider, and the community (19). Multi-faceted interventions have been proven effective in improving the processes of diabetes care (19). The addition of patient education to these interventions has led to improvements in patient outcomes, including the ABCs of diabetes (19). However, despite their proven effectiveness, few attempts to implement multi-faceted approaches to improve quality of care have been made (10; 19). Moreover, in studies that do implement these approaches, very little is understood about the factors that contribute to improvement.

It was therefore our objective to determine which individual-level patient characteristics, including demographic, psychological, psychosocial, environmental, and clinical factors contribute to improvements observed in the ABCs of diabetes at 12 months following a multi-faceted diabetes care intervention.

9.3 METHODS

The methods of this trial have been previously described (20). Briefly, this study was a multi-level, non-blinded, cluster design, randomized controlled trial (RCT) that took place in an underserved, urban suburb of Pittsburgh, Pennsylvania between 1999 and 2003. The study was carried out in three phases: Phase I: cross-sectional chart review to determine baseline patterns of care; Phase II: randomization and provision of the diabetes self-management education (DSME) intervention with 12-month follow-up including clinical assessment; and Phase III: repeat chart review to catalog post intervention patterns of care. The study design is outlined in Figure 1. This report will focus on Phase II of the study.

Study Population

Providers

Twenty-four general, family, and internal medicine practices, encompassing 42 providers, with admitting privileges to the local community hospital were eligible for the study. Letters were sent to all providers in these practices inviting them to participate. Eleven practices, representing 24 providers (21 physicians, 2 nurse practitioners/physician assistants, and 1 behaviorist) participated in a baseline chart audit (Phase I), which served as the source of eligible subjects for the RCT and was used to determine generalizability of the RCT population. Charts for 762 patients met the diagnosic criteria for diabetes (4; 20) and were audited. One hundred percent of providers within each of the practices participated. All provided informed consent.

Upon completion of the chart audit, practices were randomized into one of three study groups (Figure 1). A block randomization procedure was undertaken with practice size (determined by the number of people with diabetes in each practice) as the blocking factor. The randomization resulted in three practices receiving the Chronic Care Model (CCM) intervention; three practices receiving only provider education (PROV), and five practices receiving usual care (UC).

Patients

Recruitment of participants began in September 2001 when the consented providers mailed letters, written for them by study investigators, to their patients with diabetes, inviting them to participate in the study. The 762 patients, identified from the chart audit, made up the pool of eligible subjects. One hundred and nineteen subjects, 30 from the CCM group, 38 from the PROV group, and 51 from the UC group, chose to participate. Recruitment ended in June 2002.

Interventions

Chronic Care Model (CCM) Intervention

A full description of the interventions has been previously described (20). Briefly, the CCM intervention involved patient and provider education, as well as the provision of other CCM elements in the community, including, community partnerships and collaborations, delivery system redesign, decision support, clinical information systems, and organization support (13; 14). Provider-based diabetes education was offered to all providers via attendance at one problem-based learning (PBL) session. Additionally, providers randomized to the CCM intervention were encouraged to redesign the process in which they saw patients with diabetes for routine visits. A certified diabetes educator (CDE) was placed in the practices to provide DSME on provider specified "diabetes days" and was available to all patients with diabetes and to the providers for consultation. The CDE remained in the practices for 6 months.

Patients receiving care from providers randomized to the CCM intervention were invited to participate in six diabetes self-management education (DSME) sessions, which were facilitated by a certified diabetes educator (CDE), and held weekly, followed by monthly support groups held until the time of their one-year follow-up visit. The curriculum for the sessions was based on the University of Michigan DSME curriculum (21). All DSME sessions were structured in a similar manner according to the National Standards for DSME and the American Diabetes Association recognition process (22) and were based on the empowerment approach to diabetes education (23).

Provider Education Only Group (PROV)

This intervention consisted of the providers attending one PBL session in which they were taught elements of DSME. All providers in the CCM and PROV groups received their chart

audit results. The reports were reviewed by the CDE using academic detailing (24). In contrast to those providers in the CCM intervention group, the CDE did not provide DSME in these practices but was made available to these providers for consultation during a 6-month period of the study.

Usual Care (UC)

Providers in the UC group were mailed their practice's chart audit report and decision support items.

Measures

After providing informed consent at baseline, all participants had height, weight, and blood pressure measured according to standard protocol. Participants also had a non-fasting blood draw for lipids and HbA1c and provided a urine sample to test for microalbuminuria. HbA1c was determined with the DCA 2000® analyzer (Bayer healthcare, Elkhart, IN). The Cholestech LDX System® (Hayward, CA) was used to measure total cholesterol, HDL-c, and triglycerides. Non-HDL-c was calculated (total cholesterol – HDL-c). Microalbuminuria was measured using Chemstrip Micral® test strips.

Following testing, all subjects (n=105) participated in a one-hour question and answer session with a CDE at which time they completed a series of questionnaires [Modified Diabetes Care Profile (25), Diabetes Empowerment Scale (DES) (26), the Barriers to Diabetes Care Instrument (BDI) (27), and the World Health Organization (Ten) Quality of Well-Being Index (WHO 10) (28)], which have all been validated and tested in adult populations with type 2 diabetes. One hundred and seven participants had follow-up data. Two provided no clinical data. The final population for these analyses consisted of 105 participants.

Variables

Demographic/Lifestyle

Treatment intensification for glycemia, blood pressure, and lipids were binary variables that were defined as change in the number medications being used to treat glycemia, hypertension, and hyperlipidemia, respectively, and/or a change in the class of medications. Socio-economic position (SEP) was measured using self-reported education status, employment status, income level, and ownership of a home. The following constituted high SEP:

- Education beyond high school ***and***
- Full time employment, ***or*** part time employment, ***or*** being a home maker, ***or*** attending school, ***or*** being retired ***and***
- Income level > $20,000/year ***and***
- Ownership of a home

Any other combination defined low SEP. A subject was considered to have ever smoked if they answered yes to being asked "have you ever smoked cigarettes?" or "do you now smoke cigarettes?"

Comorbidities

A subject had diabetic eye disease if they reported that a health care provider told them that they had diabetic changes in the back of one or both eyes, if they were blind in one or both eyes, or if they reported macular edema in one or both eyes. Neuropathy was self-reported as either peripheral neuropathy, or gangrene, or foot ulcers. A subject was considered to have CVD if they self-reported any one of the following: heart attack, angina, coronary artery bypass surgery, coronary angioplasty, peripheral vascular disease, amputation of a toes, foot, part of a leg, or all of a leg for a poorly healing sore or poor circulation, stroke, transient ischemic attack.

Psychological/Psychosocial

The WHO 10 (28) is a self-administered questionnaire that assesses perceived current well-being and provides an overall indicator of mental health over the past 2 weeks. The first subscale range from 0-15 and consists of questions on depression, anxiety, energy, sleep, and positive well-being. Subscale 2 ranges from 0-15 and assesses positive well-being. A total score is obtained by adding the two subscales together.

The DES (26) has three subscales that all range from 1-5. "Assessing Dissatisfaction and Readiness to Change" assesses patients' perceived ability to identify aspects of caring for diabetes that they are dissatisfied with and their ability to determine whey they are ready to change their diabetes self-management plan. "Managing the Psychosocial Aspects of Diabetes" assesses the patients' perceived ability to obtain social support, manage stress, be self-motivating, and make diabetes-related decisions that are right for them. Setting and Achieving diabetes Goals assesses patients' perceived ability to set realistic goals and reach them by overcoming the barriers to achieve their goals (26).

The University of Pittsburgh Institutional Review Board approved the study protocols and all subjects gave informed consent.

Statistical Methods

Based on results published previously (20), additional analyses were performed to determine which patient characteristics were associated with improvements observed in HbA1c and Non-HDLc at 12-month follow-up. Measures of central tendency (e.g. proportions, means, standard deviations, medians, etc.) were used for all descriptive analyses. Additionally, t-tests were used to test for univariate associations between change in the ABCs and explanatory variables. Based on the results of the univariate analyses, nested forward linear regression was

used as a screening mechanism to identify sets of variables that contribute to the change observed in each outcome of interest. Explanatory variables chosen for inclusion were not limited based on statistical significance but were based on literature review and analyses previously conducted in addition to the current analyses. An adjusted R^2 was used to determine the amount of variability accounted for in each model and Akaike's Information Criteria (AIC) was used to determine the best fitting model.

After a set of contributing variables were identified for each outcome of interest, a series of multivariate generalized linear models were constructed to determine what factors independently contribute to improvement in the ABCs. This type of analysis also allows for the investigation of the possible effect of the clustering of patients within provider practices for each outcome of interest. Baseline clinical value, age centered at mean age 67.4 years, insulin use, study group, and the nesting of provider practices within study group were forced into all model (base model). The nesting of provider practices within study group was treated as a random effect. A series of multivariate generalized linear regression models were then constructed, based on the results of nested forward linear regression, to determine what factors independently contribute to the improvement in the ABCs. Due to small sample size, results were determined significant at the p=0.1 level.

9.4 RESULTS

Baseline Characteristics

Of the original 119 participants, 88.2% had complete 12-month follow-up data. Individuals providing data for the 12-month follow-up did not differ for any demographic characteristics by intervention group, except for age, which was significantly older in the CCM intervention group (CCM: 69.7 years, PROV: 64.4 years, UC: 68.6 years, p=0.04) (Table 9.1).

However, participants did differ by other characteristics. Subjects in the CCM intervention group had significantly higher baseline HbA1cs (CCM: 7.6%, PROV: 7.3%, UC: 6.9%, p=0.03) and significantly lower diastolic blood pressures (CCM: 73.1 mmHg, PROV: 78.7 mmHg, UC: 75.8 mmHg, p=0.07) in contrast to the other two groups. Additionally, a significantly lower proportion of subjects in the CCM group had ever smoked (CCM: 43.3%, PROV: 57.9%, UC: 66.7%, p=0.04). Finally, subjects in the CCM group were somewhat more likely to be dissatisfied with their current diabetes care and ready to make a change in their diabetes (CCM: 3.6, PROV: 3.9, UC: 3.8, p=0.08). Results of the original trial are presented in Table 9.2 (20).

Factors Associated with Improvement in the ABCs

A variety of factors from Table 9.1 were associated with improvement in the ABCs, including reporting a precontemplative barrier ("strictness of the regimen, giving up things I enjoy") which is a binary variable that is one of 30 categories from the Barriers to Diabetes Care instrument (BDC) (340). The BDC is a three question qualitative survey, which identifies 30 specific patient-identified barriers to care. Each of these barriers to care, themselves, comprises a range of issues. The thirty barrier categories are grouped into five different aspects: 1) psychological (including beliefs held by the individual); 2) their current general and specific knowledge of their situation; 3) their internal physical barriers to care; 4) community barriers to care; 5) psycho-social barriers to care (340). A precontemplative barrier is a barrier in the psychological category and was the highest individual reported barrier in univariate analyses (results not shown). Barriers were coded by three members of the research staff (2 epidemiologists and 1 medical technician) and adjudicated by the developer of the instrument.

HbA1c

Overall, higher HbA1cs at baseline ($r=0.62$, $p<0.0001$) and higher quality of well-being scores at baseline (subscale 1 score: $r=0.24$, $p=0.02$, total score: $r=0.2$, $p=0.04$) were significantly correlated with improvements in HbA1c. Additionally, a significant decline in HbA1c was observed in subjects with a high SEP compare to those with a low SEP (-0.85% vs. –0.07%, $p=0.0004$), and in those who received treatment intensification for their diabetes medication compared to those who did not (-0.62% vs. +0.04%, $p=0.007$) (Table 9.3). After a series of stepwise regression models using the aforementioned explanatory factors, our final GLM model showed that higher HbA1cs at baseline ($\beta=0.58$, $p<0.0001$), older age ($\beta=0.02$, $p=0.02$), higher scores on the WHO-QWB10 Subscale 1 ($\beta=0.07$, $p=0.05$), and being a subject in the CCM group ($\beta=0.6$, $p=0.04$) were independently associated with greater improvements in HbA1c levels ($R^2=0.6$). After adding diabetic treatment intensification to the model, there was no change in interpretation.

SBP and DBP

Although there was not an intervention effect on blood pressure levels, there was a large range of changed values for both SBP (range: -54 mm/Hg to +63 mm/Hg) and DBP (range: -23 mm/Hg to + 32 mm/Hg). For both SBP and DBP, higher baseline values (SBP: $r=0.61$, $p<0.0001$; DBP: $r=0.52$, $p<0.0001$) were significantly correlated with improvement. Higher baseline quality of well-being scores (subscale 1 score: SBP: $r=0.19$, $p=0.05$; DBP: $r=0.16$, $p=0.1$; total score: DBP: $r=0.17$, $p=0.09$) and DES scores (Setting and Achieving Diabetes-Related Goals: SBP: $r=-0.19$, $p=0.06$; DBP: $r=-0.19$, $p=0.06$; Managing the Psychosocial Aspects of diabetes: SBP: $r=-0.19$, $p=0.05$; DBP: $r=-0.18$, $p=0.08$) were also correlated with improvement. Additionally, women had greater improvements in SBP than men (-6.2 mmHg vs.

+1.6 mmHg, p=0.04). The results of the final GLM models for both SBP (R^2=0.52) and DBP (R^2=0.53) were similar as higher baseline values (SBP: β=0.54, p<0.0001; DBP: β=0.59, p<0.0001) and insulin use (SBP: β=8.8, p=0.05; DBP: β=2.8, p=0.09) were independently associated with improvements in SBP and DBP. Additionally, not having retinopathy (β=-7.9, p=0.04) and having a high SEP (β=6.7, p=0.09) were independently associated with improvements in SBP, while male gender (β=3.8 p=0.02), older age (β=0.21, p=0.02) and lower scores on the DES Subscale: Setting and Achieving Diabetes Related Goals (β=-2.9, p=0.07) were independently associated with improvements in DBP. The addition of blood pressure treatment intensification to the model made no difference in the results. Additionally, when these analyses were stratified by baseline hypertension status (SBP ≥ 130 mm/Hg or DBP ≥ 80 mm/Hg), the results remained similar (data not shown).

Non-HDLc

A similar pattern of results was observed for improvements in Non-HDLc. Baseline Non-HDLc was significantly correlated with improvement (r=0.38, p<0.0001), as was higher baseline quality of well-being scores (subscale 2 score: r=0.2, p=0.05). Additionally, scores on the Dissatisfaction and Readiness to Change Subscale of the DES were also significantly correlated with improvement (r=-0.23, p=0.02), although in the opposite direction as lower scores on the DES subscale were associated with improvement in Non-HDLc levels. Those subjects who had lipid treatment intensification also experienced larger improvements in Non-HDLc compared to those who did not (-35.8 mg/dL vs. +0.87 mg/dL, p=0.07). Based on the results of stepwise regression, the final Non-HDLc GLM model showed that higher Non-HDLcs at baseline (β=0.36, p<0.0001), insulin use (β=14.7, p=0.07) and lower scores on the DES Subscale: Dissatisfaction and Readiness to Change (β=-13.9, p=0.08) were independently

associated with larger improvements in Non-HDLc levels (R^2=0.4). The addition of lipid treatment intensification to the model made no change in interpretation.

9.5 CONCLUSION

These analyses examined individual-level factors related to improvements in the ABCs of diabetes after a one-year multi-faceted diabetes care intervention. Our intervention resulted in improvements in glycemic and lipid control, but not blood pressure control, in patients with diabetes at the 12-month follow-up visit. The CCM intervention group significantly improved HbA1c and Non-HDLc levels compared to the other study groups. Moreover results did not change following adjustment for treatment intensification.

Through a series of analyses, we were able to demonstrate that a wide variety of factors, including psychosocial, psychological, sociodemographic, and clinical factors, were associated with improvement in the ABCs. These results support our hypothesis in that psychosocial and psychological factors accounted for a greater amount of the variability in our outcomes than clinical factors. Results demonstrated that higher HbA1cs at baseline, older age, higher quality of well-being scores, and being a member of the CCM intervention group were associated with larger improvements in HbA1c levels in comparison to subjects in other study groups. Moreover, the CCM intervention group had the largest decrease in HbA1c, but had no significant change in treatment intensification. A similar pattern of results was observed when examining improvements in Non-HDLc; however psychosocial aspects played a larger role as indicated by significant correlations with both QWB subscale 2 and the dissatisfaction and readiness to change subscale of the DES. Higher Non-HDLcs at baseline, insulin use, and higher scores on the DES Subscale: Dissatisfaction and Readiness to Change, were associated with greater improvements in Non-HDLc levels in comparison to subjects in the other study groups. There

was no intervention effect on blood pressure levels. However, there was substantial variability in the range of values, which indicates that some subjects improved greatly, while others did not. Thus, the impact of the intervention may have been due to the small sample size, not the lack of an intervention effect. Higher baseline SBP values, insulin use, and high SEP were associated with greater improvements in SBP, while female subjects, higher baseline DBP values, older age, insulin use, and higher scores on the DES Subscale: Setting and Achieving Diabetes Related Goals were associated with greater improvement DBP values.

These data (20) confirm the findings of other multifaceted diabetes care interventions, which found improvements in clinical outcome measures when patient education was added (19). However, this report also adds significantly to the literature as relatively little is known about what patient characteristics contribute to the improvements. It is hypothesized that biological and behavioral characteristics of individuals with diabetes are likely to affect control of complication risk factors (2); however this theory has yet to be proven. With the exception of self-determination theory research done by Williams and colleagues (29-31), and the vast array of clinical literature on various medical treatments, to our knowledge, this is one of the few studies that examined the effect of a wide variety of patient characteristics along with the effect of a multifaceted diabetes care intervention, on improvements in clinical outcomes. Examining this aspect of diabetes care is crucial as national data demonstrate that progress in improving risk factors for complications in individuals with diabetes over the past decade has been modest (2).

The characteristics examined in this study are reflective of the patients and the underserved, urban community in which they live. Examining how race, or socio-economic position, or health care access contributes to improvements in the clinical outcomes is crucial in

understanding why some people improve, while others stay the same or worsen. Additionally, the psychological and psychosocial characteristics examined in this study are reflective of the patients' experience with diabetes and its treatment and therefore are consistent with our patient-centered intervention. Gaining perspective of what type of patient is most likely be successful as a result of a multifaceted diabetes care intervention that incorporates diabetes self-management training is critical if we are to continue to close the gap between the scientific base for the treatment of diabetes and the care and outcomes that patients experience.

Our study differs from most multifaceted interventions in that we not only examined patient characteristics, but we also expanded our outcome measures to include cardiovascular risk factor reduction and based our DSME intervention on the Empowerment approach to diabetes education (19). While the scope of outcomes measured in DSME studies has been broadened over the past few years, the majority of studies still only measure glycemic control and diabetes-related knowledge, as determinants of success of the program. Moreover, even fewer studies are based on a sound behavioral theory (32-35). Although the Diabetes Control and Complications Trial (DCCT) (6) was not a study of the effect of DSME on metabolic control, it is an excellent demonstration of the role of behavioral science in diabetes care. The DCCTs chief finding, that patients who were able to maintain glucose at near-normal levels had significantly less diabetic retinopathy, neuropathy, and nephropathy, may be attributed to the study's interventionists helping participants adhere to the intensive insulin therapy regimen (6; 36). Although the DCCT effectively addressed behavioral issues, it did not monitor the methods for addressing the many behavioral issues involved (36). Because of this, the study did not address the critical questions of what motivational variables predict long-term success and

how health care providers can promote such motivation in patients with diabetes, many of whom are not as motivationally prepared as those who participated in the DCCT (37-39).

In conducting multifaceted interventions, there are a variety of limitations that may affect study results. This study suffered from small sample size, which made our RCT underpowered to detect significant differences in the ABCs. In our case, the small sample size was largely due to regulatory constraints. The university institutional review board did not permit us to contact patients directly for recruitment. Therefore, it was the responsibility of the practices to recruit patients into the trial using predetermined recruitment methods developed by the study investigators. In initial sample size calculations, we estimated that 70 people in each of the three study groups would provide sufficient power to detect a 1.3% difference HbA1c and an 11 mg/dL difference Non-HDLc if they truly existed between the intervention group and usual care. It is possible that we did not observe significant differences for blood pressure due to Type II error. Thus, if there were small improvements in these outcomes, we may have been unable to detect them. Additionally, nearly all of our data were self-reported, with the exception of the laboratory data, which inherently biases results toward the null. One may argue that the baseline HbA1c, Non-HDLc, and blood pressure values were quite low for an underserved community. Thus, there was potential for a floor effect. One way to determine if a floor effect existed is to follow the subjects longitudinally to observe if the improvements could be sustained (manuscript 3). Another limitation is that the UC group started the study with lower mean HbA1c and Non-HDLc levels than the CCM group. We accounted for this, along with possible regression to the mean, in our multivariate models by adjusting for the baseline values. Lastly, it must be noted that this RCT was not designed to examine the contribution of psychological/psychosocial and behavioral patient characteristics to improvements in clinical outcomes. Indeed, it was designed

to determine the effectiveness of a multifaceted diabetes care intervention in the primary care setting. Therefore, the results we observed are hypothesis generating and lend credence to further research in this area.

In this report, we have demonstrated that a wide variety of patient characteristics are associated with improvement in the ABCs of diabetes in patients taking part in a multifaceted diabetes care intervention in an urban, underserved community. Additionally, we demonstrated the importance of the impact of psychosocial and psychological aspects of diabetes care and management on improvements as these aspects of diabetes care. Future research is needed to reduce the large proportion of adults with diabetes, who continue to have their HbA1c, blood pressure, and lipid levels sub-optimally controlled. Particular attention should be paid to those with high laboratory values, low socio-economic position, those with existing diabetes-related complications, and those who may have psychosocial and psychological problems. System change is essential if we are to translate therapies that have been proven effective in controlling the ABCs of diabetes, into practice.

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Table 9.1 Baseline sociodemographic characteristics, clinical characteristics, lifestyle behaviors, and psychological/psychosocial characteristics for the randomized controlled trial population by study group (n=119)

	CCM (n=30)	**PROV (n=38)**	**UC (n=51)**	**p-value**
Demographic				
Age (years)	69.7 (10.7)	64.4 (8.9)	68.6 (8.6)	0.04
Age at diagnosis (years)	60.0 (12.4)	53.1 (12.4)	55.8 (12.6)	0.09
Duration (years)	10.3 (8.4)	11.5 (9.0)	13.1 (10.9)	0.46
Gender (% male)	50.0 (15)	39.5 (15)	58.8 (30)	0.2
Race (% non-white)	13.3 (4)	2.6 (1)	9.8 (5)	0.26
Insulin use (% yes)	26.7 (8)	42.1 (16)	25.5 (13)	0.2
Socio-Economic Position (% high)	33.3 (10)	18.4 (7)	13.7 (7)	0.1
Clinical Characteristics				
HbA1c (%)	7.6 (1.5)	7.3 (1.6)	6.9 (1.3)	0.03
Non-HDLc (mm/dL)	156.4 (50.7)	165.8 (50.1)	148.8 (31.3)	0.19
Systolic BP (mm/Hg)	143.1 (21)	142.7 (18)	147.5 (28.4)	0.58
Diastolic BP (mm/Hg)	73.1 (7.7)	78.7 (11.5)	75.8 (9.5)	0.07
Retinopathy (% yes)	33.3 (8)	19.4 (7)	22 (11)	0.2
Neuropathy (% yes)	37.9 (11)	29 (11)	31.4 (16)	0.43
Cardiovascular disease (% yes)	53.3 (16)	44.7 (17)	56.9 (29)	0.25
≥ 2 complications (% yes)	56.7 (17)	47.4 (18)	60.8 (31)	0.45
Lifestyle Behaviors				
Ever smoked (% yes)	43.3 (13)	57.9 (22)	66.7 (34)	0.04
Self-monitor blood glucose (% yes)	80 (24)	81.6 (31)	82.4 (42)	0.79
≥ 2 visits to healthcare provider in past 12 months (% yes)	96.7 (29)	94.7 (36)	94 (47)	0.6
Psychological/Psychosocial Characteristics				
Quality of Well-Being Subscale 1 Score (Range 0-15)	9.3 (2.7)	8.4 (3.2)	9.5 (2.9)	0.23
Quality of Well-Being Subscale 2 Score (Range 0-15)	11.4 (2.7)	9.8 (3.8)	10.6 (3.2)	0.14
Quality of Well-Being Total Score (Range 0-30)	20.9 (4.5)	18.2 (6.6)	20 (5.8)	0.15
Empowerment Subscale: Dissatisfaction and Readiness to Change (Range 1-5)	3.6 (0.54)	3.9 (0.46)	3.8 (0.37)	0.08
Empowerment Subscale: Setting and Achieving Goals (Range 1-5)	3.8 (0.54)	4 (0.46)	4 (0.46)	0.21
Empowerment Subscale: Managing the psychosocial aspects of diabetes (Range 1-5)	3.9 (0.66)	4 (0.59)	4 (0.52)	0.15
Reported a pre-contemplative barrier (% yes)	36.7 (11)	26.8 (14)	49 (25)	0.18

Table 9.1 Continued

Treatment Intensification				
Diabetic Treatment Intensification (% yes)	30 (9)	36.8 (14)	43.1 (22)	0.24
Lipid Treatment Intensification (% yes)	13.3 (4)	7.9 (3)	7.8 (4)	0.37
Blood Pressure Treatment Intensification (% yes)	30 (9)	26.3 (10)	27.5 (14)	0.73

Data are means (SD) or % (n).

Table 9.2 Changes in Clinical Outcomes Within and Between Study Groups Following the Chronic Care Model Intervention

	CCM (n=27)			PROV (n=32)			UC (n=46)			Adjusted p-value for change in outcomes
	Baseline	Follow-up	p-value†	Baseline	Follow-up	p-value†	Baseline	Follow-up	p-value†	
A1c (%)	7.6	7.0	0.008	7.3	7.3	0.92	6.9	6.8	0.15	0.01
Non-HDL (mg/dL)	153.7	143.3	0.24	170.9	168.8	0.75	147.3	148.7	0.78	0.05
Systolic BP (mmHg)	142.5	141.8	0.84	142.2	140.5	0.62	146.7	143.3	0.3	0.43
Diastolic BP (mmHg)	73.4	73.7	0.84	77.5	75.6	0.26	76.1	76	0.96	0.43

*Effect of group is adjusted for the clustering of patients within practice, age, and insulin use. Baseline values were adjusted for if significant differences occurred between baseline and follow-up values
†P-value for within group differenc

Table 9.3 Individual level factors associated with change in the ABCs of Diabetes

	HbA1c	Non-HDLc	SBP	DBP
Demographic				
Age (years)	0.16	0.03	-0.003	-0.02
Age at diagnosis	0.07	-0.14	-0.06	-0.14
Duration (years)	0.09	0.13	0.15	0.19 *
Gender (male:female)	0.29:0.18	6.7: -0.78	-1.6:6.2 †	-0.27:1.5
Race (white:non-white)	0.22:0.43	1.7:11.3	1.9:4.3	0.73:-1.2
Insulin use (yes:no)	0.29:0.22	7.0:0.97	3.7:1.5	0.2:0.67
Socio-Economic Position (high:low)	0.85:0.07 ‡	10.9:0.33	6.8:0.8	2.3:0.05
Clinical Characteristics				
Baseline HbA1c (%)	0.62 §	--------	--------	--------
Baseline Non-HDLc (mg/dL)	--------	0.38 §	--------	--------
Baseline Systolic BP (mmHg)	--------	--------	0.61 §	--------
Baseline Diastolic BP (mmHg)	--------	--------	--------	0.52 §
Retinopathy (yes:no)	0.42:0.12	4.0:2.2	-0.67:2.4	0.96:0.02
Neuropathy (yes:no)	0.15:0.27	-2.4:4.7	-2.5:4.0	-0.76:1.0
Cardiovascular disease (yes:no)	0.25:0.22	1.9:3.3	0.33:3.8	-0.08:1.1
≥ 2 complications (yes:no)	0.29:0.18	4.6:0.36	1.8:2.5	0.4:0.73
Lifestyle Behaviors				
Ever smoked (yes:no)	0.08:0.45	3.4:1.6	0.73:4.0	0.7:0.33
Self-monitor blood glucose (yes:no)	0.2:0.41	--------	--------	--------
≥ 2 visits to healthcare provider in past 12 months (yes:no)	0.27:-0.17	2.4:11.3	2.0:4.8	0.72:-3.7
Psychological/Psychosocial Characteristics				
Quality of Well-Being Subscale 1 Score (Range 0-15)	0.24 †	0.07	0.19 †	0.16
Quality of Well-Being Subscale 2 Score (Range 0-15)	0.14	0.2 †	0.12	0.12
Quality of Well-Being Total Score (Range 0-30)	0.2 †	0.16	0.18 *	0.17 *
Empowerment Subscale: Dissatisfaction and Readiness to change (Range 1-5)	-0.14	-0.23 †	-0.15	-0.16
Empowerment Subscale: Setting and Achieving Goals (Range 1-5)	-0.04	-0.009	-0.19 *	-0.19 *
Empowerment Subscale: Managing the psychosocial aspects of diabetes (Range 1-5)	-0.02	-0.05	-0.19 *	-0.18 *
Reported a pre-contemplative barrier (yes:no)	0.3:0.2	7.6:-0.83	2.6:1.8	-0.74:1.5

Table 9.3 continued

Treatment Intensification				
Diabetic Treatment Intensification (yes:no)	0.62:-0.04 ‡	---------	--------	--------
Lipid Treatment Intensification (yes:no)	---------	35.8:-0.87 *	--------	--------
Blood Pressure Treatment Intensification (yes:no)	---------	---------	2.2:2.1	0.88:0.4

Positive values represent improvement in the ABCs
Spearman correlation coefficients presented for correlations between change in ABCs and continuous variables
Student's T-Tests means presented for associations between change in ABCs and categorical variables

*p<0.1, †p<0.05, ‡p<0.01, §p<0.0001

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10.0 MANUSCRIPT 3:

PREDICTION OF FOLLOW-UP AND SUSTAINED IMPROVEMENTS IN OUTCOMES FOLLOWING A MULTI-FACETED DIABETES CARE INTERVENTION: RESULTS OF A RANDOMIZED CONTROLLED TRIAL

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10.1 ABSTRACT

Objective: To determine if improvements observed in metabolic, behavioral, and psychological/psychosocial outcomes measured at 12-months following a multifaceted intervention were sustained at 36-month follow-up. And if so, to examine what patient factors led to the sustained improvements.

Research Design and Methods: This study was a multi-level, non-blinded, cluster design, randomized controlled trial that took place in an underserved, urban suburb of Pittsburgh, Pennsylvania between 1999 and 2003. Eleven primary care practices, along with their patients, were randomly assigned to 3 groups: Chronic Care Model (CCM) intervention (n=30), provider education only (PROV) (n=38), and usual care (UC) (n=51).

Results: Improvements observed at 12-month follow-up in HbA1c, systolic and diastolic blood pressure, and the proportion of participants who self monitor their blood glucose, were sustained at 36-month follow-up in all study groups. Additional improvements occurred in Non-HDLc levels in all study groups, and quality of well-being scores in the CCM group, but not the other groups. Diabetes empowerment scale scores declined in all study groups at 36-month follow-up. Multivariate logistic regression demonstrated that clear trends emerged in lower quality of well-being (OR=0.76, p=0.05) and diabetes empowerment scale scores (OR=0.22, p=0.07) as they largely predicted the sustained improvements in HbA1c levels, while 12-month metabolic values were the clear drivers behind the sustained improvements in Non-HDLc (OR=1.1, p=0.02) and blood pressure levels (systolic blood pressure: OR=1.1, p=0.01; diastolic blood pressure: OR=1.2, p=0.02). All of these associations remained after controlling for medication treatment intensification.

Conclusion: We have demonstrated through secondary analyses of a multifaceted diabetes care intervention, that improvements in outcomes can be sustained over time, across study groups. Additionally, we demonstrated the importance of considering a wide variety of patient factors, including psychological, psychosocial, behavioral, sociodemographic, and metabolic, in predicting these sustained improvements.

10.2 INTRODUCTION

Now the sixth leading cause of death, diabetes is a serious, costly disease that continues to rapidly increase (1). Characterized by excessive morbidity and mortality rates, diabetes represents a major public health challenge and is emerging as a pandemic (2; 3). It places an undue burden on the person diagnosed their families, communities (4), and the healthcare system (5). The complications of diabetes decrease quality of life and often result in death and disability, all at a great economic cost.

Large multicenter, randomized clinical trials have tested the efficacy of intensive diabetes treatment in preventing or delaying long-term diabetes-related complications (6-8). These trials established that achieving near-normal glucose control reduces the risk of diabetes complications, but the results also validate the complexity of diabetes care and management. Though quality diabetes care is essential to prevent long-term complications, it often falls below recommended standards regardless of health care setting or patient population, emphasizing the necessity for system change (5; 9-11). Due to its multi-faceted nature, quality diabetes care requires an integration of the patient into a health system that promotes long-term management (9; 10), not one in which care is provided episodically. Unlike acute illnesses, diabetes encompasses behavioral, psychosocial, psychological, environmental, and clinical factors, all of which play a role in the management of the disease.

The Chronic Care Model (CCM) is a multi-faceted framework for enhancing healthcare delivery (9; 10; 12; 13). The model is based on a paradigm shift from the current model of health care that centers around acute care issues, to a system that is prevention based (5; 9; 12; 14). One strategy for improving care in persons with diabetes is the use of multi-faceted interventions, which are built around a model of care such as the CCM, and aim to improve care

on multiple levels, including the patient, provider, community, and health system levels. Multi-faceted interventions are effective in improving processes and outcomes of care (15). However, despite proven effectiveness, very few efforts exist that implement these types of interventions. Moreover, even fewer measures a broad range of patient outcomes and follow patients to examine whether observed improvements in outcomes could be sustained over time.

Therefore our objectives were three-fold. First, to determine if the improvements observed in HbA1c levels, Non-HDLc levels, systolic and diastolic blood pressure levels, quality of well-being scores, and empowerment scores measured at 12-months following a multifaceted intervention were sustained at 36-month follow-up. And if so, our second objective was to examine what patient factors measured at 12-month follow-up predicted the sustained improvements. Finally, the third objective was to determine what patient factors predicted return for a 36-month follow-up visit.

10.3 METHODS

The methods of this trial have been previously described (16). Briefly, this study was a multi-level, non-blinded, cluster design, randomized controlled trial (RCT) that took place in an underserved, urban suburb of Pittsburgh, Pennsylvania between 1999 and 2003. The study was carried out in four phases: Phase I: cross-sectional chart review to determine baseline patterns of care; Phase II: randomization and provision of the DSME intervention with 12-month follow-up including clinical assessment; Phase III: repeat chart review to catalog post intervention patterns of care; Phase IV: 36-month follow-up including clinical assessment. The study design is outlined in Figure 10.1. This report will focus on Phases II and IV of the study.

Study Population

Providers

Twenty-four general, family, and internal medicine practices, encompassing 42 providers, with admitting privileges to the local community hospital were eligible for the study. Letters were sent to all providers in these practices inviting them to participate. Eleven practices, representing 24 providers (21 physicians, 2 nurse practitioners/physician assistants, and 1 behaviorist) participated in a baseline chart audit (Phase I), which served as the source of eligible subjects for the RCT and was used to determine generalizability of the RCT population. Charts for 762 patients met the diagnosis criteria for diabetes [ICD-9 codes (250.**), problem lists (type of diabetes), and lab results (≥ 2 fasting glucose readings >126mg/dl, or 2 random glucoses >200mg/dl, or HbA1c >7%, or use of diabetes medication) during or prior to calendar year 1999] and were audited. One hundred percent of providers within each of the practices participated. All provided informed consent.

Upon completion of the chart audit, practices were randomized into one of three study groups (Figure 10.1). A block randomization procedure was undertaken with practice size (determined by the number of people with diabetes in each practice) as the blocking factor. The randomization resulted in three practices receiving the Chronic Care Model (CCM) intervention; three practices receiving only provider education (PROV), and five practices receiving usual care (UC).

Patients

Recruitment of participants began in September 2001 when the consented providers mailed invitation letters to their 762 eligible patients identified from the chart audit to participate in the study. One hundred and nineteen subjects, 30 from the CCM group, 38 from the PROV group, and 51 from the UC group, chose to participate. Recruitment ended in June 2002.

Interventions

Chronic Care Model (CCM) Intervention

The CCM interventions is described elsewhere (page 129 of dissertation). Briefly, the CCM intervention involved patient and provider education, as well as the provision of other CCM elements in the community, including, community partnerships and collaborations, delivery system redesign, decision support, clinical information systems, and organization support (9; 10) Provider-based diabetes education was offered to all providers via attendance at one problem-based learning (PBL) session. Additionally, providers randomized to the CCM intervention were encouraged to redesign the process in which they saw patients with diabetes for routine visits. A certified diabetes educator (CDE) was placed in the practices on provider specified "diabetes days" and was available to all patients with diabetes and to the providers for consultation. The CDE remained in the practices for 6 months.

Patients receiving care from providers randomized to the CCM intervention were invited to participate in six diabetes self-management education (DSME) sessions, which were facilitated by a CDE, and held weekly, followed by monthly support groups held until the time of their 12-month follow-up visit. The curriculum for the sessions was based on the University of Michigan DSME curriculum. All DSME sessions were structured in a similar manner and were based on the empowerment approach (17) to diabetes education.

Provider Education Only Group (PROV)

This intervention consisted of the providers attending one PBL session. All providers in the CCM and PROV groups received their chart audit results. The reports were reviewed by the CDE using academic detailing. In contrast to those providers in the CCM intervention group, the

CDE was not placed in these practices but was made available to these providers for consultation during a 6-month period of the study.

Usual Care (UC)

Providers in the UC group were mailed their practice's chart audit report and decision support items.

Measures

After providing informed consent at baseline, all participants had height, weight, and blood pressure measured according to standard protocol. Subjects also had a non-fasting blood draw for lipids and HbA1c and provided a urine sample to test for microalbuminuria. HbA1c was determined with the DCA 2000® analyzer (Bayer healthcare, Elkhart, IN). The Cholestech LDX System® (Hayward, CA) was used to measure total cholesterol, HDL-c, and triglycerides. Non-HDL-c was calculated (total cholesterol – HDL-c). All samples were analyzed at the same laboratory. Microalbuminuria was measured using Chemstrip Micral® test strips at the time of the clinic visit.

Following testing, all subjects participated in a one-hour question and answer session with a CDE at which time they completed a series of questionnaires [Modified Diabetes Care Profile (MDCP) (18), Diabetes Empowerment Scale (DES) (19), the Barriers to Diabetes Care Instrument (BDI) (20), the World Health Organization (Ten) Quality of Well-Being Index (WHO10) (21), and the Diabetes Knowledge Test (DKT) (22)], which have all been validated and tested in adult populations with type 2 diabetes. All questionnaires were completed, again, at 12-month follow-up.

At 36-months following their baseline clinic visit, subjects were sent an invitation letter and a copy of an updated questionnaire for the 2nd follow-up assessment. During the

assessment, all clinical measures were repeated, as were all of the aforementioned questionnaires, except for the DKT.

Variables

Demographic/Lifestyle

Treatment intensification for glycemia, blood pressure, and lipids were binary variables that were defined as change in the number medications being used to treat glycemia, hypertension, and hyperlipidemia, respectively, and/or a change in the class of medications. Socio-economic position (SEP) was measured using self-reported education status, employment status, income level, and ownership of a home. The following constituted high SEP:

- Education beyond high school ***and***
- Full time employment, ***or*** part time employment, ***or*** being a home maker, ***or*** attending school, ***or*** being retired ***and***
- Income level > $20,000/year ***and***
- Ownership of a home

Any other combination defined low SEP. A subject was considered to have ever smoked if they answered yes to being asked "have you ever smoked cigarettes?" or "do you now smoke cigarettes?" The number of health care provider visits was reported as the number of visits in the past 12 months.

Comorbidities

A subject had diabetic eye disease if they reported that a health care provider told them that they had diabetic changes in the back of one or both eyes, if they were blind in one or both eyes, or if they reported macular edema in one or both eyes. Neuropathy was self-reported as either peripheral neuropathy, or gangrene, or foot ulcers. A subject was considered to have

cardiovascular disease if they self-reported any one of the following: heart attack, angina, coronary artery bypass surgery, coronary angioplasty, peripheral vascular disease, amputation of a toes, foot, part of a leg, or all of a leg for a poorly healing sore or poor circulation, stroke, transient ischemic attack.

Psychological/Psychosocial

The World Health Organization Quality of Well-Being Index 10 (21) is a self-administered questionnaire that assesses perceived current well-being and provides an overall indicator of mental health over the past 2 weeks. The first subscale range from 0-15 and consists of questions on depression, anxiety, energy, sleep, and positive well-being. Subscale 2 ranges from 0-15 and assesses positive well-being. A total score is obtained by adding the two subscales together.

The Diabetes Empowerment Scale (19) has three subscales that all range from 1-5. "Assessing Dissatisfaction and Readiness to Change" assesses patients' perceived ability to identify aspects of caring for diabetes that they are dissatisfied with and their ability to determine whey they are ready to change their diabetes self-management plan. "Managing the Psychosocial Aspects of Diabetes" assesses the patients' perceived ability to obtain social support, manage stress, be self-motivating, and make diabetes-related decisions that are right for them. Setting and Achieving diabetes Goals assesses patients' perceived ability to set realistic goals and reach them by overcoming the barriers to achieve their goals (19).

Improvement in Outcomes

Sustained improvement in outcomes for continuous variables was calculated as the 12-month follow-up value minus the 36-month follow-up value. If the difference was zero or greater, the outcome was sustained or improved. Improvement in categorical outcomes was

determined by comparing the proportion of participants who were engaged in an activity to the proportion not engaged in an activity.

The University of Pittsburgh Institutional Review Board approved the study protocols and all subjects gave informed consent.

Statistical Methods

To build on previous analyses and results (16), additional analyses were performed to determine which individual characteristics predicted whether a participant chose to return for a 36-month follow-up visit and to examine which individual characteristics at 12 F/U predicted improved and or sustained outcomes at 36 follow-up in HbA1c, blood pressure, Non-HDLc, quality of well-being, and self-monitoring of blood glucose.

Measures of central tendency (e.g. proportions, means, standard deviations, medians, etc.) were used for all descriptive analyses. In determining which 12-month individual characteristics were associated with return for a 36 follow-up visit and sustained improvement in outcomes, Student's t-tests for continuous data and Pearson's Chi-Square test for categorical data were used. P-values > 0.1 indicates that no significant change in the measure was detected between the 12 and 36 month time points thus improvement sustained.

Stepwise logistic regression was then used as a screening mechanism to identify if differences existed between the outcome and the individual characteristics. Explanatory variables chosen for inclusion were not limited based on statistical significance but were based on literature review and analyses previously conducted in addition to the current analyses. Lastly, the probability of returning for 36-month follow-up and the probability of sustained improvement in outcomes were modeled using forward logistic regression. Akaike's Information Criteria was used to determine the best fitting model. The effect of study group was considered

in all multivariate analyses with the use of indicator variables. All analyses were conducted using SAS v.8.2, Cary, North Carolina.

10.4 RESULTS

Results of the original trial are published elsewhere (16) (page 152 of dissertation). At 12-month follow-up, 105 participants provided data. Two provided no clinical data. Of the 105 who provided data at 12-month follow-up, 57 provided data at 36-month follow-up (October 2004-May 2005). Eighteen provided no clinical data. Full details of the population are provided in Figure 1. When the 39 participants who provided both questionnaire and clinical data at 36-month follow-up were compared to subjects who chose not to provide data at 36-month follow-up, no 12-month demographic differences were apparent. However, subjects who returned at 36-month follow-up had lower mean SBP levels in comparison to those who did not (return: 138 mmHg vs. no return: 145.9 mmHg, p=0.03). They were significantly less likely to be using insulin (return: 19.6% vs. no return: 41.9%, p=0.009) and to have had more than two health care provider visits in the previous 12 months (return: 26.8% vs. no return: 48%, p=0.02). Subjects who returned also were more likely to have a higher socio-economic position (return: 25% vs. no return: 12.9%, p=0.09) than those who did not return for follow-up. Additionally, subjects who returned for a 36-mohth follow-up had significantly greater improvements in HbA1c (return: -0.43% vs. no return: -0.03%; p=0.09) and Non-HDLc levels (return: -11.3 mg/dL vs. no return: +7.3 mg/dL, p=0.01) from baseline to 12-month follow-up.

Population Characteristics (12-Month Follow-up)

Characteristics of the 105 participants who had complete 12 follow-up data are presented in Table 10.1. Individuals providing data for 12 follow-up differed by demographic characteristics, including age (CCM: 69.7 years, PROV: 64.4 years, UC: 68.6 years, p=0.04) and age at

diagnosis of diabetes (CCM: 60 years, PROV: 53.1 years, UC: 55.8 years, p≤0.09). Subjects in the CCM intervention group also had significantly lower Non-HDLcs (CCM: 143.3 mg/dL, PROV: 168.8 mg/dL, UC: 148.7 mg/dL, p=0.03) in contrast to the other two groups. Additionally, a significantly greater proportion of subjects in the CCM group self-monitored their blood glucose (CCM: 100%, PROV: 90.6%, UC: 81.3%, p=0.04) in comparison to the other two groups. Quality of well-being scores also differed by group. Subjects in the PROV group had lower quality of well-being scores on all scales (WHO10 Subscale 1: CCM: 9.2, PROV 7.9, UC: 9.3, p=0.08; WHO10 Subscale 2: CCM: 11.2, PROV: 9.3, UC: 10.5, p=0.06; WHO10 Total Score: CCM: 20.4, PROV: 17.2, UC: 19.8, p=0.05) in comparison to the other two groups (Table 10.1). Results of the original trial are published elsewhere (16).

12-Month Predictors of Sustained Improvements in Outcomes at 36 Month Follow-Up

HbA1c

Improvements observed in HbA1c at 12-month follow-up were sustained at 36-month follow-up in the CCM group (12-month: 7.0% vs. 36-month: 7.1%, p=0.85) as well as the other two groups (PROV: 12-month: 7.1% vs. 36-month: 7.3%, p=0.89; UC: 12-month: 6.7% vs. 36-month 6.6%, p=0.76) (Table 10.2). Univariate predictors of sustained improvements are presented in Table 10.3. After controlling for study group, age, and diabetic treatment intensification, participants with lower QWB Subscale 1 scores (OR=0.76, 95% CI: 0.57-1.005, p=0.05) and lower scores on the DES: Dissatisfaction and Readiness to Change Scale (OR=0.22, 95% CI: 0.04-1.2, p=0.07) were more likely to have sustained improvements in HbA1c levels as both of these factors independently predicted the observed sustained improvement in HbA1c.

Non-HDLc

The same pattern of sustained improvement was observed for Non-HDLc. Mean Non-HDLc values were sustained and/or improved from 12-month F/U to 36-month follow-up in all study groups (CCM: 12-month: 148.6 mg/dL vs. 36-month: 135.3 mg/dL, p=0.07; PROV: 12-month: 161.3 mg/dL vs. 36-month: 133.8 mg/dL, p=0.03; UC: 12-month: 136.8 mg/dL vs. 36-month: 125.8 mg/dL, p=0.14) (Table 2). After examining a various combinations of contributing factors from Table 10.3, multivariate analyses, controlling for study group, age, lipid treatment intensification, the proportion of participants having two or more diabetes related complications at 12-month follow-up, 12-month Non-HDLc levels, and the proportion of participants self-monitoring their blood glucose at 12-month F/U was carried out. Analyses demonstrated that participants with higher Non-HDLc values (OR=1.1, 95% CI: 1.01-1.1, p=0.02), who did not have intensification to their lipid medication (OR=0.01, 95% CI: <0.001-0.62, p=0.03), who had more than two diabetes related complications (OR=14.5, 95% CI: 1.4-152.3, p=0.03), and who did not self-monitor their blood glucose (OR=0.02, 95% CI: <0.001-0.9, p=0.04) were more likely to experience sustained and/or improved Non-HDLc levels at 36 month follow-up.

Systolic and Diastolic Blood Pressure

Sustained improvements in SBP from 12-month follow-up to 36-month follow-up occurred across all study groups (CCM: 12-month SBP: 139.7 mmHg vs. 36-month SBP: 138.7 mmHg, p=0.9; PROV: 12-month SBP: 130.6 mmHg vs. 36-month SBP: 134.6 mmHg, p=0.47; UC: 12-month SBP: 136.8 mmHg vs. 139.5 mmHg, p=1.0). The same pattern was observed for DBP (CCM: 12-month DBP: 74.1 mmHg vs. 36-month DBP: 72.7 mmHg, p=0.04; PROV: 12-month DBP: 74.2 mmHg vs. 36-month DBP: 78 mmHg, p=0.43; UC: 12-month DBP: 77.7 mmHg vs. 36-month DBP: 75.4 mmHg, p=0.85) (Table 10.2). After considering factors from Table 10.3, multivariate analyses were carried out to determine which patient characteristics predicted the

sustained improvements in blood pressure levels. Models controlling for study group, age, blood pressure treatment intensification, and 12-month blood pressure values were used to model both SBP sustained improvements and DBP sustained improvements. Analyses demonstrated that subjects with higher 12-month SBP (OR=1.1, 95% CI: 1.02-1.1, p=0.01) and DBP levels (OR=1.2, 95% CI: 1.03-1.3, p=0.02) were likely to have sustained improvements in blood pressure levels at 36-month follow-up.

Self-Monitoring of Blood Glucose

Participants continued to SMBG at 36-month follow-up in all study groups (CCM: 12-month: 100% vs. 36-month: 93.3%, p=1.000; PROV: 12-month: 88.9% vs. 36-month: 94.4%, p= 0.11; UC: 12-month: 87.5% vs. 36-month: 91.7%, p=0.01) (Table 10.2). Out of the 57 participants who provided 36-month follow-up data, only one had stopped monitoring since 12-month follow-up. Multivariate analyses were not conducted, as the overall rate of monitoring at 36-month follow-up was 93%.

Quality of Well-Being

Similar to the clinical outcomes, quality of well-being total scores improved and/or sustained in all groups from 12-month follow-up to 36-month follow-up (CCM: 12-month: 20.8 vs. 36-month 22.8, p=0.08; PROV: 12-month: 17.6: vs. 36-month: 19.3, p=0.19; UC: 12-month: 21.1 vs. 36-month: 20.1, p=0.29) (Table 2). However, unlike the clinical outcomes, no 12-month patient characteristics predicted the observed sustained improvements (Table 10.3).

Diabetes Empowerment Scale

Unlike the aforementioned outcomes, Diabetes Empowerment Scale total scores worsened in all study groups from 12 to 36-month follow-up (CCM: 12-month: 4.1 vs. 36-month: 3.6, p=0.02; PROV: 12-month: 3.9 vs. 36-month: 3.2, p=0.03; UC: 12-month: 4.0 vs. 36-

month 3.8, p=0.24) (Table 2). However, a variety of 12-month factors predicted the improvement (Table 10.3). Of those who improved or sustained their DES scores compared to those who did not, age at diabetes diagnosis was significantly younger (51.0 vs. 59.3, p=0.01). Twelve month HbA1c levels were significantly lower (6.4% vs. 7.1%, p= 0.005), as were scores on the DES Dissatisfaction and Readiness to Change subscale (3.7 vs. 4.0, p=0.03) in those who improved/sustained (Table 3) compared to those who did not. Logistic regression models controlling for study group, age, insulin use, 12-month Non-HDLc and SBP values, 12-month scores on the DES Dissatisfaction and Readiness to Change subscale, and 12-month DKT scores demonstrated that participants who had higher SBP levels (OR=1.04, 95% CI: 1.009-1.072), participants using insulin (OR=4.9, 95% CI: 1.42-17.2), and subjects with lower scores on the DES Dissatisfaction and Readiness to Change subscale (OR=0.32, 95% CI: 0.13-0.84) were more likely to experience sustained improvements in empowerment scores at 36-month follow-up.

12-Month Predictors of a 36-Month Follow-up Visit

Overall, the 36-month follow-up rate was 54%. The follow-up rate was similar when examined by study group (CCM: 56%, PROV: 56%, UC: 52%). A variety of factors from Table 10.1 were associated with return for a 36 follow-up visit. Overall, participants with higher 12-month DKT scores were more likely to return for a 36 follow-up visit (OR=1.04, 95% CI: 1.01-1.07), as were those participants who had not seen a healthcare provider greater than two times in the past 12 months (OR=0.4, 95% CI: 0.18-0.89). Additionally, participants not using insulin were also more likely to return at 36 months (OR=0.33, 95% CI: 0.14-0.76), along with those participants with lower 12-month SBPs (OR=0.98, 95% CI: 0.96-1.0). Our final logistic regression model, which controlled for study group, age, insulin use, 12-month DKT scores, and

12-month SBP levels, confirmed that higher 12 month DKT scores (OR=1.05, 95% CI: 1.02-1.08) not using insulin (OR=0.18, 95% CI: 0.06-0.54), and having lower 12-month SBP levels (OR=0.97, 95% CI: 0.95- 0.99) independently predicted return for a 36 follow-up visit. Ancillary tables are listed in Appendix M (Tables A9-A13).

10.5 CONCLUSION

These secondary analyses of our randomized controlled trial of a multi-faceted diabetes care intervention were able to demonstrate that improvements observed in outcomes at 12-months following the intervention were able to be sustained at 36-months following the intervention in the Chronic Care Model group, along with the other two study groups. Sustained improvements were observed in HbA1c levels, systolic and diastolic blood pressure levels and the proportion of participants who self-monitor their blood glucose. Additional improvements occurred in Non-HDLc levels in all study groups, and quality of well-being scores in the CCM group only. Diabetes empowerment scale scores decreased during this time period. The sustained improvements observed in the PROV group and UC group may be related to secular improvements in diabetes care or regression to the mean.

Once we established that improvements were sustained, we were able to determine which 12-month participant factors predicted the sustained improvements in outcomes. Our multivariate analyses demonstrated that a variety of factors contributed to the sustained improvements, however, clear trends emerged where lower quality of well-being and diabetes empowerment scale scores accounted for the sustained improvements in HbA1c levels, while 12-month metabolic values were more important in the sustained improvements in Non-HDLc and blood pressure levels. All of these associations remained after controlling for medication treatment intensification.

A range of reasons could explain the variation in predictors of sustained improvements. For example, it could be that lower quality of well-being and diabetes empowerment scores predicted sustained improvements in HbA1c levels because participants who experienced improvements were “psychologically exhausted” from the strictness of the regimen that is required to manage their disease and/or the worry of diabetes-related complications. The clinical markers that predicted sustained improvements in Non-HDLc and blood pressure levels may indicate that these participants had the largest range of values to improve. When the psychological and psychosocial outcomes were examined, demographic, behavioral, and metabolic values helped to predict the sustained improvements in diabetes empowerment scale scores. The sustained improvements may be largely due to participants actively self-monitoring their blood glucose, which is a patient centered behavior. This, in turn, could have had an effect on improvements HbA1c levels at 12 months, and consequently the participant had higher self-efficacy regarding their diabetes self-care and management at 36-month follow-up. While a variety of factors contributed to the sustained improvements in diabetes empowerment scores, there were no predictors of sustained improvements in quality of well-being scores.

Given our low 36-month follow-up rate, we deemed it necessary to examine what patient factors predicted return at 36 months. We found that participants with higher diabetes knowledge test scores, those who saw a healthcare provider less than two times in the previous 12 months, those with lower systolic blood pressure levels, and participants not using insulin were more likely to return for a 36-month follow-up visit.

These data confirm the findings of other multifaceted diabetes care interventions, which resulted in improvements in clinical outcomes (15). However, this study also adds

significantly to the existing literature in a number of ways. To our knowledge, it is one of the only studies that followed a group of participants who received a multi-faceted diabetes care intervention (including DSME) over an extended period of time. In a systematic review of multifaceted interventions to improve the management of diabetes in primary care, outpatient, and community settings (15), the longest follow-up time was 18 months. Additionally, Norris and colleagues (23) reviewed the effectiveness of DSME in type 2 diabetes, in studies that used a collaborative approach, as we did. While positive effects on glycemic control occurred in the short term (23), there are few data on the long-term effects. Moreover, there are even fewer data on cardiovascular risk reduction mediating outcomes (i.e. Non-HDLc and systolic and systolic blood pressure levels), psychological and psychosocial outcomes, and behavioral outcomes. Norris and colleagues point out that a shortcoming of most effectiveness studies is that glycemic control and diabetes-related knowledge are the only outcomes on which success of the intervention is based (23).

Additionally, relatively little is known about what patient characteristics predict sustained improvements in outcomes. Numerous studies report that outcomes improve after an intervention; however, very few report data on factors that predict the improvement. For the most part, studies only hypothesize as to why improvements occur. However, there is a fair amount of research that examines what patient characteristics predict relapse in metabolic outcomes after an educational intervention (24-28), although psychological, psychosocial, and behavioral outcomes are rarely considered. Moreover, this relapse usually occurs in single faceted, efficacy-based interventions (27), which may fail to generate long standing behavioral change in the participants. We closed this gap by using a patient-centered approach and basing our DSME intervention on the Empowerment approach to diabetes education (17).

The literature demonstrates that diabetes encompasses behavioral, psychosocial, psychological, environmental, and clinical factors, all of which play a role in the management of the disease (29). It is assumed that biological and behavioral characteristics of individuals with diabetes are likely to affect control of complication risk factors (30). We believe that our previous work (16; 31) and our work in this report will provide further evidence for testing this theory.

The current study also adds to the existing literature by quantifying what type of person is most likely to return for a follow-up visit. The majority of the literature on this topic examines the reverse situation (i.e. predicting what type of patient will "drop out" or not return for a follow-up visit) (26; 32-35). The literature demonstrates that an entire host of factors may predict whether a participant drops out of a program, including distance from home to clinic (26), lack of insulin treatment (26), cigarette smoking (26; 32), high initial clinical parameters (32), the presence of psychosocial problems (34), and several demographic characteristics (34). While these characteristics are helpful in determining factors that explain why participants do not follow-up, knowing what type of patient is most likely to return for a follow-up visit may aid in a variety of settings as well. For example, it can aid researchers in understanding what populations of patients to target when planning diabetes care interventions and minimize loss to follow-up in these interventions. It can also be translated into the clinical practice setting to guide changes in scheduling patterns or to recognize patients appropriate for additional diabetes or non-diabetes related interventions to change behavior. Acquiring this type of information about participants living in an underserved, urban community may help to explain some of the challenges of living with diabetes in this area. This type of information is crucial if

we are to continue to close the gap between the scientific base for the treatment of diabetes and the care and outcomes that patients experience.

In conducting multifaceted diabetes care interventions; there are a variety of limitations that may affect study results. This study suffered from small sample size, which made this pilot study underpowered to detect significant differences in outcomes at 36-month follow-up and to detect all of the possible significant predictors of sustained improvements in outcomes and return for a 36-month follow-up visit. The university institutional review board did not permit us to contact patients directly for initial recruitment into the study. Therefore, it was the responsibility of the provider practices to recruit patients using predetermined recruitment methods developed by the study investigators. At 36-month follow-up, participants not being able to be contacted (possibly because they are now living in a nursing home as the majority of the cohort was elderly) and seven participants dying hampered recruitment. In initial sample size calculations, we estimated that 70 people in each of the three study groups would provide sufficient power to detect a 1.3% difference in HbA1c and a 17 mg/dL difference Non-HDLc, and an 8.4 mmHg difference in systolic blood pressure (80% power, non-directional alpha=0.05) if differences truly existed between the CCM group and usual care. Thus, with 15 people in the CCM group at 36-month F/U and 24 people in the usual care group at 36-months, we were underpowered to detect significant differences in outcomes if they truly existed. It is possible that we did not observe significant differences in blood pressure and quality of well-being scores due to Type II error. Thus, if there were smaller improvements in these outcomes, we may have been unable to detect them. Additionally, one may argue that the baseline A1c values were quite low for an underserved community. Thus, there was potential for a floor effect. However, we overcame this problem by following the subjects longitudinally to determine if the improvements could be

sustained. Another possible limitation to our study is that, with the exception of the laboratory data, nearly all of our data are self-reported which inherently biases results toward the null. Lastly, it must be noted that this randomized controlled trial was not designed to examine the contribution of patient characteristics to improvements in clinical outcomes or to examine why participants return for a 36-month follow-up visit. Indeed, it was designed to determine the effectiveness of a multifaceted diabetes care intervention in the primary care setting. Therefore, the results we observed are hypothesis generating and lend credence to further research in this area.

We have demonstrated through secondary analyses of this pilot, randomized controlled trial of a multifaceted diabetes care intervention, that improvements in outcomes can be sustained over time, across study groups. Additionally, we demonstrated the importance of considering a wide variety of patient factors, including psychological, psychosocial, behavioral, sociodemographic, and metabolic, in predicting these sustained improvements and predicting what type of participant is most likely to return for a follow-up visit. Future research in this area is necessary to understand what type of patient fairs the best from multifaceted diabetes care interventions that incorporate DSME. If we are to reduce the large proportion of adults with diabetes, who continue to have their HbA1c, blood pressure, and lipid levels sub-optimally controlled, and those people with diabetes who suffer from psychological and/or psychosocial problems, incorporating novel methods to redesign the way in which care is delivered is essential.

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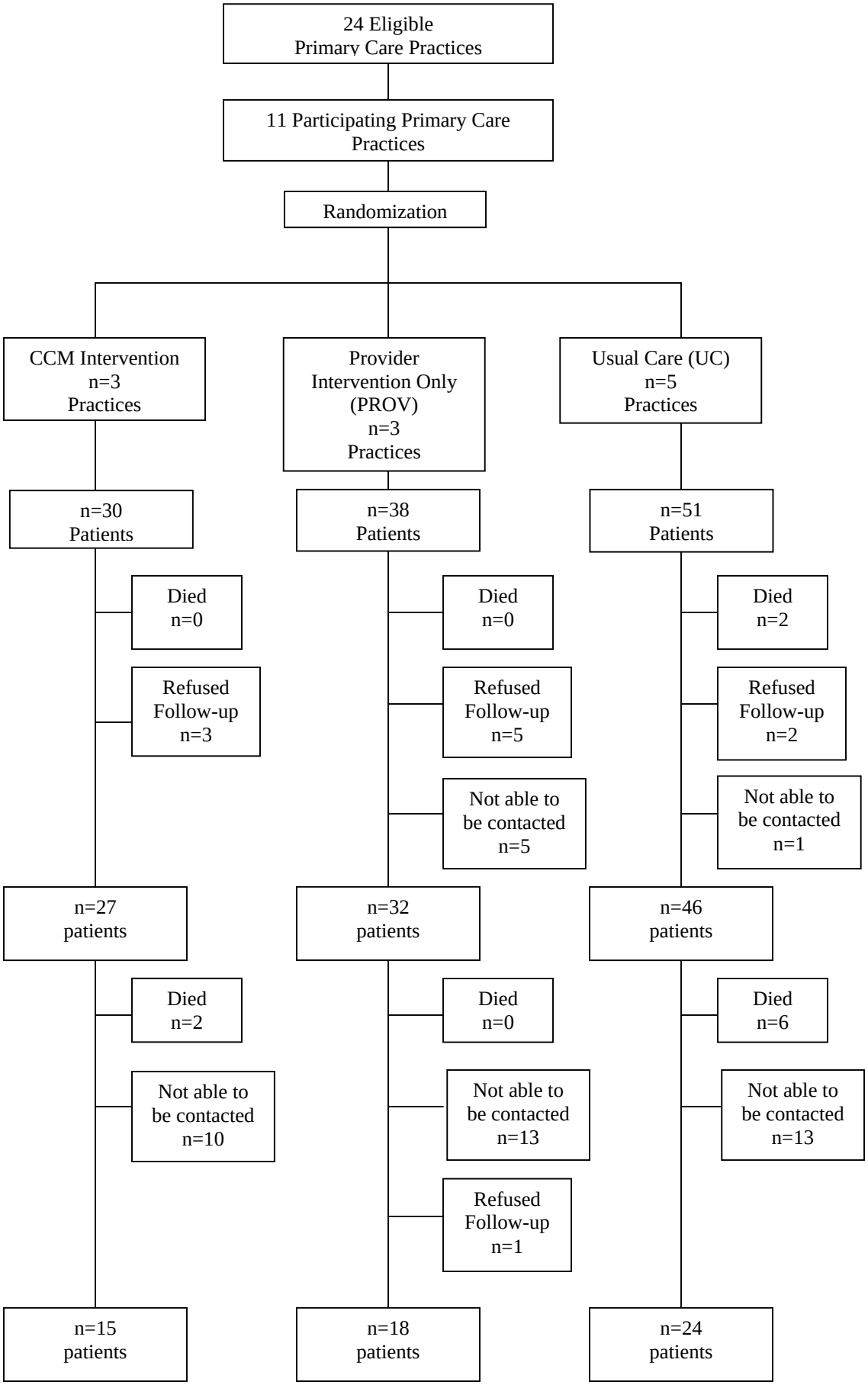

Figure 10.2 36 Month Follow-up study Design [216]

Table 10.1 Twelve-month follow-up sociodemographic characteristics, clinical characteristics, lifestyle behaviors, and psychological/psychosocial characteristics for the randomized controlled trial population by study group (n=57)

	CCM (n=15)	**PROV (n=18)**	**UC (n=24)**	**p-value**
Demographic				
Age	69.0 (12.3)	64.4 (6.8)	66.3 (7.3)	0.32
Age at diagnosis	60.7 (12.9)	55.5 (8.2)	53 (13.7)	0.18
Duration (years)	9.6 (10.6)	9.2 (6.7)	13.2 (11.9)	0.41
Gender (% male)	53.3 (8)	33.3 (6)	58.3 (14)	0.26
Race (% non-white)	20 (3)	5.6 (1)	4.2 (1)	0.2
Insulin use (% yes)	13.3 (2)	27.8 (5)	16.7 (4)	0.53
Socio-Economic Position (% high)	23.3 (7)	15.8 (6)	17.7 (9)	0.71
Clinical Characteristics				
HbA1c (%)	6.9 (0.8)	7.1 (1.3)	6.7 (0.88)	0.43
Non-HDLc (mm/dL)	148.6 (33.8)	161.3 (45.6)	136.8 (32.6)	0.13
Systolic BP (mm/Hg)	139.7 (19.9)	130.6 (14.3)	144.6 (18.7)	0.05
Diastolic BP (mm/Hg)	74.1 (7.4)	74.2 (8.5)	77.7 (7.9)	0.26
Retinopathy (% yes)	20 (3)	11.1 (2)	20.8 (5)	0.68
Neuropathy (% yes)	20 (3)	44.4 (8)	33.3 (8)	0.33
Cardiovascular disease (% yes)	40 (6)	44.4 (8)	54.2 (13)	0.66
≥ 2 complications (% yes)	53.3 (8)	66.7 (12)	75 (18)	0.38
Lifestyle Behaviors				
Ever smoked (% yes)	26.7 (4)	61.1 (11)	62.5 (15)	0.06
Self-monitor blood glucose (% yes)	100 (15)	88.9 (16)	87.5 (21)	0.37
≥ 2 visits to healthcare provider in past 12 months (% yes)	33.3 (5)	16.7 (3)	29.2 (7)	0.51
Psychological/Psychosocial Characteristics				
Quality of Well-Being Subscale 1 Score (Range 0-15)	9.4 (2.4)	8.0 (3.3)	9.9 (2.8)	0.11
Quality of Well-Being Subscale 2 Score (Range 0-15)	11.4 (2.6)	9.6 (3.0)	11.2 (4.2)	0.23
Quality of Well-Being Total Score (Range 0-30)	20.8 (4.0)	17.6 (5.9)	21.1 (6.5)	0.12
Empowerment Subscale: Dissatisfaction and Readiness to change (Range 1-5)	4.0 (0.49)	3.8 (0.44)	3.9 (0.65)	0.58
Empowerment Subscale: Setting and Achieving Goals (Range 1-5)	4.2 (0.66)	3.9 (0.49)	4.1 (0.66)	0.47

Table 10.1 continued

Empowerment Subscale: Managing the psychosocial aspects of diabetes (Range 1-5)	4.2 (0.43)	3.9 (0.5)	4.0 (0.62)	0.31
Treatment Intensification				
Diabetic Treatment Intensification (% yes)	13.3 (2)	38.9 (7)	54.2 (13)	0.04
Lipid Treatment Intensification (% yes)	13.3 (2)	11.1 (2)	12.5 (3)	0.98
Blood Pressure Treatment Intensification (% yes)	26.7 (4)	27.8 (5)	29.2 (7)	0.99

*Data are mean (S.D.) or %(n)

Table 10.2 Sustained Improvements in Clinical, Psychological, and Behavioral Outcomes across Study Groups (12-Month Follow-Up to 36-Month Follow-up) Following a Randomized Controlled Trial of a Multifaceted Diabetes Care Intervention

	CCM (n=15)				PROV (n=18)				UC (n=24)			
	Baseline	12 Month Follow-up	36-month follow-up	*p-value	Baseline	12 Month Follow-up	36-month follow-up	*p-value	Baseline	12 Month Follow-up	36-month follow-up	*p-value
HbA1c (%)	7.4	6.9	7.1	0.85	7.3	7.1	7.3	0.89	7.1	6.7	6.6	0.76
Non-HDLc (mg/dL)	169.3	148.6	135.3	0.07	174.3	161.3	133.8	0.03	151.0	136.8	125.8	0.14
Systolic BP (mmHg)	144.5	139.7	138.7	0.9	137.6	130.6	134.6	0.47	146.9	144.6	139.5	1.0
Diastolic BP (mmHg)	74.5	74.1	72.7	0.04	79.1	74.2	78	0.43	76.1	77.7	75.4	0.85
WHO 10 Quality of Well-Being Index Total Score (Range 0-30)	21.7	20.8	22.8	0.08	20.4	17.6	19.3	0.19	21.5	21.1	20.1	0.29
Empowerment Scale Total Score (Range 1-5)	3.8	4.1	3.6	0.02	4.0	3.9	3.2	0.03	3.9	4.0	3.8	0.24
Self-Monitoring of Blood Glucose (% yes)	86.7	100	93.3	1.000	83.3	88.9	94.4	0.11	87.5	87.5	91.7	0.01

*p-values represent differences from 12-month follow-up to 36-month follow-up. p-values <0.1 indicate sustained improvement in outcomes

Table 10.3 12-month Follow-up Sociodemographic Characteristics, Clinical Characteristics, Lifestyle Behaviors, and Psychological/Psychosocial Characteristics as Predictors of Sustained Improvements in Outcomes in Participants Returning for a 36-Month Follow-up Visit

	Sustained Improvements in HbA1c (yes:no)	**Sustained Improvements in Non-HDLc (yes:no)**	**Sustained Improvements in Systolic Blood Pressure (yes:no)**	**Sustained Improvements in Diastolic Blood pressure (yes:no)**	**Sustained Improvements in Quality of Well-Being Total Score (yes:no)**	**Sustained Improvements in Empowerment Scale Total Score (yes:no)**
Demographic						
Age (years)	63.5:66.4	65.6:63.9	64.8:65.3	64.8:65.3	67.7:64.3	63.7:67.7
Age at diagnosis (years)	56:56.3	56.6:53.4	56.1:56.8	55.9:57.4	56.7:55.8	51.0:59.3 †
Duration (years)	8.4:9.9	7.9:10	9.4:8.5	9.4:8.1	11.9:8.3	12.4:9.2
Gender (% male)	50(11): 41.2 (7)	50(12): 50(7)	63.2(12): 33.3(7) *	54.2 (13): 37.5 (6)	51.5(17): 47.8(11)	42.1(8): 54.1(20)
Race (% non-white)	9.1 (2): 17.7 (3)	16.7 (4): 7.1 (1)	15.8(3): 9.5 (2)	12.5(3) 12.5(2)	3.0(1): 17.4(4)	5.3(1): 10.8(4)
Insulin use (%)	13.6 (3): 23.5 (4)	8.3 (2): 28.6(4)	0 (0): 33.3 (7) ‡	12.5 (3): 25 (4)	12.1(4): 30.4(7)	15.8(3): 21.6(8)
Socio-Economic Position (% high)	18.2 (4): 35.3 (6)	16.7 (4): 42.9 (6)	26.3(5): 23.8(5)	26.3 (5): 23.8 (5)	21.2(7): 30.4(7)	36.8(7): 18.9(7)
Clinical Characteristics						
HbA1c (%)	7.2:6.7	----------	----------	----------	6.8:6.9	6.4:7.1 ‡
Non-HDLc (mm/dL)	---------	159.3:128 ‡	----------	----------	148.1:147.1	145.3:148.9
Systolic BP (mmHg)	---------	----------	144.6:129.2 ‡	----------	140.4:134.7	140.8:136.6
Diastolic BP (mmHg)	---------	----------	----------	78.3:71.8 ‡	75.8:75.3	75.6:75.6
≥ 2 complications (%)	59.1(13): 64.7 (11)	70.8(17): 42.9 (6) *	57.9(11): 66.7(14	57.9(11): 66.7(14)	60.6(20): 73.9(17)	57.9(11): 70.3(26)
Lifestyle Behaviors						
Ever smoked (%)	54.6(12): 52.9 (9)	58.3(14): 57.1 (8)	52.6(10): 57.1(12)	52.6(10): 57.1(12)	48.5(13): 56.5(16)	36.8(7): 59.5(22)

Table 10.3 continued

Self-Monitor blood glucose (%)	95.5 (21): 82.4 (14)	87.5(21): 92.9 (13)	94.7(18): 85.7(18)	94.7(18): 85.7(18)	90.9(30): 91.3(7)	89.5(17): 91.9(34)
≥ 2 visits to healthcare provider in past 12 months (%)	36.4 (8): 29.4 (5)	33.3 (8): 35.7 (5)	42.1(8): 23.8(5)	42.1(8): 23.8(5)	24.2(8) 30.4(7)	26.3(5): 27(10)
Psychological/Psychosocial Characteristics						
Quality of Well-Being Subscale 1 Score (Range 0-15)	8.3:10.3 †	8.8:9.4	9.1:9.1	8.8:9.5	9.2:9.0	9.7:8.8
Quality of Well-Being Subscale 2 Score (Range 0-15)	9.9:11.4	10.2:10.5	10.9:10.0	10.1:11	11.2:10.0	11.2:10.5
Quality of Well-Being Total Score (Range 0-30)	18.1:21.6 *	19:19.9	19.9:19.1	18.9:20.5	20.4:19.1	20.9:19.3
Empowerment Subscale: Dissatisfaction and Readiness to Change (Range 1-5)	3.8:4.1	4.0:4.3	4.0:3.8	3.9:3.9	3.9:3.9	3.7:4.0 †
Empowerment Subscale: Setting and Achieving Diabetes Related Goals (Range 1-5)	3.9:4.4 †	3.8:3.9	4.3:3.9 *	4.0:4.2	4.0:4.1	3.9:4.1
Empowerment Subscale: Managing the Psychosocial Aspects of Diabetes (Range 1-5)	3.9:4.2	3.9:4.2	4.1:3.9	3.9:4.1	4.0:4.0	3.9:4.1
Medication Treatment Intensification and Study Group						

Table 10.3 continued

Diabetic Treatment Intensification (% yes)	18.2 (4): 47.1 (8) †	----------	---------	---------	39.4(13): 34.8(8)	42.1(8): 61.9(13)
Lipid Treatment Intensification (% yes)	----------	8.3 (2): 21.4 (3)	---------	---------	9.1(3): 17.4(4)	15.8(3): 10.8(4)
Blood Pressure Treatment Intensification (% yes)	----------	----------	36.8(7): 19.1(4)	*33.3(8):* 18.8(3)	36.4(12): 13(3)	31.6(6): 24.3(9)
CCM group (% yes)	33.4(8): 23.5 (4)	29.2(7): 28.6 (4)	36.8(7): 23.8(5)	41.7(10): 12.5(2) *	33.3(11): 17.4(4)	15.8(3): 32.4(12)
PROV group (% yes)	41.8(7): 29.4 (5)	33.3(8): 28.6(4)	21.1(4): 38.1(8)	*20.8(5):* 43.8(7)	30.3(10): 34.8(8)	31.6(6): 32.4(12)

*Data presented are Student's T-Test means for continuous variables or Pearson's Chi-Square Test proportions %(n) for categorical variables
*p<0.1, †p<0.05, ‡p<0.01, §p<0.0001

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11.0 DISCUSSION

Diabetes mellitus is a chronic disease that has increased dramatically over the past decade and is expected to grow substantially over the next several years (372). It has become a significant public health problem as it places increased burden on patients, health care professionals, and society. Diabetes has always been a challenge (372) to manage due to the complexity of the disease. However, it is more than merely abnormal glucose metabolism with consequent microvascular and macrovascular complications. Diabetes encompasses clinical, behavioral, and psychosocial factors, all of which play a role in the care and management of the disease. Despite scientific advances in our understanding of its pathophysiology (373), awareness of many factors that affect its care (302), and improved treatment options (374), diabetes remains a complex and challenging chronic condition. Thus its care often falls below recommended standards regardless of health care setting or patient population, emphasizing the necessity for system change in the way diabetes care is delivered.

The Chronic Care Model (CCM) (76; 77; 85; 86) is a multi-faceted framework for enhancing health care delivery that is based on a paradigm shift from the current model of dealing with acute care issues, to a system that is prevention based (76; 84-86; 100). The premise of the model is that quality diabetes care is not delivered in isolation (i.e. implementing one type of intervention at a time) and can be enhanced by community resources, self-management support, delivery system redesign, decision support, clinical information systems, and organizational support working in tandem to enhance patient-provider interactions (76; 77; 84-87; 103; 114; 272).

Currently, few efforts exist that implement multifaceted approaches to improve quality of care in diabetes (76; 77; 87; 122; 344). Of those that do, little is known about whether it is feasible for entire model of chronic care to be implemented into the community setting, whether

the implementation results in improvements in patient outcomes, what patient factors predict improvements in these outcomes and whether improvements can be sustained over time. As the number of individuals with diabetes continues to increase at epidemic proportions, research focused on understanding the key issues of health systems and patients of improving the quality of healthcare for people with diabetes is crucial.

11.1 SUMMARY OF FINDINGS

This dissertation examined the implementation of the Chronic Care Model into the community in order to improve health outcomes in people with diabetes who receive care in the primary care setting. The aims were to: 1) examine the effect of a multifaceted diabetes care intervention, based on the Chronic Care Model patient clinical outcomes (HbA1c, Non-HDL-c, and blood pressure), behavioral outcomes (self-monitoring of blood glucose), and psychological/psychosocial outcomes (quality of well-being and empowerment) at 12 months following the education intervention, overall, and across three study groups; 2) determine which patient characteristics, including demographic, psychological/psychosocial, healthcare delivery and clinical factors, predict improvements in clinical outcomes (HbA1c, Non-HDL-c, and blood pressure) at 12 months following a multifaceted diabetes care intervention both overall, and between three the study groups; and 3) determine which patient factors predict returning for a 36-month follow-up visit. Additionally, determine if the improvements in clinical outcomes (HbA1c, Non-HDL-c, and blood pressure), psychological/psychosocial outcomes (quality of well-being and empowerment scale scores) and behavioral outcomes (self-monitoring of blood glucose) observed at 12 month follow-up are sustained at 36 months follow-up, overall, and between the three study groups, and if so, what factors predict and contribute to the sustained improvements.

In the first aim, we sought to determine if using the CCM in an underserved, urban community led to improved clinical and behavioral outcomes for people with diabetes receiving care in the primary care setting. We found that the CCM-based intervention was effective in improving clinical, behavioral, psychological/psychosocial, and diabetes knowledge outcomes in patients with diabetes. The CCM group, which received the multifaceted intervention, demonstrated significantly improved HbA1c levels, non-HDL-c levels, and rates of self-monitoring of blood glucose compared to the other study groups. Moreover, clinical outcomes improved even after adjusting for treatment intensification. In addition, within the CCM group, improvements in HDL-c levels, diabetes knowledge, and empowerment scores were observed. These findings demonstrated that a multifaceted intervention is able improve diabetes outcomes in an underserved, urban community. These results support the literature on the effectiveness of multifaceted diabetes care interventions in improving patient outcomes (117).

In specific aim two, the impact of individual level factors on the improvements in the ABCs (HbA1c, blood pressure, and Non-HDL cholesterol) of diabetes, observed at 12 months following the multifaceted intervention, was examined. We demonstrated that a wide variety of factors, including psychosocial, psychological, sociodemographic, and clinical factors, were associated with improvement in the ABCs. Participants with higher HbA1c levels at baseline, who had higher quality of well-being scores at baseline, and who were members of the CCM intervention group experienced larger improvements in HbA1c levels in comparison to subjects in other study groups. A similar pattern of results was observed when examining improvements in Non-HDLc; however psychosocial aspects played a larger role as indicated by significant correlations with both baseline quality of well-being scores and the dissatisfaction and readiness to change subscale of the diabetes empowerment scale. There was no intervention effect on

blood pressure levels; however, there was substantial variability in the range of values, which indicates that some subjects improved greatly, while others did not. Higher baseline systolic blood pressure values, insulin use, and high socio-economic position were associated with greater improvements in systolic blood pressure, while female gender, higher baseline diastolic blood pressure values, older age, insulin use, and higher scores on the diabetes empowerment scale subscale: setting and achieving diabetes related goals were associated with greater improvement diastolic blood pressure values. The results of this aim provide evidence that a wide variety of individual factors impact improvements in metabolic outcomes. In particular psychosocial and psychological factors may account for a greater amount of variability in metabolic outcomes than clinical factors and may contribute to improvement. Although, the contribution of "non-traditional" patient factors (i.e. psychological, psychosocial, etc) to improving metabolic outcomes in people with diabetes is alluded to in the literature, this theory is still in its infancy. The work in specific aim two helps to provide further quantitative evidence to help support this theory.

Specific aim three investigated whether improvements observed in the primary (HbA1c, Non-HDLc, and blood pressure levels) and secondary outcomes (self-monitoring of blood glucose, quality of well-being, and empowerment scores) at 12-months following the multifaceted intervention could be sustained at 36-month follow-up. The analyses demonstrated that improvements observed in outcomes at 12-months following the multifaceted intervention were sustained at 36-months following the intervention in the CCM group, along with the other two study groups. Sustained improvements were observed in HbA1c levels, systolic and diastolic blood pressure levels, quality of well-being scores, and the proportion of participants who self-monitor their blood glucose. Additional improvements occurred in Non-HDLc levels in all study

groups. However, diabetes empowerment scale scores decreased during this time period. Numerous studies report that improved outcomes are sustained over time after an intervention; however, very few report data on factors that predict the improvement.

We also examined what patient factors from 12-month follow-up predicted the sustained improvements at 36-month follow-up. A variety of factors contributed to the sustained improvements, however, clear trends emerged in lower quality of well-being and diabetes empowerment scale scores as they largely predicted the sustained improvements in HbA1c levels, while 12-month metabolic values were the clear drivers behind the sustained improvements in Non-HDLc and blood pressure levels. All of these associations remained after controlling for medication treatment intensification, which is a trend that emerged in all three specific aims.

The last point that was investigated in specific aim three was the influence of patient factors on returning for a 36-month follow-up visit. We found that participants with higher diabetes knowledge test scores, those who saw a healthcare provider less than two times in the previous 12 months, those with lower systolic blood pressure levels, and participants not using insulin were more likely to return for a 36-month follow-up visit. Therefore it may be hypothesized that the participants who chose to return at 36-months were a healthier population than those who chose not to return.

In summary, this dissertation explored the effectiveness of implementing a multifaceted diabetes care intervention, based on the Chronic Care Model, into an urban, underserved community, with the goal of changing the way diabetes care is delivered in order to improve outcomes in patients who receive their diabetes care in the primary care setting. The effectiveness of the intervention, the factors that predict the improvements in outcomes

observed following the intervention, the sustainability of those improvements, and the factors that predict the sustainability of the improvements have been described and identified. The findings of this dissertation are significant and help to close a gap in the literature on improving the quality of care for people with diabetes through redesigning the process of diabetes care delivery.

11.2 CONTRIBUTION TO THE LITERATURE

The work presented in this dissertation helped to close a gap in the existing literature by examining the effectiveness of a multifaceted diabetes care intervention to improve outcomes in people with diabetes, and to ultimately improve diabetes quality of care in the community setting. There is a paucity of literature regarding implementation of the entire model in diabetes care. The first manuscript incorporated into this report is the first study published from a U.S. cohort that reports on the implementation of the entire model Chronic Care Model into a community setting. With the exception of a Danish study (116), in which representative general practices significantly improved long term control of diabetes through a variety of educational interventions, there have not been other published randomized controlled trials, to our knowledge, that implemented a combination of interventions to improve quality of care for people with diabetes. In contrast to the Danish study (116) and our current study, most studies choose to implement one aspect of the Chronic Care Model (103). Bodenheimer and colleagues (354) conducted a systematic review of studies of diabetes care programs featuring the four main elements of the Chronic Care Model (self management support, decision support, delivery system design, and clinical information systems). Each study was classified on the basis of whether it detected significant improvements in the processes of care, patient outcomes, or both, based on the number of elements that were implemented. Patient outcomes improved in the 5

studies that implemented the 4 main elements of the model, however, outcomes also improved in the majority of studies that did not implement all 4 elements. Although specific elements of the CCM can not be teased out of the aforementioned studies or our study as essential to improvement, Bodenheimer and colleagues note that 19 of 20 interventions that included a self-management component, improved a process or outcome of care (354).

The second manuscript that is incorporated into this report adds significantly to the literature, as relatively little is known about what patient characteristics contribute to improvements in metabolic outcomes. It is hypothesized that biological and behavioral characteristics of individuals with diabetes are likely to affect control of complication risk factors (355); however this concept is still in its infancy. With the exception of self-determination theory research done by Williams and colleagues (269-271), and the vast array of clinical literature on various medical treatments, to our knowledge, this is one of the few studies that examined the effect of a variety of patient characteristics along with the effect of a multifaceted diabetes care intervention, on improvements in clinical outcomes. Examining this aspect of diabetes care is crucial as national data demonstrate that progress in improving risk factors for complications in individuals with diabetes over the past decade has been modest (355).

The third manuscript of this dissertation examined if improvements in outcomes observed at 12-month follow-up could be sustained at 36-month follow-up, and if so, what variables predicted these sustained improvements. Although the sample size was small, this was the first study that followed a group of participants for more than 18 months after they completed a multifaceted diabetes care intervention. The 36-month follow-up data is distinctive in that it was able to demonstrate that improvements in outcomes could be sustained over a long period of time, and without an active intervention. This concept may lend credence to a theory that it may

only take one intensive intervention experience for outcomes to improve and stay improved over time. Although this statement must be interpreted with caution, due to the small sample size, generalizing these results beyond this population may be problematic.

In the current literature, studies generally hypothesize as to why improvements occur. However, there is a fair amount of research that examines what patient characteristics predict relapse in metabolic outcomes after an educational intervention (362-366), although psychological, psychosocial, and behavioral outcomes are rarely considered. Moreover, this relapse usually occurs in single faceted, efficacy-based interventions (365), which may fail to generate long standing behavioral change in the participants. We closed this gap by using a patient-centered approach and basing our DSME intervention on the Empowerment approach to diabetes education (79), combined with provider education, community, and health system changes.

The third manuscript also adds to the existing literature by quantifying the type of person with diabetes is most likely to return for a follow-up visit. The majority of the literature on this topic examines the reverse situation (i.e. predicting what type of patient will "drop out" or not return for a follow-up visit) (364; 368-371). The literature demonstrates that an entire host of factors may predict whether a participant drops out of a program, including distance from home to clinic (364), lack of insulin treatment (364), cigarette smoking (364; 368), high initial clinical parameters (368), the presence of psychosocial problems (370), and several demographic characteristics (370). While these characteristics are helpful in determining factors that explain why participants do not follow-up, knowing what type of patient is most likely to return for a follow-up visit may aid in a variety of settings as well.

This dissertation focused on one of the few randomized controlled trials that examined the aforementioned issues in a robust, epidemiological manner, incorporating randomization at the provider level and the use of advanced statistical methods to control for the effect clustering of patients within provider practices. Indeed, most multifaceted studies to date (117) have included inadequate concealment allocation, randomization errors, and have not controlled for the effect of clustering, thereby making them prone to contamination with results that are difficult to interpret. These factors, along with the aforementioned limited measurement of outcomes, limit studies' ability to be generalizable and translatable into the general population.

11.3 APPLICABILITY OF THE CHRONIC CARE MODEL ACROSS POPULATIONS AND SETTINGS

Reducing morbidity and mortality and improving quality of life for people with diabetes is an ongoing challenge for a variety of populations and settings. Diabetes management is not only complex and difficult from the patient's perspective, but it is also difficult from the provider, the community, and the health care system perspective (375). This difficulty is evident in the sub-optimal levels of diabetes care that currently exist (376). For successful diabetes self-management, people with diabetes need adequate patient education and social support. Providers encounter high rates of resource consumption by people with diabetes, making collaboration with patients to achieve behavior change frustrating. Providers need support from health-care systems to educate, monitor, and manage patients with diabetes. Further coordination is needed among patients, providers, health-care delivery systems, and communities in order for care to improve. By implementing interventions reported to be effective (114; 117; 119; 123; 124; 149; 166; 192; 278; 299; 305; 307-309; 326; 358; 366; 377-380), policy makers and health-care and public health providers can help their communities achieve health goals while using community resources efficiently (375).

New models of health-care delivery, including disease and case management, have emerged in the last decade in response to the failure of traditional models to meet the needs of people with diabetes and in response to societal changes that include changing demographics, new technology, a shift in the focus of patient care toward quality of life and other patient-oriented outcomes, and limited health-care resources (375). The Chronic Care Model (76; 77; 85; 86) is an example of a disease management model. The Chronic Care Model is an organized, proactive, multifaceted approach to healthcare delivery, involving all members of a population having or treating a specific disease. Consequently, diabetes care is focused on, and integrated across, the spectrum of the disease and its complications, prevention of comorbid conditions, and relevant aspects of the delivery system (375).

The research presented in this report is an example of an effective multi-faceted diabetes care intervention that involved members of an urban, underserved community. The multifaceted approach to the intervention and the results found in this research can be generalized and translated into other communities so that the possible benefits can be realized in a variety of populations and settings. In implementing this type of multifaceted approach to diabetes care and management, patients are not only able to benefit from the patient-centered approach to diabetes self-management, but they also benefit from having community and health system resources that they can access when they need information. They also benefit from having primary care providers who are aware of the recommended standards of care for persons with diabetes and who are following them. In turn, health care providers benefit from this multifaceted approach by treating patients who are self-efficacious about their diabetes management. Providers also have the opportunity to redesign the way in which they deliver diabetes care by implementing certified diabetes educators into their practices at no extra cost to

them. Indeed, not only can the patient receive specialized diabetes care in the primary care setting, but also, the certified diabetes educator can sustain his/herself by billing for their services, making it a “win-win” situation for both the patient and the provider.

The benefits of multifaceted diabetes care interventions at the community and health-systems level are evident as well. Care can be evaluated with guidelines and treatment goals based on scientific standards to improve system-level and patient outcomes. Community and system-level approaches to diabetes care and management can then be developed to address health disparities and improve care and quality of life for people with diabetes.

Given the substantial public health burden of diabetes, improving care for persons with diabetes should be a priority in the majority of communities and health-care systems. In selecting and implementing approaches to improve care and management for diabetes, communities and health-care systems should strive to develop comprehensive strategies to promote healthy lifestyles and to help people with diabetes and their health-care providers and systems to improve glycemic control, decrease diabetes complications, and improve quality of life, just as we did in this research. Choosing interventions that are effective and well matched to local needs are vital steps toward improving outcomes for people with diabetes.

11.4 STUDY LIMITATIONS

In conducting translational research, circumstances and environments are not “controllable,” like efficacy-based research (323); therefore, limitations exist. First, the small sample size of the original trial and the even smaller sample size of the 36-month follow-up data must be acknowledged. In initial sample sizes calculations, we estimated that 70 people in each of the three study groups would provide sufficient power to determine a 1.3% unit difference in HbA1c levels, an 11 mg/dL unit difference in Non-HDLc levels, and an 8.3 mmHg unit

difference in systolic blood pressure levels between the intervention group and usual care if the differences truly existed. Thus, it is possible that we did not observe significant differences due to Type II error. If there were small improvements in these outcomes, we may have been unable to detect them. Our small sample size was largely due to regulatory constraints from the university's institutional review board. They did not permit us to contact patients directly for recruitment. Therefore, it was the responsibility of the provider practices to recruit patients into the trial using predetermined recruitment methods developed by the study investigators.

Secondly, one may argue that the baseline HbA1c, Non-HDLc, and blood pressure values were quite low for an urban, underserved community, creating the potential for a floor effect. We combated this issue in specific aim three by following the participants longitudinally to observe if the improvements in outcomes could be sustained. The UC group started the study with lower mean HbA1c and Non-HDLc levels than the CCM group. We accounted for this, along with possible regression to the mean, in our multivariate models by adjusting for the baseline values.

Another possible limitation to our study is that nearly all of our data are self-reported, with the exception of the laboratory data, which inherently biases results toward the null. Additionally, we found that the participants who chose to return for a 36-month follow-up visit were healthier than those who chose not to return. This "healthy volunteer" population biases our 36-month results toward the null as well.

Lastly, it must be noted that this pilot study was not designed to examine the contribution of patient characteristics to improvements in clinical outcomes. Indeed, it was designed to determine the effectiveness of a multifaceted diabetes care intervention in the primary care setting. Therefore, the results we observed in specific aims two and three are hypothesis generating and lend credence to further research in this area.

11.5 FUTURE RESEARCH

Several promising interventions designed to optimize implementation of efficacious diabetes treatments are available (278; 306; 326-330). However, many of these interventions need to be more formally tested in larger randomized or quasi-experimental trials using outcomes of special interest to patients (i.e. patient satisfaction and quality of life) (331) and to policymakers (i.e. cost-effectiveness). More often than not, patient glycemic control and diabetes knowledge are the only outcomes on which the success of these types of interventions is based (136). Further, there remains a lack of knowledge about the long-term impact on health outcomes, quality of life and cost of strategies aimed at improving diabetes care at the patient provider, and system levels (202; 203; 319; 332). The Institute of Medicine (100) has argued that new systems of care and new ways of thinking are needed to tackle the complexity of quality diabetes care and management. Therefore, it is critical that future diabetes translational research be designed in a way that understands the system as a whole and not simply its parts (319).

Continued research in this area, encompassing a variety of fields such as epidemiology, health services research, psychology, sociology, health policy, and economics (205; 319), is necessary if we are to realize the full potential of landmark trials, such as the DCCT (5), UKPDS (4), and DPP (6), and prevent the enormous aggregate burden of diabetes on our society. A wider application of system change strategies in the community and health system settings, based on scientific findings, represents an essential tool to improve the quality of care and the quality of life for all persons with diabetes and to reduce health disparities.

Diabetes translational research has the capabilities of accelerating the transfer of new scientific knowledge into clinical and public health practice. More translational research is needed to develop effective public health approaches to motivate and sustain the required

changes, on the part of the health care provider, the patient, and the health system, needed to improve diabetes care and management.

11.6 PUBLIC HEALTH SIGNIFICANCE

The 21st century has brought increased globalization and industrialization, longer life spans, and changes in lifestyles worldwide (1). As a consequence of these changes, shifts in the patterns of disease have occurred (100). There are no longer epidemics of acute illnesses. Instead they have been replaced by epidemics of chronic illnesses, including diabetes (100). The growing problem of diabetes does not fit the "traditional" model of public health emergencies, unlike infectious diseases, which are easily perceived as a threat to the public at large. Thus, it is necessary to change the traditional definitions of what constitutes a significant public health problem and its accompanying priorities (88).

Diabetes is an important public health problem as it is equally burdensome to individuals and to society, and disproportionately affects disadvantaged people and nations (88). While it is estimated that ~30-50% of diabetes cases remain undiagnosed, there were approximately 30 million people worldwide diagnosed in 1985 (381; 382). By 1995, this number increased to 135 million, and projections indicate there may be 300 million people with diabetes by 2025, representing a 42% increase in industrialized nations, and a 170% increase in non-industrialized nations (383). However, despite the growing number of possibilities for reducing much of this burden, along with the increasing public concern over the disease, the number of people with diabetes continues to grow as does the number of people with diabetes related complications, and consequently diabetes-related mortality (372). This often results from the sub-optimal degree of implementation of a number of treatments for diabetes. Understanding the reasons for the sub-optimal implementation is necessary if we are to reduce the increasing burden of the disease (1).

Non-industrialized nations must learn from the mistakes that many of the industrialized nations have made when trying to implement treatment strategies on the population level (1). A more holistic approach to diabetes care and management may be important. Implementation of models of chronic care, that focus on communities and partnerships, the healthcare system, self-management support, redesigning the way in which care is delivered, provider adherence to national standards, and a variety of information technology strategies to help in the care and management of diabetes, may be what is needed for improvements to occur at the systems and population levels (76; 77; 123). The challenge, however, will be to translate this knowledge into public health policy and into the clinical practice setting so that the burden of diabetes and its complications can be avoided worldwide (1).

The research presented in this dissertation is a small step in translating existing knowledge into the community. By examining and testing the effectiveness of a multifaceted approach to improve diabetes care and management at the patient, provider, and systems levels, we were able to partner with community members, offer self-management support to patients, redesign the way in which diabetes care is delivered in the primary care practice setting, offer primary care providers reports of how they were doing in comparison to their peers in the community and to the national standards, determine the burden of diabetes in an urban, underserved community through a population-based chart audit, and most importantly, improve patient outcomes and understand why these outcomes improved. Through this approach we were able to make a small impact in reducing the avoidable burden of diabetes.

12.0 CONCLUSION

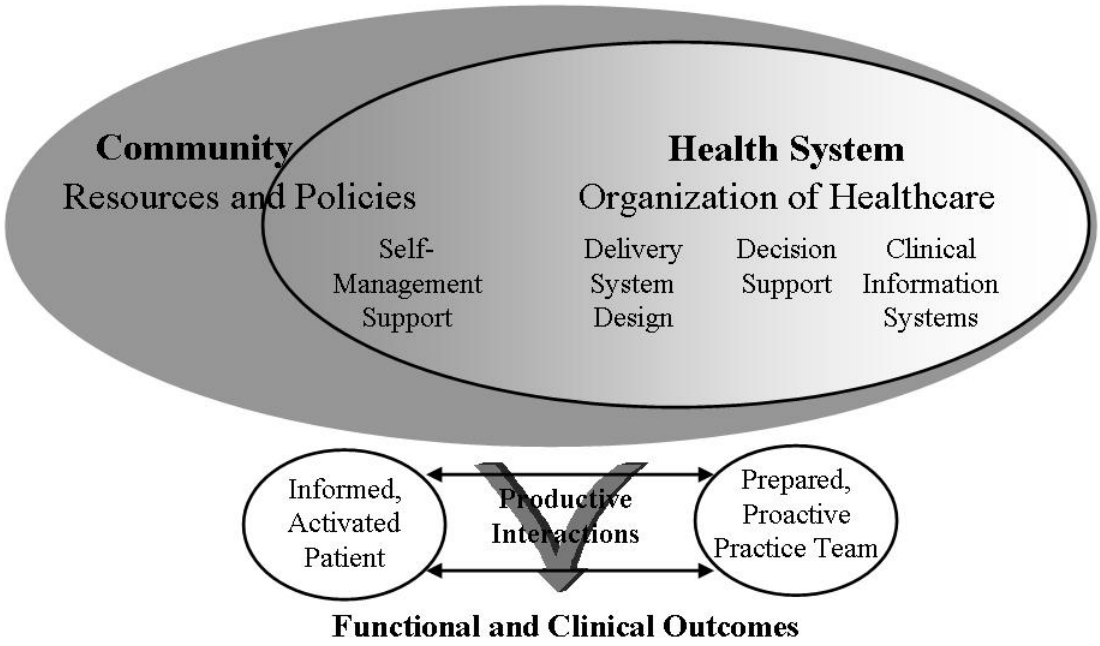
In this research, the effectiveness of implementing the Chronic Care Model into an urban, underserved community was examined. As the burden of diabetes continues to escalate, new approaches to how diabetes care is delivered are needed if we are to improve care at the patient,

provider, community, and health systems levels. Implementing the Chronic Care Model resulted in improvements in patients' clinical, behavioral, psychological, and psychosocial outcomes. Many variables predicted the improvements, however, psychological and psychosocial factors drove the improvement, regardless of medication treatment intensification. Not only did improvements occur one year after the initial intervention, but also, the improvements were sustained over time.

Our community partnerships, population-based sample of participants, flexible patient-centered approach to diabetes self-management training, and primary care practice redesign suggest that this model for improving diabetes care in the community is feasible, effective and could be applied to other chronic illnesses.

Appendix A: Chronic Care Model

Chronic Care Model



Appendix B: American Association of Diabetes Educators Seven Self-Care Behaviors

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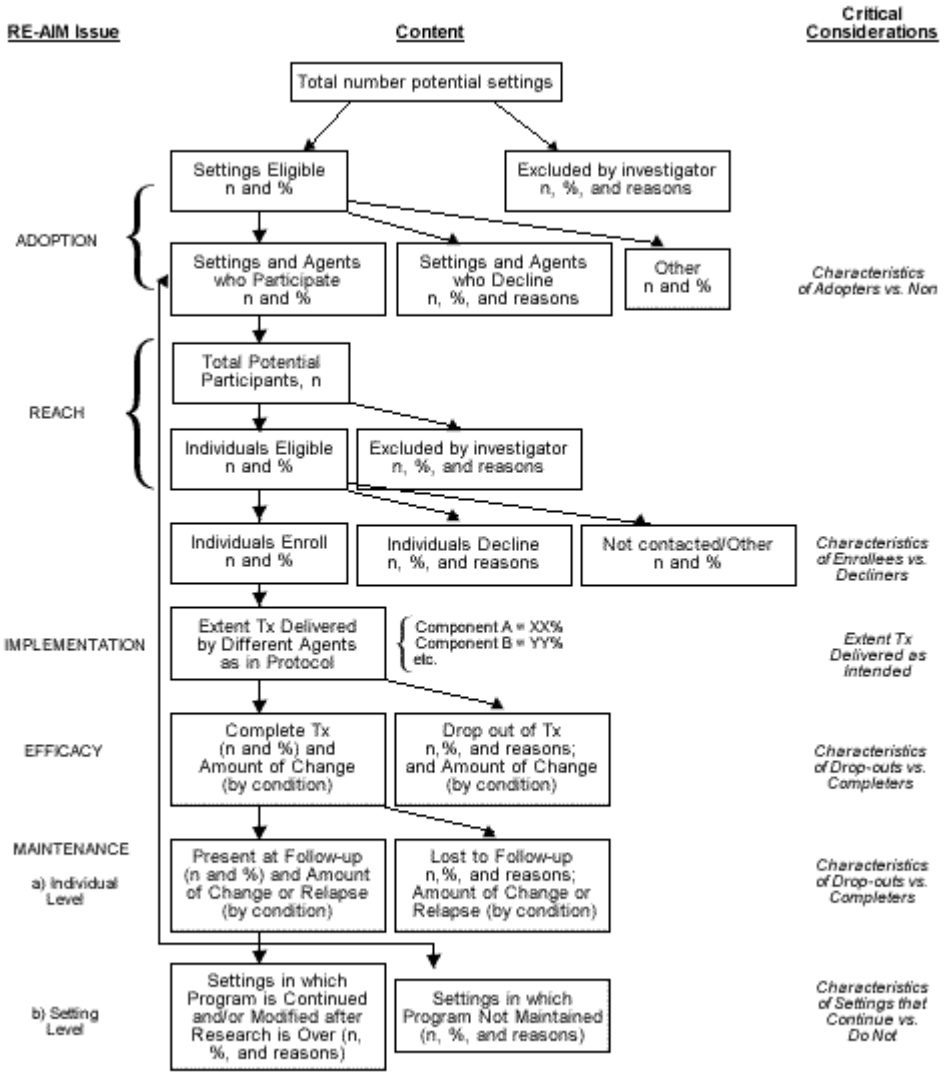
Healthy Eating
Being Active
Monitoring
Taking Medication
Problem Solving
Healthy Coping
Reducing Risks

-

Appendix C: The Re-AIM Framework



*At each step, record qualitative information on factors affecting each RE-AIM dimension and step in the flow chart.

Appendix D: Chart Review Protocol

-

Chart Audit Protocol

This form should be completed for every identified non-pregnant, non-imprisoned patient with diabetes over the age of 18. Patients with diabetes will be identified either by billing code 250.**, or other physician/office tracking system (e.g. electronic medical record, file tags, etc).

Inclusion Criteria:

- At least one visit during calendar year 1999
- Diabetes for the entire calendar year 1999

When reviewing the chart, no item should be left blank. If an item is not in the chart, it should be documented accordingly (see data extraction form). All items should be circled where appropriate. If a process item for review is not documented in the chart, it is considered not done. At no time is the verbal confirmation of the office staff or physician to replace written documentation of a process in the chart.

Upon completing the chart audits, forms should be reviewed for completeness and submitted to the Project Director for final review and data entry.

-

Instructions for chart review by question

Audit date:

Date of chart review

Physician name/Group:

Record the physician of record. If the patient sees multiple physicians within a practice, record the group practice name.

Patient Study Number:

DO NOT RECORD PATEINT NAME, MEDICAL RECORD NUMBER, SOCIAL SECURITY NUMBER, OR ANY OTHER SPECIFIC INDENTIFIER AT ANY TIME. In order to preserve patient confidentiality, no patient identifiers are to be recorded. Each record will be consecutively numbered within each practice. For example: each practice will have an alphabetical identifier A through Z, followed by a patient number 1, 2, 3, …, etc. Therefore patient study number A23 is patient 23 from office A. Patient number and corresponding name will be kept on a chart review log at the physician's office. ONLY the office staff keeps this log and at NO TIME should the research team have a copy of this log.

Reviewer:

This is the name of the person conducting the chart review.

Patient date of birth:

This is usually recorded on the chart in several places: insurance card, patient form filled out at first visit, patient notes.

Confirmed diagnosis:

Chart reviews will be conducted only for those patients with a confirmed diagnosis of diabetes during calendar year 1999. Confirmation of diabetes will be a positive response to one of the following:

1. Treatment:

   Diabetes treatments include but are not limited to:

   Insulin
   Diabinese (Chlorpropamide)
   Amaryl (Glimepiride)
   Glucotrol (Glipizide)
   Diabeta (Glyburide)
   Micronase (Glyburide)
   Glynase (Glyburide, micronized)
   Metformin
   Acarbose
   Prandin OR

2. Fasting blood sugar (FBS) >126 mg/dl prior to January 1999 OR
3. Random blood sugar >200mg/dl prior to January 1999 OR

-

4. HbA1c >7% prior to January 1999.

If none of the above is true, do not continue with chart review.

Year of diagnosis/age at diagnosis:

Record either or both the year of diagnosis or age at diagnosis

Gender:

Circle one: either male or female

Patient level of education:

This may or may not be documented. Some searching of the history and physical or other chart notes may be necessary. An attempt should be made to determine if the level of education is a high school equivalent or less, or education beyond high school.

Occupation:

Record the patient's occupation during 1999. IF more than one occupation was held, record the position held for the largest part of 1999.

Race:

This variable may or may not be recorded. Again some searching through the history and physical section of the chart may be helpful. This may also be recorded on the EKG. Race may be recorded as "WF" meaning "white female", or "BF" meaning "black female".

Insurance:

Did the patient have insurance during 1999? If so, what type? If the patient has more than one type of insurance record both. If the patient had different types of insurance throughout the year, record the insurance type held for the majority of the year. Record up to three insurance companies.

Smoker:

Is the patient currently a smoker (check History and Physical notes)
Check old medical records for documentation of smoking status.

If yes, is there any report of smoking cessation counseling during 1999.

Current Height and Weight:

Record the most recent value available in the chart for the year 1999.

Diabetes Therapy:

Circle all medication categories that apply to the patient's current therapy. See Chart Audit Appendix A for medication names and categories.

Diabetes Education:

-

During calendar year 1999, did the patient receive diabetes education for nutrition, exercise, or outpatient education? For nutrition and/or exercise any mention of a discussion on either of these would be "yes". For outpatient education, this will include one on one education or group education from a diabetes educator in the outpatient setting.

Self monitor blood glucose:

Does the patient check their own blood sugar outside of the doctor's office or clinic. Identify how often the patient checks their blood sugar per week. If daily numbers are provided, convert to weekly values (multiply by 7). There may be blood glucose logs in the chart where an average per week can be calculated.

Laboratory Measures:

All measures are for calendar year 1999.

There will most likely be laboratory sheets in the chart that will have the variables of interest on them.

HbA1c (glycosylated hemoglobin): was the test performed? Circle the appropriate response. If yes, record the date and corresponding value for all HbA1c measures performed during calendar year 1999. Also record the name of the laboratory where the specimen was analyzed. IF no, skip to lipid profile.

Lipid Profile (total cholesterol, triglycerides, LDL, HDL): was the test performed? Circle the appropriate response. If yes, record the corresponding value. If more than one lipid profile was performed during 1999, record the last value for 1999. IF no, skip to urinalysis.

Urinalysis (for proteinuria/microalbuminuria): was the test performed? Circle the appropriate response. If yes, indicate the type: dipstick, 24 hour, etc.

Serum Creatinine: was the test performed? Circle the appropriate response. If yes record the corresponding value. If more that one serum creatinine was measured during 1999, record the last value for 1999.

Exams in the previous 12 months (calendar year 1999):

Circle the appropriate response for all categories. Remember, if it is not recorded in the chart, the exam is considered not done.

Dilated eye exam: this is not the retinal exam performed in the office. For this exam the pupils are dilated to look for proliferative changes, and is most often performed by an ophthalmologist. The doctor may record "will see Dr. so and so". This is a "no". If the doctor records "saw Dr. so and so" the answer is yes. The ideal is to look for documentation from the eye doctor that the patient was seen.

-

Foot exam: Evidence that the physician examined the feet includes pulses, monofilament, vibration, and proprioception.

Monofilament: This is most often recorded as normal or #/7 or #/5 or #/10. Record the score if available. If more than one recording, record the last one for 1999.

Electrocardiogram: either the tape will be in the chart or perhaps a letter from a cardiologist.

Blood Pressure: Record the last blood pressure recording for 1999.

Flu vaccine:

Look for documentation in the chart for the vaccine being given either in the office, or from an outside source. As you look through the chart, focus on the fall of the year, as this is when flu vaccines are usually given.

Symptoms/problems:

The conditions are severe forms of acute complications in patients with diabetes.

Complication Assessment:

This is the most difficult part of the chart review process and should be carried out with as little subjective judgment as possible. Documentation of these complications can be derived from history and physical notes, exam notes, letters from other physicians, etc. It is critical to review the entire chart until a valid conclusion about the complication can be reached.

Eyes:

Retinopathy: this is marked "yes" if there is documentation from the eye doctor, laser therapy for proliferative changes ever. It is only marked no if there is a letter from an eye doctor during 1999 stating there are no proliferative changes. If there is no eye exam documentation from the eye doctor this is marked unknown.

Laser therapy: This is most often a yes or no and seldom unknown.

Blindness: This is marked yes if there is documentation by the physician for blindness due to diabetes or DR (diabetic retinopathy). It is marked no if there is no documentation of blindness.

Cataracts: This follows the same protocol as for retinopathy. Documentation from the eye doctor or evidence of cataract surgery.

Maculopathy: This follows the same protocol as for retinopathy where documentation from the eye doctor is required.

Kidneys:

Microalbuminuria: In order for this to be documented yes, specific tests for MA will have to be performed including a 24 hour urine. The methodology should be documented, and if the test was confirmed and how many samples were used to confirm.

Proteinuria: See above (MA). This can also be determined using dipstick.

IF no urine test for protein was performed the answer to both of these is unknown.

-

Throughout the chart, if someone is on dialysis, has had a transplant or has renal failure, it will be documented in the chart. If there is evidence of these conditions, the answer is no.

By recording the medications (last item of chart review form) you will be able to determine ACE inhibitor or ARB use.

Lower Extremity Arterial Disease

All of these items will be documented in the chart if done. If the exams (for loss of hair, color change, pedal pulses, edema) were not performed then the answer is unknown. For bypass this is a lower extremity bypass not coronary artery bypass. Other ischemic changes-note any other problems with feet. Check all old records to find evidence of ulcers or problems.

Cardiovascular Disease:

All of these items will be recorded in the chart if the patient has these conditions. If not documented as having these conditions, the answer is no.
If a patient has had an MI, treatment will be documented in the medication list. If a patient has had a stent record as positive for angioplasty.

Cerebrovascular Disease:

All of these items will be recorded in the chart if the patient has these conditions. If not documented as having these conditions, the answer is no.
Physicians may record stroke as brain infarct.

Hypertension:

This is physician-diagnosed hypertension. If listed in the problem list or in the notes, the response is positive, otherwise mark no. Do not rely on blood pressure values to answer this question.

Neuropathy:
Only mark this positive if the physician has documented it, other wise mark unknown unless physician specifically has a documentation procedure for negative findings.

-

Appendix E: Baseline Chart Review Form

-

Assessment of Diabetes Care

Audit Date ___/____/____ **Physician name/group** _____

Patient Study Number_____ **PCP (1)yes (0)no**

Reviewer_____

Patient Date of Birth ___/___/_____

Confirmed diagnosis of diabetes:

(1)by treatment (insulin, oral hypoglycemic meds) ***OR***
(2)2 FBS gt 126mg/dl ***OR***
(3)2 random bs gt 200mg/dl ***OR***
(4)HbA1c >7%

If none, of the above, **STOP: DO NOT REVIEW CHART**

Year of diagnosis _____ ***OR*** **Age at diagnosis** __

Gender

(0)male
(1)female

Patient level of education:

(1) less than HS
(2) HS graduate
(3) Some college
(4) College graduate
(5) Graduate education
(.) Could not determine

Occupation _____

Race

(1)Caucasian
(2)African American
(3)Asian American
(4)Native American
(5)Unknown
(.)Could not determine

Health insurance:

(1)yes
(0)no

Type of insurance: _____

-

Smoker

(1) Yes
If yes, smoking cessation counseling? (1) yes
(0) no

(0) no

Current Height:

___ ft ___ in (.)not recorded

Current Weight:

____ lbs (.)not recorded **BMI_____**

Diabetes Therapy

(1)Diet and exercise alone
(2)Insulin
(3)Sulfonylurea
(4)Metformin(Glucophage)
(5)Acarbose(Precose)
(6)Thiazoladinediones(Rezulin)
(7)Combination (oral+ insulin)
(8)Meglitinide
(.) unknown/not recorded

Diabetes Education (Calendar year 1999)

Nutrition

(1)yes
(0)no

Exercise instruction

(1)yes
(0)no

Outpatient Diabetes Education

(1)yes
(0)no

Self monitor blood glucose

(1)yes
If yes, time per week _____
(.)unkown
(0)no
(.)unknown

-

Laboratory Measures (calendar year 1999)

HbA1c

Test done: Lab:_____

(1)yes

Date: ___/___/____ Value: ____ (.) not recorded
Date: ___/___/____ Value: ____ (.) not recorded
Date: ___/___/____ Value: ____ (.) not recorded
Date: ___/___/____ Value: ____ (.) not recorded
Date: ___/___/____ Value: ____ (.) not recorded

(0)no

Lipid Profile

Test done: Lab:_____

(1)yes

Total Cholesterol _____ mg/dl (.)not recorded
Triglycerides _____ mg/dl (.)not recorded
LDL _____ mg/dl (.)not recorded
HDL _____ mg/dl (.)not recorded

(0)no

Urinalysis (for proteinuria/microalbuminuria)

(1)yes

If yes, type: _____

(0)no

Serum Creatinine

(1)yes Value: _____

(0)no

Exams (calendar year 1999)

Dilated eye exam (by ophthalmologist/optometrist)

(1)yes
(0)no

Foot exam

(1)yes
(0)no

Monofilament

(1)yes
(0)no

Electrocardiogram

(1)yes
(0)no

Blood Pressure

(1)yes

_____ SBP _____ DBP

(0)no

-

Flu vaccine in previous year
(1)yes
(0)no

Symptoms/problems (calendar year 1999)
(1)Hypoglycemia(requiring 3rd party assistance)
(2)Hyperglycemia(emergency)
(0)None
(3)Both

Complication Assessment	**yes(1)**	**no(0)**	**unk(.)**
Eyes:			
Diagnosis of retinopathy	□	□	
Laser therapy (for PR or macular edema)	□	□	
Blindness (attributable to diabetes)	□	□	
Cataract	□	□	
Maculopathy	□	□	
Kidneys:			
Microalbuminuria	□	□	
Methodology	_____		
Confirmed?	□	□	
number of samples	_____		
Proteinuria	□	□	
Methodology	_____		
Confirmed?	□	□	
number of samples	_____		
Dialysis	□	□	
Transplant	□	□	
Treated with ACE inhibitor?	□	□	
Renal Failure	□	□	
Lower Extremity Arterial Disease			
Loss of hair (1999)	□	□	
Color change (1999)	□	□	
Absent pedal pulses (1999)	□	□	
Amputation	□	□	
Bypass	□	□	
Ulcer (foot/leg)	□	□	
Other ischemic changes	□	□	
Describe			_____
Edema (1999)	□	□	
Cardiovascular:			
Unstable angina	□	□	
CHF	□	□	
Myocardial infarction	□	□	
Treated with: ACEI	□	□	
ASA	□	□	
B-blockers	□	□	
Bypass Surgery	□	□	

-

Angioplasty	□	□
Cerebrovascular		
TIA	□	□
Stroke	□	□
Carotid endarterectomy	□	□
Revascularization	□	□
Hypertension:	□	□
Treated with ACE inhibitor	□	□
Neuropathy	□	□

Current Medications

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

-

Appendix F: Provider Chart Audit Report

-

Patient-Provider Partnership:

Improving Diabetes Care in the Community

Results of Your Practice's Diabetes Chart Audit

Calendar Year 1999

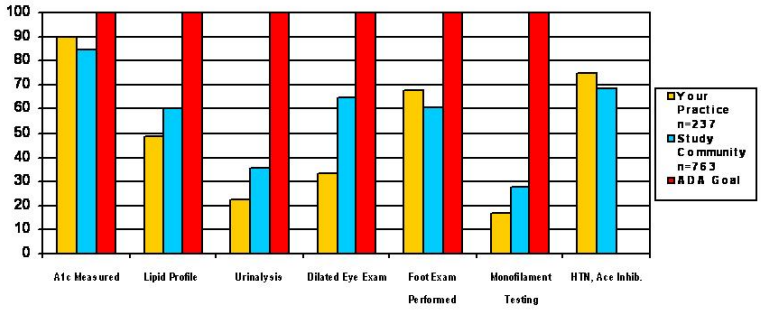
n=237

Your Practice's Demographics Compared to Other Practices in the Study Community

	Your Practice (n=237)	Study Commu-nity (n=763)
% Male	54.2	53.1
% Non-White	4.0	8.2
% Smoker	7.6	11.4
Average Age	69.9	65.0

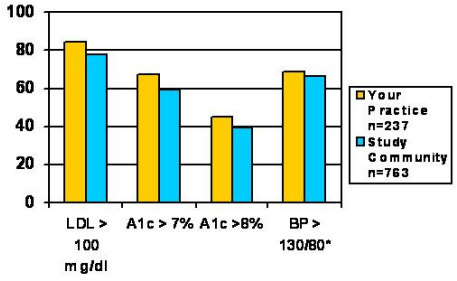
How Does Your Practice Compare to the ADA's Standards of Care?

Process Outcomes based on the ADA's Standards of Care

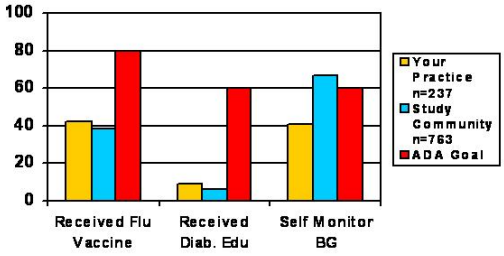


Is Your Practice Meeting the ADA's Therapeutic Goals and Standards of Practice?

The ADA currently recommends the following therapeutic goals: **LDL<100 mg/dl, HbA1c < 7%, and BP < 130/80**



Percent of Your Patients Adhering to the ADA's Standards of Practice Compared to Other Patients in the Study Community



An A1c of > 8% indicates an **ACTION LEVEL**

The ADA goal for BP at the time of chart audit was 130/85

Appendix G: Diabetes Risk Profile

-

Name _____

Date _____

Diabetes Risk Profile

Height: _____ Weight: _____ pounds (lightly clothed, without shoes)

My goal is: _____

Losing even small amounts of weight can lower your blood sugar, and reduce your risk for joint problems and heart disease.

To lose weight you can:

- Exercise more
- Eat less fat
- Eat smaller portions
- Change how often you eat
- Drink less alcohol
- Other _____
  _____

-

Hemoglobin A_1C: _____ %

Normal Range 4-6.5%

My goal is: _____ %

The average blood sugar level over the last two to three months. When your blood sugar is close to normal, you are likely to have more energy and think more clearly than when your blood sugar is high. This number tells you about your risk for the complications and gives you an idea of how your blood sugar is affecting your body. Keeping your Hemoglobin A_1C closer to normal reduces your risks for long-term damage to your eyes, kidneys and nerves.

To help lower your blood sugar you can:

- Eat fewer sweets
- Eat smaller portions
- Change how often you eat
- Reach a reasonable weight
- Exercise more
- Drink less alcohol
- Take medicine (pills or insulin)
- Take a different medicine
- Take a combination of medicines (pills or insulin)
- Add or adjust insulin dose, timing, or shots per day

-

Blood Pressure: _____ mm/Hg

Ideal: 130/80 or lower

My goal is: _____

A blood pressure reading has two numbers. The top number is called systolic blood pressure. This is the amount of pressure against the blood vessel walls when your heart pumps. The bottom number is called diastolic blood pressure. This is the amount of pressure against the blood vessel walls when your heart relaxes, that is between heartbeats.

In general, high blood pressure means that the systolic blood pressure, diastolic blood pressure, or both may be too high. For people with diabetes, high blood pressure is 130/80 or higher. High blood pressure increases your risk for strokes, heart attacks, kidney damage, and eye disease.

To lower your blood pressure you can:

- Eat less salt
- Take blood pressure medicine
- Exercise
- Stop smoking
- Monitor blood pressure
- Drink less alcohol
- Maintain reasonable weight
- Other _____
  _____

-

Cholesterol: _____

Normal: 200 mg/dl or below

My goal is: _____

A waxy, fat-type substance in your blood. Your body makes some cholesterol from saturated fats and you also get it from certain foods. There are different kinds of cholesterol. High cholesterol adds to your risk for heart and blood vessel disease.

To lower your cholesterol you can:

- Eat less saturated fat
- Exercise
- Eat more fiber
- Eat less saturated (hard) fat
- Maintain a reasonable weight
- Take medicine

Low Density Lipoproteins (LDL): Your level _____

Normal: 100 mg/dl or less

The kind of cholesterol that deposits fat in your blood vessels. High LDL adds to your risk for heart and blood vessel disease.

To lower your LDL you can:

- Eat less fat
- Eat less saturated (hard) fat
- Exercise regularly
- Maintain a reasonable weight

-

High Density Lipoproteins (HDL): Your level _____

Normal: Males – 35 mg/dl or higher Females – 45 mg/dl or higher

It removes fat deposits from your blood vessels. High HDL helps to protect you against heart and blood vessel disease.

Some ways to improve your HDL:

- Exercise more
- Lower triglycerides
- Maintain a reasonable weight

Triglycerides: Your level _____

Normal: 200 or less

Another kind of fat carried in the blood stream that is linked to high blood sugars. High triglycerides may contribute to heart and blood vessel disease.

Some ways to lower your triglycerides:

- Lower your blood sugar
- Eat fewer sweets
- Drink less sweet liquids (including unsweetened fruit juice)
- Drink less alcohol

-

Smoking: Amount you smoke _____

Not smoking is ideal. Smoking increases your risk for heart, blood vessel and kidney disease.

Some ways to cut back and quit smoking are:

- Exercise
- Take anti-smoking medicine
- Attend classes
- Smoke less often
- Drink less alcohol

-

Appendix H: Height, Weight, and Blood Pressure Measurement Protocol

-

Clinical Measurement Guidelines

1.0 Blood Pressure

Blood pressure measurements (beginning of first phase, systolic and end of fourth phase, diastolic) will be measured using a standard manometer. After the procedure has been explained to the patient, blood pressure measurements will be taken seated. The measurement will be made twice.

1.1 Position

1. The body

The blood pressure should be measured after resting, with no change of position or posture for at least 5 minutes. This means that patients must remain seated in a chair with a back, with feet firmly on the ground, for at least 5 minutes prior to the first measurement. Changes in posture or activity cause blood pressure to change.

2. The Arm

For routine purposes the observer should always use the same arm, preferably the right arm. On average, the blood pressure measured from the right arm is slightly higher than that from the left. Therefore, one should consistently measure the pressure from the same arm if comparison of pressure from one occasion to another, in one person and between different people, need to be made. If the left arm is used it should be noted on the screening data form.

3. Position of Arm

When seated the patient's arm should be allowed to rest on a desk, table, bench top or suitable surface, so that the inner aspect of the bend at the elbow (cubital fossa) is level with the apex of the heart (left 4th intercostal space). The forearm should be allowed to rest comfortably on the table with the inside of the arm facing upwards. The palm of the hand may face downwards or upwards, whichever is most comfortable for the patient.

1.2 Equipment

1. Cuff
2. Sphygmomanometer
3. Stethoscope with bell
4. Watch with second hand
5. Chair with back
6. Table or bench to place manometer
7. Mercury Spill Kit (if using mercury manometers)

1. Cuff

The appropriate size cuff should be chosen. This is accomplished by using the guide on the inside of the cuff. After determining the correct cuff, locate the brachial artery. If necessary, make a mark at the point of maximum pulsation. This point is where the bell of the stethoscope should be placed during BP reading. Place the end containing the rubber bladder across the front of the upper arm so that each rubber tube lies symmetrically across the arm. This will ensure that

-

the midline of the rubber bladder will lie over the brachial artery on the inner side of the arm. The lower edge of the cuff should be 1” to 1.5” (one to one and a half inches) above the cubital fossa. This is to allow sufficient room for the bell of the stethoscope to be placed over the brachial artery immediately below the cuff. The top edge of the cuff should not be restricted by clothing. The inner edge of the cuff should lie within the marked acceptable range for cuff bladder width to arm circumference ratio marked on the inside of the cuff.

The observer then places the left hand on top of the cuff and pulls the other end with the right hand, underneath the arm in a wrapping movement. The outer edge of the cuff must be kept aligned so that the cuff is wrapped evenly around the arm. The cuff should be applied firmly-not enough to exert pressure on the brachial artery but firm enough to prevent the cuff from slipping. This can be tested by trying to slip two fingers under the edge of the cuff. Only the tip of the fingers should be able to fit between the cuff and the arm. Then, connect the cuff to the sphygmomanometer. Applying the cuff, in this manner, at the beginning of the resting period saves time and allows the patient to get accustomed to the cuff.

2. Sphygmomanometer

After the point for listening to the brachial artery has been found the cuff is wrapped around the arm and the cubital fossa is adjusted to the level of the 4th intercostal space at the sternum. The patient should again be asked if he/she is comfortable. If using a table top manometer, the mercury sphygmomanometer column should be perfectly upright. A tilt, however slight, of the column will cause a falsely high reading to be obtained and will make it difficult to read the upper margin (meniscus) of the column. The center of the mercury column should be at the eye level of the examiner, so that the examiner does not have to move his/her head very much. This will prevent reading the top of the meniscus from an angle that would change the apparent position of the top of the meniscus, in relation to the scale (parallax error). The mercury column should face the examiner and should not be within the patient’s view. This is important because some patients misinterpret the initial level of the mercury as an indication of their blood pressure and they become unduly alarmed. If the sphygmomanometer is placed too high, then the examiner will have to stand to avoid peering up, which is uncomfortable. Whenever possible, it is better to be sitting with the center of the manometer scale at eye level. For accurate blood pressure recording, it is not necessary to have the sphygmomanometer at heart level, like the arm.

3. Stethoscope

A standard Littman Classic II stethoscope with a bell is preferred. Korotkoff sounds are best heard with the bell because of their low pitch. Stethoscope tubing should be about 10-12 inches from the bell piece to the Y branching. This length provides optimal acoustic properties and allows the observer to read the sphygmomanometer at eye level in a comfortable position.

When ready to use the stethoscope, check that the ear pieces are pointing downward and forwards, and insert into the ears. The stethoscope should be removed from the ears when not listening for sounds so that the observer may converse with the patient and also to avoid discomfort.

4. Watch with secondhand

-

The watch will be used to correctly record the 5 minutes rest period prior to each blood pressure, the 30 second period between blood pressures, and the 5 seconds the patients raise his/her arm.

5. Chair with back
To ensure that each patient is comfortable, a chair with a back is recommended.

6. Table/bench/desk
To allow for the manometer to be at eye level of the examiner and for the patients arm to be at the 4th intercostal space.

7. Mercury spill kit
For those clinics using mercury manometers, it is recommended that each clinic have on hand a mercury spill kit in case the sphygmomanometer is damaged.

1.3 Preparation

Patient
The patient should be asked not to engage in vigorous exercise, ingest food or caffeine or smoke within 1/2 hour prior to the BP measurement.

Observer

It is important for the observer to be comfortable. This means that the following should be obtained:
a. The stethoscope should fit the ears, comfortably.
b. When seated, the chair should be at a comfortable height relative to the surface on which the patient is resting his/her arm and the level of the sphygmomanometer column.
c. The BP measurement should be made in a quiet room where no other activity is taking place. After the cuff is applied and connected to the sphygmomanometer, and the patient has rested in position for 5 minutes, the radial pulse should be palpated at the inside of the right wrist, above the thumb. To locate this point, use the tips of four fingers on the right hand, simultaneously. Once the radial pulse has been located, it can usually best be felt by keeping light pressure on it with the middle finger of the observer's hand.

1.4 Pulse Obliteration Pressure
The purpose of the pulse obliteration pressure is to determine an approximate range for the systolic blood pressure, so that when measuring the pressure the cuff is inflated to an appropriate level. Tell the patient that you are going to inflate the cuff and the cuff may feel a little tight on the upper arm for a short time. If this warning is not given, the patient is likely to respond to the discomfort of the tightness with a rise of blood pressure, due to fright or pain. You may demonstrate the sensation by squeezing over the cuff with both hands.

After connecting the cuff and sphygmomanometer, with the middle finger of the left hand over the right radial pulse, take the bulb of the cuff in the right hand and close the valve tightly. This will prevent air from escaping while the cuff is being inflated. Inflate the cuff briskly to 70

-

mmHg, then slowly in 10 mm intervals, until the pulse is not longer felt; observe the mercury column level at the point of pulse obliteration. Then, deflate the cuff rapidly by full opening the valve on the bulb. Immediately after deflating, write down the level reached by the mercury column at the pulse obliteration to the nearest 10 mm reading in the source document (although there will be no formal entry of this data it will be checked at quality control site visits to the clinics). Add 30 to this number and write down the sum. The resultant value is called the peak inflation level.
Therefore, if the pulse disappeared when the meniscus was nearest to 130, the peak inflation level will be 160 (130 + 30 = 160). The peak inflation level is the level to which the mercury in the sphygmomanometer should be pumped for the following measurement of the blood pressure level of the patient. Any time the cuff is inflated, there must be at least 30 seconds between readings. During this interval the cuffed arm will be raised for 5 seconds, without fist clenching, to minimize the effect of forearm engorgement.

1.5 Seated Blood Pressure Measurement
Step 1: Have the patient sit down in a chair with a back, so that the right arm is adjacent to the table/structure that you plan to use to elevate the arm to the desired level for blood pressure measurement.

Step 2: Palpate the Brachial Artery. Wrap cuff (after determining the correct size) with the center of the bladder over the brachial pulse. Attempt to place the bottom edge of the cuff about 1" - 1.5" above the antecubital fossa. (Once you have determined the cuff size based on the circumference of the arm, if the cuff does not fit the person, based on the length of arm, use the next size down).

Step 3: Explain to the patient that he/she needs to rest quietly, not speaking, for 5 minutes before blood pressure is measured. If necessary, use extra books or adjust the seating posture of the patient to ensure that the arm (cubital space) is at a level even with the heart (4th
intercostal space). The patient should be sitting comfortably with legs uncrossed and feet resting flat on the floor. Begin a 5 minutes rest period and record the time resting starts and ends. Let the patient know that they should not speak until all blood pressure measurements are completed.

Step 4: After the five minute rest, take and record the 30 second radial pulse.

Step 5: Establish peak inflation level as follows:
a. Rapidly inflate cuff to 70 mmHg, and then slowly inflate the cuff in 10 mm increments, while palpating the radial artery until the pulse can no longer be felt. This is called the Pulse Obliteration Point (see above section additional detail).
b. Deflate and disconnect the manometer.
c. Have patient raise their cuffed arm for 5 seconds.
d. Record the level at which the pulse disappeared, then add 30 mm to that level. This is the Peak Inflation Level, the level to which the mercury must be pumped before blood pressure reading is taken for the patient.

-

Step 6: The ear pieces of the stethoscope, pointing forwards, are inserted in the ears and the bell of the stethoscope is place over the brachial artery, below the cuff and held there with one hand. Both the bell and the tubing of the stethoscope should not be touching the cuff or any other rubber tubing or clothing. The observer should be comfortable and looking at the manometer with the center of the scale at eye level and with the column perfectly upright.

Step 7: Rapidly inflate the cuff to a pressure equal to the peak inflation level. Hold at this level for 3 seconds, then steadily reduce the pressure at 2 mmHg/sec intervals until you are able to record the onset of the first and the end of the 4th phase of Korotkoff phases (synonymous to systolic and diastolic levels) (See Figure ?). Continue to slowly deflate the cuff for another 4-6 mmHg to assure the true diastolic end point (last sound heard, the 5th phase is silence and diastolic will be recorded at the last sound heard). Record these levels and deflate the cuff. Record the blood pressure values to the nearest 2 mmHg.

Step 8: Deflate cuff after second 'absent' sound. Disconnect the manometer from the cuff.

NOTE: After pumping the cuff pressure to peak inflation level, occasionally, the Korotkoff sounds may be heard as soon as the observer places the stethoscope over the brachial pulse and begins to listen. If this happens, the observer should immediately deflate the cuff by releasing the thumbscrew and disconnecting the cuff tube from the manometer. The patient should then hold the cuff-wrapped arm vertically for five seconds. Increase the original number by 10 and using the new peak inflation level check the blood pressure again. The possible reasons why a Pulse Obliteration Pressure would be much lower that the actual systolic blood pressure could be:

a. The observer may put too much pressure on radial artery pulse, causing the artery to collapse.
b. The pulse may actually obliterate at a point far below the systolic blood pressure.

Step 9: Have the patient raise cuffed arm above the head to a vertical position (without fist clenching) for 5 seconds. Wait 30 seconds. Then, repeat Steps 6-9 to obtain a second blood pressure measurement. Record in the screening data form.

1.6 Maintenance for Standard Sphygmomanometer:

It is important to make sure that the equipment being used is in good condition. It is recommended that clinics should check their sphygmomanometers periodically in the following way:

Mercury sphygmomanometers

a. With the instrument placed flat on the table, and the inflation system disconnected, the level of mercury should read zero in the standard instrument. If the reading is either above or below the zero mark, the instrument may need to be replaced or repaired. The top of the meniscus is on the zero line when the eyes are level with this line and the mercury is correctly adjusted.

-

b. The inflation system should then be reconnected, and the cuff rolled around a cylinder and secured. The valve should be closed on the Air Flow system, and the instrument inflated until the mercury rises to 240 mmHg. The Air Flow valve should then be slowly opened and the mercury allowed to fall to 20 mmHg. The valve should then be closed, at which time the mercury column should remain stable. If the column continues to fall, there is an air leak, and the following steps should be taken:

1. The system should be re-inflated until the column rises to 240 mmHg.
2. The tubing should be pinched at various locations to localize the area of the leak.
3. Appropriate replacement of the tubing, cuff or valve should be performed.

c. With the instrument inflated above full calibration, the screw cap should be examined for mercury leaks. If this happens, the screw cap should be tightened. If the leaks persist or the mercury is seen at the bottom of the tube, the silicone rubber that provides a seat for both ends of the glass tube should be replaced.

d. With time, the mercury will become dirty and an oxide may be deposited on the inside of the glass tube. The instrument should be laid nearly on its side (on a tray) so that the mercury will return to the reservoir and none can be seen in the glass tube. The tube should be removed carefully and cleaned out using the long pipe cleaner supplied with the instrument. The tube should then be replaced and the zero level rechecked.

NOTE: Any cleaning or repair must be done in a local instrument shop and is not to be attempted by clinical personnel. Mercury is a toxic substance.

1.7 Certification

All staff members performing clinical measures must be certified. Certification in blood pressure requires measurements in two individuals by the staff member, which are confirmed by the coordinator or her representative.

2.0 Body Size Measurements

All measurements are to be made with the patients wearing light clothing (e.g. a short sleeve shirt or blouse (or surgical gown), shorts and socks and without shoes (for weight and height patient should be sure pockets are empty.) All values should be rounded to the nearest unit indicated for each measure. If the value is exactly between two such units, round up if the lower unit is even and round down if the lower unit is odd (e.g. if weight is 74.55 Kg, record as 74.5 Kg, if weight is 74.65 Kg record as 74.7 Kg).

2.1 Body Weight

A balance scale should be used. Be sure the scale is balanced so that the indicator is at zero when no weight is on the scale. The scale should be level and on a firm surface (not a carpet). The patient should be instructed to stand in the middle of the platform of the balance scale with head erect and eyes looking straight ahead. Adjust the weight on the indicator until it is balanced. Record the results to the nearest pound. Have subject step off scale, reset balance to zero and repeat. If measures differ by more than 0.2 kilograms OR 0.5 pounds, repeat a third time.

-

2.2 Waist Girth

Patient should be gowned and stand with feet together. Measure using a cloth tape around the abdomen horizontally at midpoint between highest point of the iliac crest and lowest part of the costal margin in the midaxillary line. (Mark both sides using a washable marker, e.g. an eye liner.) Ask subject to have arms at side and to breathe in, out and hold, and measure at end of expiration. Record to nearest 0.1 cm. Remove tape and perform first hip measurement then return and perform second waist measure. If the second waist measurement differs by more than 0.5 cm, a third reading should be done

2.3 Body Height

A clinic stadiometer is to be used whenever possible. The subject stands erect on the horizontal platform with his/her back parallel to the vertical mounted measure scale (but not touching the wall), looking straight ahead with his/her head in the Frankfort horizontal plane (the horizontal plane is defined by the lower margin of the bony orbit - the bony socket containing the eye - and the most forward point in the supratragal notch - the notch just above the anterior cartilaginous projections of the external ear). The horizontal measuring block is brought down snugly, but not tightly, on the top of the head. The subject's height is recorded to the nearest or 0.5 cm or 0.2 inches. Ask the subject to step off the platform, raise measuring block and ask subject to return to platform and repeat measure. If measures differ by more than 0.5 centimeter OR 0.2 inches, repeat a third time. The subject should be instructed to stand as straight as possible but with feet flat on the floor. If a stadiometer is not used, the patient should be instructed as above using the height-measuring instrument available.

-

Appendix I: Baseline Questionnaire

-

ID# _____

Name _____

Patient Address_____

_____

Phone Number_____

Today's Date _____

Patient-Provider Partnership:
Improving Diabetes Care in the Community

Baseline Interview

Education Session Site:

_____

Interviewer's Initials: _____

Certain portions of this survey are from the
Michigan Diabetes Research and Training Center

-

Section 1 - Barriers to Diabetes Care

1. Are you worried (concerned) about your diabetes? ☐ Yes ☐ No

   If yes, why?

   _____

   _____

   _____

2. In general, are you satisfied with your diabetes care? ☐ Yes ☐ No

   How would you improve your diabetes care in McKeesport?

   _____

   _____

   _____

3. What do you feel prevents you (or others) from looking after (caring for) your diabetes properly?

   _____

   _____

   _____

-

Section II - Demographics

Please answer each of the following questions by filling in the blanks with the correct answers or by choosing the single best answer.

Note: For this survey, a Health Care Provider refers to a doctor, nurse practitioner, or physician assistant.

Q1. Age: __ __ years old

Q2. Birth date: __ __ /__ __ /__ __
(Month / Day / Year)

Q3. Zip Code: __ __ __ __ __

Q4. Sex: ☐1 Male ☐2 Female

Q5. What year were you first told you had diabetes? (Please enter the year) __ __ __ __

Q6. What is your marital status? (check one box)

☐1 Never married
☐2 Married
☐3 Separated/Divorced
☐4 Widowed
☐5 Living with partner

Q7. What is your ethnic origin/race? (check one box)

☐1 White
☐2 Black
☐3 Hispanic
☐4 Native American
☐5 Asian or Pacific Islander
☐6 Arabic
☐7 Other _____

Q8. How many people live with you? (check one box)

-

☐0 I live alone
☐1 1 person
☐2 2 people
☐3 3 people
☐4 4 people
☐5 5 or more

Q9. How much schooling have you had? (Years of formal schooling completed) (check one box)

☐1 8 grades or less
☐2 Some high school
☐3 High school graduate or GED
☐4 Some college or technical school
☐5 College graduate (bachelor's degree)
☐6 Graduate degree

Q10. Which of the following best describes your current employment status? (check one box)

☐1 Working full-time, 35 hours or more a week
☐2 Working part-time, less than 35 hours a week
☐3 Unemployed or laid off and looking for work
☐4 Unemployed and not looking for work
☐5 Homemaker
☐6 In school
☐7 Retired
☐8 Disabled, not able to work
☐9 Something else? (Please specify): _____

Q11/Q12. During the past 2 weeks, did you work at any time at a job or business, not counting work around the house?

☐1 No ☐2 Yes →

-

Q12. What kind of work were you doing?

(For example: electrical engineer, stock clerk, typist, farmer.)

_____

Q13. How would you describe the insurance plan(s) you have had in the past 12 months? (check all that apply)

- ☐ 1 An individual plan – the member pays for the plan premium
- ☐ 2 A group plan through an employer, union, etc. – the employer pays all or part of the plan premium
- ☐ 3 U.S. Governmental Health Plan (e.g., Military, CHAMPUS, VA)
- ☐ 4 Medicaid
- ☐ 5 Medicare
- ☐ 6 I have not had an insurance plan in the past 12 months

Q14. What type(s) of insurance plans have you had in the past 12 months
Specify:

_____
_____
_____

Q15. Which of the categories best describes your total annual combined household income from all sources? (check one box)

- ☐ 01 Less than $5,000
- ☐ 02 $5,000 to $9,999
- ☐ 03 $10,000 to $14,999
- ☐ 04 $15,000 to $19,999
- ☐ 05 $20,000 to $29,999
- ☐ 06 $30,000 to $39,999
- ☐ 07 $40,000 to $49,999
- ☐ 08 $50,000 to $59,999

-

☐09 $60,000 to $69,999

☐10 $70,000 and over

Q16. Altogether, how many people live on this income (that is, it provides at least half of their income)?

_____ People

Q17. Do you own your own home?

☐1 NO

☐2 YES

IF YES: Do you own it outright or are you still paying on a mortgage?

☐1 Own it outright

☐2 Still paying

Q18. Are your assets and financial resources sufficient to meet medical and household emergencies?

☐1 YES

☐2 NO

Q19. Are your expenses so heavy that you cannot meet your bills (or household expenses) or can you barely meet your bills, or are your bills no problem to you?

☐1 Cannot meet my bills

☐2 Can barely meet my bills

☐3 Bills are no problem

Q20. How well do you think you (and your family) are doing financially as compared to other people your age?

-

☐1 Better

☐2 About the same

☐3 Worse

Q21. How well does the amount of money you have take care of your needs ?

☐1 Very well

☐2 Fairly well

☐3 Poorly

Q22. Do you usually have enough to buy those little "extras" --- that is, those small luxuries?

☐1 NO

☐2 YES

Q23. Do you feel that you will have enough for your needs in the future?

☐1 NO
☐2 YES

Section III – Quality of Life

Please check the appropriate box for each of the following ten statements indicating how often you feel each of them has applied to you in the last two weeks.

Please read each statement carefully	**Higher scores mean better well-being**			
The first five statements are:	**All of the time**	**More than half of the time**	**Less than half of the time**	**None of the time**
1. I feel downhearted and sad	☐0	☐1	☐2	☐3
2. I feel calm and peaceful	☐3	☐2	☐1	☐0
3. I feel energetic, active and full of strength	☐3	☐2	☐1	☐0
4. I wake up feeling fresh and rested	☐3	☐2	☐1	☐0
5. My daily life is full of things that are	☐3	☐2	☐1	☐0

-

interesting to me				
The last five statements are:	**All of the time**	**More than half of the time**	**Less than half of the time**	**None of the time**
6. I feel well adjusted to my daily situation	☐3	☐2	☐1	☐0
7. I live the kind of life I want	☐3	☐2	☐1	☐0
8. I feel motivated to do my daily tasks or make new decisions	☐3	☐2	☐1	☐0
9. I feel I can easily handle or cope with any serious problem or major change in my life	☐3	☐2	☐1	☐0
10. I am happy, satisfied or pleased with my personal life	☐3	☐2	☐1	☐0

Section IV - Control Problems

For the following questions, please check the appropriate response.

Q1.How many **times** in the last **month** have you had a **low blood sugar** (glucose) reaction with symptoms such as sweating, weakness, anxiety, trembling, hunger or headache?

☐1 0 times
☐2 1-3 times
☐3 4-6 times
☐4 7-12 times
☐5 More than 12 times
☐6 Don't know

Q2.How many **days** in the last **month** have you had **high blood sugar** with symptoms such as thirst, dry mouth and skin, increased sugar in the urine, less appetite, nausea, or fatigue?

☐1 0 days
☐2 1-3 days
☐3 4-6 days
☐4 7-12 days
☐5 More than 12 days
☐6 Don't know

-

Section V -- Diabetes History

We would now like to ask you about the health care you have received recently.

Please answer every question by filling in the blank(s), circling the correct answer, or checking the correct box.

Resource Use

Q1. During the past 4 weeks, how many total visits to health care providers (doctors, nurse practitioners, etc.) did you make? (fill in the blanks)

_____ visits in the past 4 weeks

Q2. During the past 12 months, how many total visits to health care providers did you make? (fill in the blanks)

_____ visits in the past 12 months

Q3. When was your last visit with the following health care providers?

a. My last visit with an **ophthalmologist** was: (check one box)
(An ophthalmologist is a physician who specializes in the care and surgery of eye diseases, not an optometrist)

☐1 Within the last 12 months
☐2 1-2 years ago
☐3 2-3 years ago
☐4 More than 3 years ago
☐5 Never had a visit with an opthamologist

---

b. My last visit with an **optometrist** was: (check one box)
(An optometrist is a person professionally trained to test the eyes and to detect and treat eye problems and some diseases, not an ophthalmologist)

☐1 Within the last 12 months
☐2 1-2 years ago
☐3 2-3 years ago
☐4 More than 3 years ago

-

☐5 Never had a visit with an optometrist

c. When was the last time that you had an eye exam during which the doctor put drops in your eyes that made your pupils large? (You may have been unable to see enough to drive or had to wear dark glasses afterward.) (check one box)

☐1 Within the last 12 moths
☐2 1-2 years ago
☐3 2-3 years ago
☐4 More than 3 years ago
☐5 Never had this type of eye exam

d. My last visit with a **podiatrist** was: (check one box)
(A podiatrist is a physician who treats and takes care of people's feet)

☐1Within the last 12 months
☐2 1-2 years ago
☐3 2-3 years ago
☐4 More than 3 years ago
☐5 Never had a visit with a podiatrist

e. My last visit with a **dietitian** was: (check one box)

☐1Within the last 12 months
☐2 1-2 years ago
☐3 2-3 years ago
☐4 More than 3 years ago
☐5 Never had a visit with a dietitian

f. My last visit with a **diabetes educator** was: (check one box)

☐1Within the last 12 months
☐2 1-2 years ago
☐3 2-3 years ago
☐4 More than 3 years ago
☐5 Never had a visit with a diabetes educator

-

Q4. When was the last time that you had the following blood tests?

a. My last **Hemoglobin A1c test** was: (check one box)
(This is also known as glycohemoglobin or glycosylated hemoglobin, a test that measures your average blood sugar level over the past couple of months)

☐1 Within the last 12 months	☐2 1-2 years ago	☐3 2-3 years ago	☐4 More than 3 years ago	☐5 Never had a Hemoglobin A1c Test

b. My last **Cholesterol blood test** was: (check one box)

☐1 Within the last 12 months	☐2 1-2 years ago	☐3 2-3 years ago	☐4 More than 3 years ago	☐5 Never had a cholesterol blood test

c. My last **Urine analysis** was: (check one box)
(Gave a urine sample to be tested by the health care provider, clinic, or laboratory)

☐1 Within the last 12 months	☐2 1-2 years ago	☐3 2-3 years ago	☐4 More than 3 years ago	☐5 Never had a urine analysis

Q5. Do you test your blood sugar? (check one box)

☐1 No ☐2 Yes → Q5a. How many days a week do you test your blood sugar?

_____ (days / week)

If no, go to question #6

Q5b. On days that you test, how many times do you test your blood sugar?

_____ (times / day)

-

Q5c. Do you keep a record of your blood sugar test results? (check one box)

☐1 No ☐2 Yes ☐3 Only Unusual Values

Q6. During the past 12 months, were you a patient in a hospital overnight? (check one box)

☐1 No ☐2 Yes → Q6a. How many times in the past 12 months did you you stay overnight in a hospital?

__ __ times

↓

Q6b. How many nights altogether during the past 12 months did you stay in a hospital?

__ __ __ nights

If no, go to question #7

Q7. Have you ever been hospitalized for diabetic ketoacidosis (DKA)? (check one box)

☐1 No
☐2 Yes
☐3 Don't Know

-

Medication Use

Q1. Do you currently use insulin? (check one box)

☐1 No

☐2 → Yes

If no, go to question #2

Q1a. How many times during the day do you usually take your insulin? (check one box)

☐1 Once a day (Taken in the Morning)

☐2 Once a day (Taken in the Evening)

☐3 Twice a day

☐4 Three times a day

☐5 Four or more times a day

☐6 I use an infusion pump

Q1b. How long have you taken insulin?

__ __ years

(i) Q1c. Have you taken insulin for as long as you have had diabetes? (check one box)

☐1 No

☐2 Yes

Q2. Are you currently taking medications for high cholesterol? (Check one box)

☐1 No

☐2 Yes

☐3 Don't know

-

Q3. Are you currently taking medication for high blood pressure? (Check one box)

☐1 No

☐2 Yes

Q4. Please list **all** medications you are currently taking

_____

_____

_____

_____

_____

_____

_____

_____

Comorbidities

Q1. Have you ever been told by a health care provider that you have any of the following problems with your eyes? (circle one answer on each line)

		No	Yes, on one eye	Yes, on both eyes
A.	Cataracts	1	2	3
B.	Glaucoma	1	2	3
C.	Detached retina	1	2	3
D.	Blurred vision (not correctable with eye glasses)	1	2	3
E.	Retinopathy (diabetic changes in the back of the eye)	1	2	3
F.	Blindness	1	2	3
G.	Macular degeneration (an aging change in the back of the eye)	1	2	3
H.	Macular Edema	1	2	3

-

Q2. Have you ever had any of the following operations on your eyes? (circle one answer on each line)

		No	Yes, on one eye	Yes, on both eyes
A.	Cataract Surgery	1	2	3
B.	Laser Treatment	1	2	3
C.	Other (please specify below): _____	1	2	3

Q3. Have you ever been told by a health care provider that you have any of the following problems related to your heart or circulation? (circle one answer on each line)

		No	Yes
A.	Heart attack	1	2
B.	Heart failure	1	2
C.	High cholesterol	1	2
D.	Angina	1	2
E.	High blood Pressure	1	2

Q4. Have you ever had any of the following operations or procedures related to your heart? (circle one answer on each line)

		No	Yes
A.	Coronary artery bypass surgery (open heart surgery)	1	2
B.	Coronary angioplasty (“balloon” heart procedure)	1	2
C.	Heart catheterization (angiogram)	1	2

-

Q5. Have you ever been told by a health care provider that you have any of the following bladder, kidney, or urinary problems? (circle one answer on each line)

		No	Yes
A.	Kidney or bladder infections	1	2
B.	Kidney failure	1	2
C.	Protein in your urine	1	2
D.	Enlarged prostate (Men only)	1	2
E.	Vaginitis (Women only)	1	2

Q6. Have you ever been told by a health care provider that you have any of the following problems with your feet or legs? (circle one answer on each line)

		No	Yes
A.	Peripheral vascular disease (poor circulation in the legs)	1	2
B.	Intermittent claudication (cramping in the calves after exercise)	1	2
C.	Peripheral neuropathy (nerve problems causing numbness, tingling, or burning)	1	2
D.	Gangrene	1	2
E.	Foot ulcers	1	2
F.	Athlete's foot or fungus infection of the feet	1	2

-

Q7. Have you ever had an amputation of a toe, foot, part of a leg, or all of a leg **for a poorly healing sore or poor circulation**? (An amputation that is **not** due to an injury or accident [car crash, power tool injury, war injury, etc.])?

		No	Yes, right side only	Yes, left side only	Yes, both sides
A.	Toes	1	2	3	4
B.	Part of a foot (or feet)	1	2	3	4
C.	Leg, below the knee	1	2	3	4
D.	Leg, above the knee	1	2	3	4

Q8. Have you ever been told by a health care provider that you have had any of the following problems?

		No	Yes
A.	Stroke	1	2
B.	Transient ischemic attacks (TIA or "mini-strokes")	1	2
C.	Epilepsy or seizure disorder	1	2
D.	Parkinson's Disease	1	2

Background Information

Q1. Have you ever smoked cigarettes? (check one box)

☐1 No
☐2 Yes

Q2. Do you now smoke cigarettes? (check one box)

☐1 No ☐2 Yes → Q6a. How many packs per day do you smoke?

____ packs per day

Please continue

-

Section VIII -- Attitudes Toward Diabetes – DES

In general, I believe that I:	Strongly Agree (5)	Agree (4)	Neutral (3)	Disagree (2)	Strongly Disagree (1)
1. ...know what part(s) of taking care of my diabetes that I am **satisfied** with.	( )	( )	( )	( )	( )
2. ...know what part(s) of taking care of my diabetes that I am **dissatisfied** with.	( )	( )	( )	( )	( )
3. ...know what part(s) of taking care of my diabetes that I am ready to change.	( )	( )	( )	( )	( )
4. ...know what part(s) of taking care of my diabetes that I am <u>not</u> ready to change.	( )	( )	( )	( )	( )
5. ...can choose realistic diabetes goals.	( )	( )	( )	( )	( )
6. ...know which of my diabetes goals are **most** important to me.	( )	( )	( )	( )	( )
7. ...know the things about **myself** that either help or prevent me from reaching my diabetes goals.	( )	( )	( )	( )	( )
8. ...can come up with good ideas to help me reach my goals.	( )	( )	( )	( )	( )
9. ...am able to turn my diabetes goals into a workable plan.	( )	( )	( )	( )	( )

-

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
In general, I believe that I:					
10. ...can reach my diabetes goals once I make up my mind.	( )	( )	( )	( )	( )
11. ...know which **barriers** make reaching my diabetes goals more difficult.	( )	( )	( )	( )	( )
12. ...can **think** of different ways to overcome barriers to my diabetes goals	( )	( )	( )	( )	( )
13. ...can try out different ways of overcoming barriers to my diabetes goals.	( )	( )	( )	( )	( )
14. ...am able to decide which way of overcoming barriers to my diabetes goals works best for me.	( )	( )	( )	( )	( )
15. ...can tell how I'm feeling about **having** diabetes.	( )	( )	( )	( )	( )
16. ...can tell how I'm feeling about **caring** for my diabetes	( )	( )	( )	( )	( )
17. ...know the ways that having diabetes causes stress in my life.	( )	( )	( )	( )	( )
18. ...know the **positive** ways I cope with diabetes-related stress.	( )	( )	( )	( )	( )
19. ...know the **negative** ways I cope with diabetes-related stress.	( )	( )	( )	( )	( )

-

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
In general, I believe that I:					
20. ...can cope well with diabetes-related stress.	( )	( )	( )	( )	( )
21. ...know where I can get support for having and caring for my diabetes.	( )	( )	( )	( )	( )
22. ...can ask for support for having and caring for my diabetes when I need it.	( )	( )	( )	( )	( )
23. ...can support myself in dealing with my diabetes.	( )	( )	( )	( )	( )
24. ...know what helps me stay motivated to care for my diabetes.	( )	( )	( )	( )	( )
25. ..can motivate myself to care for my diabetes.	( )	( )	( )	( )	( )
26. ...know enough about diabetes to make self-care choices that are right for me.	( )	( )	( )	( )	( )
27. ...know enough about myself as a person to make diabetes care choices that are right for me.	( )	( )	( )	( )	( )
28. ...am able to figure out if it is worth my while to change how I take care of my diabetes.	( )	( )	( )	( )	( )

-

29. Please circle the number that indicates how able you are to fit diabetes into your life in a positive manner.

Not At All Able						Very Able
1	2	3	4	5	6	7

30. Please circle the number that indicates how comfortable you feel asking your doctor questions about diabetes.

Not At All Able						Very Able
1	2	3	4	5	6	7

Thank you very much for completing this questionnaire.

-

Appendix J: 12-Month Follow-up Questionnaire

-

Study ID:

Name: _____

Today's Date _____

Patient-Provider Partnership:
Improving Diabetes Care in the Community

Follow-Up Interview

THE FOLLOWING SHOULD ONLY TO BE FILLED OUT BY CLINIC STAFF

Education Session Site:
_____

Verified Date: _____

Verified Time: _____

Interviewer's Initials: _____

Certain portions of this survey are from the
Michigan Diabetes Research and Training Center

-

Section 1 - Barriers to Diabetes

1. Are you worried (concerned) about your diabetes? ☐ Yes ☐ No

   If yes, why?

   _____

   _____

   _____

2. In general, are you satisfied with your diabetes care? ☐ Yes ☐ No

   How would you improve your diabetes care in McKeesport?

   _____

   _____

   _____

What do you feel prevents you (or others) from looking after (caring for) your diabetes properly?

_____

_____

_____

-

Section II - Demographics

Please answer each of the following questions by filling in the blanks with the correct answers or by choosing the single best answer.

Note: For this survey, a Health Care Provider refers to a doctor, nurse practitioner, or physician assistant.

Q1. Age: __ __ years old

Q2. Birth date: __ __ /__ __ /__ __
(Month / Day / Year)

Q3. Zip Code: __ __ __ __ __

Q4. Sex: ☐1 Male ☐2 Female

Q5. What year were you first told you had diabetes?
(Please enter the year) __ __ __ __

Q6. What is your marital status? (check one box)

☐1 Never married
☐2 Married
☐3 Separated/Divorced
☐4 Widowed
☐5 Living with partner

Q7. What is your ethnic origin/race? (check one box)

☐1 White
☐2 Black
☐3 Hispanic
☐4 Native American
☐5 Asian or Pacific Islander
☐6 Arabic
☐7 Other _____

Q8. How many people live with you? (check one box)

☐0 I live alone
☐1 1 person
☐2 2 people

-

☐3 3 people
☐4 4 people
☐5 5 or more

Q9. How much schooling have you had? (Years of formal schooling completed) (check one box)

☐1 8 grades or less
☐2 Some high school
☐3 High school graduate or GED
☐4 Some college or technical school
☐5 College graduate (bachelor's degree)
☐6 Graduate degree

Q10. Which of the following best describes your current employment status? (check one box)

☐1 Working full-time, 35 hours or more a week
☐2 Working part-time, less than 35 hours a week
☐3 Unemployed or laid off and looking for work
☐4 Unemployed and not looking for work
☐5 Homemaker
☐6 In school
☐7 Retired
☐8 Disabled, not able to work
☐9 Something else? (Please specify): _____

Q11/Q12. During the past 2 weeks, did you work at any time at a job or business, not counting work around the house?

☐1 No ☐2 Yes →

Q12. What kind of work were you doing?
(For example: electrical engineer, stock clerk, typist, farmer.)

_____

Q13. How would you describe the insurance plan(s) you have had in the past 12 months? (check all that apply)

-

☐1 An individual plan – the member pays for the plan premium
☐2 A group plan through an employer, union, etc. – the employer pays all or part of the plan premium
☐3 U.S. Governmental Health Plan (e.g., Military, CHAMPUS, VA)
☐4 Medicaid
☐5 Medicare
☐6 I have not had an insurance plan in the past 12 months

Q14. What type(s) of insurance plans have you had <u>in the past 12 months</u>
Specify:
_____
_____
_____

Q15. Which of the categories best describes your total annual <u>combined</u> household income from <u>all</u> sources? (check one box)

☐01 Less than $5,000

☐02 $5,000 to $9,999

☐03 $10,000 to $14,999

☐04 $15,000 to $19,999

☐05 $20,000 to $29,999

☐06 $30,000 to $39,999

☐07 $40,000 to $49,999

☐08 $50,000 to $59,999

☐09 $60,000 to $69,999

☐10 $70,000 and over

Q16. Altogether, how many people live on this income (that is, it provides at least half of their income)?

_____ People

-

Q17. Do you own your own home?

☐1 NO

☐2 YES

IF YES: Do you own it outright or are you still paying on a mortgage?

☐1 Own it outright

☐2 Still paying

Q18. Are your assets and financial resources sufficient to meet medical and household emergencies?

☐1 YES

☐2 NO

Q19. Are you expenses so heavy that you cannot meet your bills (or household expenses) or can you barely meet your bills, or are your bills no problem to you?

☐1 Cannot meet my bills

☐2 Can barely meet my bills

☐3 Bills are no problem

Q20. How well do you think you (and your family) are doing financially as compared to other people your age--

Better, about the same, or worse?

☐1 Better

☐2 About the same

☐3 Worse

Q21. How well does the amount of money you have take care of your needs --- very well, fairly well, or poorly?

☐1 Very well

-

☐2 Fairly well

☐3 Poorly

Q22. Do you usually have enough to buy those little "extras" --- that is, those small luxuries?

☐1 NO

☐2 YES

Q23. Do you feel that you will have enough for your needs in the future?

☐1 NO
☐2 YES

Section III – Quality of Life

Please check the appropriate box for each of the following ten statements indicating how often you feel each of them has applied to you in the last two weeks.

Please read each statement carefully	**Higher scores mean better well-being**			
The first five statements are:	**All of the time**	**More than half of the time**	**Less than half of the time**	**None of the time**
1. I feel downhearted and sad	☐0	☐1	☐2	☐3
2. I feel calm and peaceful	☐3	☐2	☐1	☐0
3. I feel energetic, active and full of strength	☐3	☐2	☐1	☐0
4. I wake up feeling fresh and rested	☐3	☐2	☐1	☐0
5. My daily life is full of things that are interesting to me	☐3	☐2	☐1	☐0
The last five statements are:	**All of the time**	**More than half of the time**	**Less than half of the time**	**None of the time**
6. I feel well adjusted to my daily situation	☐3	☐2	☐1	☐0
7. I live the kind of life I want	☐3	☐2	☐1	☐0
8. I feel motivated to do my daily tasks or make new decisions	☐3	☐2	☐1	☐0
9. I feel I can easily handle or cope with any serious problem or major change in my life	☐3	☐2	☐1	☐0
10. I am happy, satisfied or pleased with my personal life	☐3	☐2	☐1	☐0

-

Sub total (first five statements) ☐

Sub total (last five statements) ☐

Total (ten) score ☐

Section IV - Control Problems

For the following questions, please check the appropriate response.

Q1. How many **times** in the last **month** have you had a **low blood sugar** (glucose) reaction with symptoms such as sweating, weakness, anxiety, trembling, hunger or headache?

☐1 0 times
☐2 1-3 times
☐3 4-6 times
☐4 7-12 times
☐5 More than 12 times
☐6 Don't know

Q2. How many **days** in the last **month** have you had **high blood sugar** with symptoms such as thirst, dry mouth and skin, increased sugar in the urine, less appetite, nausea, or fatigue?

☐1 0 days
☐2 1-3 days
☐3 4-6 days
☐4 7-12 days
☐5 More than 12 days
☐6 Don't know

Section V -- Diabetes History

We would now like to ask you about the health care you have received recently.

Please answer every question by filling in the blank(s), circling the correct answer, or checking the correct box.
Resource Use

Q1. During the past 4 weeks, how many total visits to health care providers (doctors, nurse practitioners, etc.) did you make? (fill in the blanks)

-

_____ visits in the past 4 weeks

Q2. During the past 12 months, how many total visits to health care providers did you make? (fill in the blanks)

_____ visits in the past 12 months

Q3. When was your last visit with the following health care providers?

a. My last visit with an **ophthalmologist** was: (check one box)
(An ophthalmologist is a physician who specializes in the care and surgery of eye diseases, not an optometrist)

☐1 Within the last 12 months ☐2 1-2 years ago ☐3 2-3 years ago ☐4 More than 3 years ago ☐5 Never had a visit with an ophthamologist

b. My last visit with an **optometrist** was: (check one box)
(An optometrist is a person professionally trained to test the eyes and to detect and treat eye problems and some diseases, not an ophthalmologist)

☐1 Within the last 12 months ☐2 1-2 years ago ☐3 2-3 years ago ☐4 More than 3 years ago ☐5 Never had a visit with an optometrist

c. When was the last time that you had an eye exam during which the doctor put drops in your eyes that made your pupils large? (You may have been unable to see enough to drive or had to wear dark glasses afterward.) (check one box)

☐1 Within the last 12 months ☐2 1-2 years ago ☐3 2-3 years ago ☐4 More than 3 years ago ☐5 Never had this type of eye exam

d. My last visit with a **podiatrist** was: (check one box)
(A podiatrist is a physician who treats and takes care of people's feet)

☐1 Within the last 12 months ☐2 1-2 years ago ☐3 2-3 years ago ☐4 More than 3 years ago ☐5 Never had visit with a podiatrist

-

e. My last visit with a **dietitian** was: (check one box)

☐1 Within the last 12 months ☐2 1-2 years ago ☐3 2-3 years ago ☐4 More than 3 years ago ☐5 Never had a visit visit with a dietitian

f. My last visit with a **diabetes educator** was: (check one box)

☐1 Within the last 12 months ☐2 1-2 years ago ☐3 2-3 years ago ☐4 More than 3 years ago ☐5 Never had a visit with a diabetes educator

Q4. When was the last time that you had the following blood tests?

a. My last **Hemoglobin A1c test** was: (check one box)
(This is also known as glycohemoglobin or glycosylated hemoglobin, a test that measures your average blood sugar level over the past couple of months)

☐1 Within the last 12 months ☐2 1-2 years ago ☐3 2-3 years ago ☐4 More than 3 years ago ☐5 Never had a Hemoglobin A1c Test

b. My last **Cholesterol blood test** was: (check one box)

☐1 Within the last 12 months ☐2 1-2 years ago ☐3 2-3 years ago ☐4 More than 3 years ago ☐5 Never had a cholesterol blood test

c.My last **Urine analysis** was: (check one box)
(Gave a urine sample to be tested by the health care provider, clinic, or laboratory)

☐1 Within the last 12 months ☐2 1-2 years ago ☐3 2-3 years ago ☐4 More than 3 years ago ☐5 Never had a urine analysis

-

Q5. Do you test your blood sugar? (check one box)

☐1 No ☐2 Yes → Q5a. How many days a week do you test your blood sugar?

_____ (days / week)

If no, go to question #6

Q5b. On days that you test, how many times do you test your blood sugar?

_____ (times / day)

Q5c. Do you keep a record of your blood sugar test results? (check one box)

☐1 No ☐2 Yes ☐3 Only Unusual Values

Q6. During the <u>past 12 months</u>, were you a patient in a hospital overnight? (check one box)

☐1 No ☐2 Yes → Q6a. How many times in the <u>past 12 months</u> did you stay in a hospital overnight?

__ __ times

Q6b. How many nights altogether during the <u>past 12 months</u> did you stay in a hospital?

f no, go to question #7

__ __ __ nights

Q7. Have you <u>ever</u> been hospitalized for diabetic ketoacidosis (DKA)? (check one box)

-

☐ 1 No
☐ 2 Yes
☐ 3 Don't Know

Medication Use

Q1. Do you now use insulin? (check one box)

☐ 1 No ☐ 2 Yes → Q1a. How many times during the day do you usually take your insulin? (check one box)

If no, go to question #2

☐ 1 Once a day (Taken in the Morning)
☐ 2 Once a day (Taken in the Evening)
☐ 3 Twice a day
☐ 4 Three times a day
☐ 5 Four or more times a day
☐ 6 I use an infusion pump

Q1b. How long have you taken insulin?

__ __ years

Q1c. Have you taken insulin for as long as you have had diabetes? (check one box)

☐ 1 No
☐ 2 Yes

Q2. Are you currently taking medications for high cholesterol? (Check one box)

☐ 1 No
☐ 2 Yes
☐ 3 Don't know

Q3. Are you currently taking medication for high blood pressure? (Check one box)
☐ 1 No
☐ 2 Yes

-

Q4. Please list **all** medications you are currently taking

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

Comorbidities

Q1. Have you ever been told by a health care provider that you have any of the following problems with your eyes? (circle one answer on each line)

		No	**Yes, on one eye**	**Yes, on both eyes**
A.	Cataracts	1	2	3
B.	Glaucoma	1	2	3
C.	Detached retina	1	2	3
D.	Blurred vision (not correctable with eye glasses)	1	2	3
E.	Retinopathy (diabetic changes in the back of the eye)	1	2	3
F.	Blindness	1	2	3
G.	Macular degeneration (an aging change in the back of the eye)	1	2	3
H.	Macular Edema	1	2	3

-

Q2. Have you ever had any of the following operations on your eyes? (circle one answer on each line)

		No	Yes, on one eye	Yes, on both eyes
A.	Cataract Surgery	1	2	3
B.	Laser Treatment	1	2	3
C.	Other (please specify below): _____	1	2	3

Q3. Have you ever been told by a health care provider that you have any of the following problems related to your heart or circulation? (circle one answer on each line)

		No	Yes
A.	Heart attack	1	2
B.	Heart failure	1	2
C.	High cholesterol	1	2
D.	Angina	1	2
E.	High blood Pressure	1	2

Q4. Have you ever had any of the following operations or procedures related to your heart? (circle one answer on each line)

		No	Yes
A.	Coronary artery bypass surgery (open heart surgery)	1	2
B.	Coronary angioplasty (“balloon” heart procedure)	1	2
C.	Heart catheterization (angiogram)	1	2

Q5. Have you ever been told by a health care provider that you have any of the following bladder, kidney, or urinary problems? (circle one answer on each line)

		No	Yes
A.	Kidney or bladder infections	1	2
B.	Kidney failure	1	2
C.	Protein in your urine	1	2
D.	Enlarged prostate (Men only)	1	2
E.	Vaginitis (Women only)	1	2

Q6. Have you ever been told by a health care provider that you have any of the following problems with your feet or legs? (circle one answer on each line)

-

		No	Yes
A.	Peripheral vascular disease (poor circulation in the legs)	1	2
B.	Intermittent claudication (cramping in the calves after exercise)	1	2
C.	Peripheral neuropathy (nerve problems causing numbness, tingling, or burning)	1	2
D.	Gangrene	1	2
E.	Foot ulcers	1	2
F.	Athlete's foot or fungus infection of the feet	1	2

Q7. Have you ever had an amputation of a toe, foot, part of a leg, or all of a leg **for a poorly healing sore or poor circulation**? (An amputation that is **not** due to an injury or accident [car crash, power tool injury, war injury, etc.])?

		No	Yes, right side only	Yes, left side only	Yes, both sides
A.	Toes	1	2	3	4
B.	Part of a foot (or feet)	1	2	3	4
C.	Leg, below the knee	1	2	3	4
D.	Leg, above the knee	1	2	3	4

Q8. Have you ever been told by a health care provider that you have had any of the following problems?

		No	Yes
A.	Stroke	1	2
B.	Transient ischemic attacks (TIA or "mini-strokes")	1	2
C.	Epilepsy or seizure disorder	1	2
D.	Parkinson's Disease	1	2

Background Information

Q1. Have you ever smoked cigarettes? (check one box)

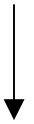
☐1 No
☐2 Yes

-

Q2. Do you now smoke cigarettes? (check one box)

☐1 No ☐2 Yes → Q6a. How many packs per day do you smoke?

____ packs per day



Please Continue

-

Section VIII -- Attitudes Toward Diabetes – DES

In general, I believe that I:	Strongly Agree (5)	Agree (4)	Neutral (3)	Disagree (2)	Strongly Disagree (1)
1. ...know what part(s) of taking care of my diabetes that I am **satisfied** with.	( )	( )	( )	( )	( )
2. ...know what part(s) of taking care of my diabetes that I am **dissatisfied** with.	( )	( )	( )	( )	( )
3. ...know what part(s) of taking care of my diabetes that I am ready to change.	( )	( )	( )	( )	( )
4. ...know what part(s) of taking care of my diabetes that I am <u>not</u> ready to change.	( )	( )	( )	( )	( )
5. ...can choose realistic diabetes goals.	( )	( )	( )	( )	( )
6. ...know which of my diabetes goals are **most** important to me.	( )	( )	( )	( )	( )
7. ...know the things about **myself** that either help or prevent me from reaching my diabetes goals.	( )	( )	( )	( )	( )
8. ...can come up with good ideas to help me reach my goals.	( )	( )	( )	( )	( )
9. ...am able to turn my diabetes goals into a workable plan.	( )	( )	( )	( )	( )

-

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
In general, I believe that I:					
10. ...can reach my diabetes goals once I make up my mind.	( )	( )	( )	( )	( )
11. ...know which **barriers** make reaching my diabetes goals more difficult.	( )	( )	( )	( )	( )
12. ...can **think** of different ways to overcome barriers to my diabetes goals	( )	( )	( )	( )	( )
13. ...can try out different ways of overcoming barriers to my diabetes goals.	( )	( )	( )	( )	( )
14. ...am able to decide which way of overcoming barriers to my diabetes goals works best for me.	( )	( )	( )	( )	( )
15. ...can tell how I'm feeling about **having** diabetes.	( )	( )	( )	( )	( )
16. ...can tell how I'm feeling about **caring** for my diabetes	( )	( )	( )	( )	( )
17. ...know the ways that having diabetes causes stress in my life.	( )	( )	( )	( )	( )
18. ...know the **positive** ways I cope with diabetes-related stress.	( )	( )	( )	( )	( )
19. ...know the **negative** ways I cope with diabetes-related stress.	( )	( )	( )	( )	( )

-

	Strongly Agree	Agree	Neutral	Disagree	Strongly Disagree
In general, I believe that I:					
20. ...can cope well with diabetes-related stress.	( )	( )	( )	( )	( )
21. ...know where I can get support for having and caring for my diabetes.	( )	( )	( )	( )	( )
22. ...can ask for support for having and caring for my diabetes when I need it.	( )	( )	( )	( )	( )
23. ...can support myself in dealing with my diabetes.	( )	( )	( )	( )	( )
24. ...know what helps me stay motivated to care for my diabetes.	( )	( )	( )	( )	( )
25. ..can motivate myself to care for my diabetes.	( )	( )	( )	( )	( )
26. ...know enough about diabetes to make self-care choices that are right for me.	( )	( )	( )	( )	( )
27. ...know enough about myself as a person to make diabetes care choices that are right for me.	( )	( )	( )	( )	( )
28. ...am able to figure out if it is worth my while to change how I take care of my diabetes.	( )	( )	( )	( )	( )

-

Please circle the number that indicates how able you are to fit diabetes into your life in a positive manner.

Not At All Able						Very Able
1	2	3	4	5	6	7

Please circle the number that indicates how comfortable you feel asking your doctor questions about diabetes.

Not At All Able						Very Able
1	2	3	4	5	6	7

Thank you very much for completing this questionnaire.

-

Appendix K: Follow-Up Chart Review Form

-

Patient Study Number

_____

Assessment of Diabetes Care

Follow-Up Chart Review

Audit Date ____/____/____ **Physician name/group** _____

Patient Study Number _____

Reviewer _____

Confirmed diagnosis of diabetes:

(1) by treatment (insulin, oral hypoglycemic meds) *OR*
(2) 2 FBS gt 126mg/dl *OR*
(3) 2 random bs gt 200 mg/dl *OR*
(4) HbA1c > 7%

If none of the above, STOP: DO NOT REVIEW CHART

Year of Diagnosis _____ *OR* **Age at diagnosis** _____

Gender:

(0) male
(1) female

Health Insurance:

(1) yes
(0) no

Smoker:

(1) yes
If yes, smoking cessation counseling? (1) yes
(0) no
(0) no

Current Height:

_____ ft _____ in (.) not recorded

-

Current Weight:

_____ lbs (.) not recorded

Diabetes Therapy:

(1) Diet and exercise alone
(2) Insulin
(3) Sulfonylurea
(4) Metformin (Glucophage)
(5) Acarbose (Precose)
(6) Thiazoladinediones (Rezulin)
(7) Combination (oral+insulin)
(8) Meglitinide
(9) Glucovance
(.) unknown/not recorded

Diabetes Education

Nutrition:
(1) yes
(0) no

Exercise instruction:
(1) yes
(0) no

Outpatient Diabetes Education:
(1) yes
(0) no

Self monitor blood glucose:
(1) yes
If yes, times per week _____
(.) unknown
(0) no
(.) unknown

Laboratory Measures

HbA1c
Test done: Lab: _____
(1) yes

-

Date: ____/____/____ Value: _____ (.) not recorded
Date: ____/____/____ Value: _____ (.) not recorded
Date: ____/____/____ Value: _____ (.) not recorded
Date: ____/____/____ Value: _____ (.) not recorded
Date: ____/____/____ Value: _____ (.) not recorded
(0) no

Lipid Profile
Test done: Lab: _____
(1) yes
Total Cholesterol _____ mg/dl (.) not recorded
Triglycerides _____ mg/dl (.) not recorded
LDL _____ mg/dl (.) not recorded
HDL _____ mg/dl (.) not recorded
(0) no

Urinalysis (for proteinuria/microalbuminuria):
(1) yes
If yes, type: _____
(0) no

Serum Creatinine:
(1) yes Value: _____
(0) no

Exams

Dilated eye exam (by ophthalmologist/optometrist)
(1) yes
(0) no

Foot exam
(1) yes
(0) no

Monofilament
(1) yes
(0) no

Electrocardiogram
(1) yes
(0) no

-

Blood Pressure

(1) yes _____ SBP _____ DBP
(0) no

Flu vaccine in previous year

(1) yes
(0) no

Symptoms/problems

(1) Hypoglycemia (requiring 3rd party assistance)
(2) Hyperglycemia (emergency)
(0) None
(3) Both

Current Medications

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

-

Appendix L: 36 Month Follow-Up Questionnaire

-

Name: _____

Today's Date _____

Patient-Provider Partnership:
Improving Diabetes Care in the Community

2nd Follow-Up Interview

THE FOLLOWING SHOULD ONLY BE FILLED OUT BY CLINIC STAFF

Education Session Site:
_____

Verified Date: _____

Verified Time: _____

Interviewer's Initials: _____

Certain portions of this survey are from the
Michigan Diabetes Research and Training Center
unless otherwise noted.

-

Section 1 - Barriers to Diabetes

1. Are you worried (concerned) about your diabetes? ☐ Yes ☐ No

If yes, why?

_____

_____

_____

2. In general, are you satisfied with your diabetes care? ☐ Yes ☐ No

How would you improve your diabetes care in McKeesport?

_____

_____

_____

3. What do you feel prevents you (or others) from looking after (caring for) your diabetes properly?

_____

_____

_____

Source: Simmons D. Diabetic Medicine. 1998. 15(11) 958-964

-

Section II - Demographics

Please answer each of the following questions by filling in the blanks with the correct answers or by choosing the single best answer.

Note: For this survey, a Health Care Provider refers to a doctor, nurse practitioner, or physician assistant.

Q1. Age: __ __ years old

Q2. Birth date: __ __ /__ __ /__ __
(Month / Day / Year)

Q3. Which of the following best describes your current employment status? (check one box)

- ☐ 1 Working full-time, 35 hours or more a week
- ☐ 2 Working part-time, less than 35 hours a week
- ☐ 3 Unemployed or laid off and looking for work
- ☐ 4 Unemployed and not looking for work
- ☐ 5 Homemaker
- ☐ 6 In school
- ☐ 7 Retired
- ☐ 8 Disabled, not able to work
- ☐ 9 Something else? (Please specify): _____

Q4. How would you describe the insurance plan(s) you have had in the past 12 months? (check all that apply)

- ☐ 1 An individual plan – the member pays for the plan premium
- ☐ 2 A group plan through an employer, union, etc. – the employer pays all or part of the plan premium
- ☐ 3 U.S. Governmental Health Plan (e.g., Military, CHAMPUS, VA)
- ☐ 4 Medicaid
- ☐ 5 Medicare
- ☐ 6 I have not had an insurance plan in the past 12 months

Q5. What type(s) of insurance plans have you had in the past 12 months
Specify:

-

_____
_____
_____

Q15. Which of the categories best describes your total annual <u>combined</u> household income from <u>all</u> sources? (check one box)

☐ 01 Less than $5,000

☐ 02 $5,000 to $9,999

☐ 03 $10,000 to $14,999

☐ 04 $15,000 to $19,999

☐ 05 $20,000 to $29,999

☐ 06 $30,000 to $39,999

☐ 07 $40,000 to $49,999

☐ 08 $50,000 to $59,999

☐ 09 $60,000 to $69,999

☐ 10 $70,000 and over

-

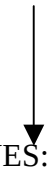
Q16. Altogether, how many people live on this income (that is, it provides at least half of their income)?

_____ People

Q17. Do you own your own home?

☐0 NO

☐1 YES



IF YES: Do you own it outright or are you still paying on a mortgage?

☐0 Own it outright

☐1 Still paying

Q18. Are your assets and financial resources sufficient to meet medical and household emergencies?

☐1 YES

☐0 NO

Q19. Are you expenses so heavy that you cannot meet your bills (or household expenses) or can you barely meet your bills, or are your bills no problem to you?

☐1 Cannot meet my bills

☐2 Can barely meet my bills

☐3 Bills are no problem

Q20. How well do you think you (and your family) are doing financially as compared to other people your age

Better, about the same, or worse?

☐1 Better

☐2 About the same

☐3 Worse

Q21. How well does the amount of money you have take care of your needs --- very well, fairly well, or poorly?

☐1 Very well

☐2 Fairly well

☐3 Poorly

Q22. Do you usually have enough to buy those little "extras" --- that is, those small luxuries?

☐0 NO

☐1 YES

Q23. Do you feel that you will have enough for your needs in the future?

☐0 NO

☐1 YES

Section III – Quality of Well-Being

Please check the appropriate box for each of the following ten statements indicating how often you feel each of them has applied to you in the last two weeks.

Please read each statement carefully	**Higher scores mean better well-being**			
The first five statements are:	**All of the time**	**More than half of the time**	**Less than half of the time**	**None of the time**
1. I feel downhearted and sad	☐0	☐1	☐2	☐3
2. I feel calm and peaceful	☐3	☐2	☐1	☐0
3. I feel energetic, active and full of strength	☐3	☐2	☐1	☐0
4. I wake up feeling fresh and rested	☐3	☐2	☐1	☐0
5. My daily life is full of things	☐3	☐2	☐1	☐0

that are interesting to me				
The last five statements are:	**All of the time**	**More than half of the time**	**Less than half of the time**	**None of the time**
6. I feel well adjusted to my daily situation	☐3	☐2	☐1	☐0
7. I live the kind of life I want	☐3	☐2	☐1	☐0
8. I feel motivated to do my daily tasks or make new decisions	☐3	☐2	☐1	☐0
9. I feel I can easily handle or cope with any serious problem or major change in my life	☐3	☐2	☐1	☐0
10. I am happy, satisfied or pleased with my personal life	☐3	☐2	☐1	☐0

Source: Bech P. et al. *Psychotherapy and Psychosomatics* v65 1996

Section IV – Blood Glucose Control

For the following questions, please check the appropriate response.

Q1.How many **times** in the last **month** have you had a **low blood sugar** (glucose) reaction with symptoms such as sweating, weakness, anxiety, trembling, hunger or headache?

☐1 0 times
☐2 1-3 times
☐3 4-6 times
☐4 7-12 times
☐5 More than 12 times
☐6 Don't know

Q2.How many **days** in the last **month** have you had **high blood sugar** with symptoms such as thirst, dry mouth and skin, increased sugar in the urine, less appetite, nausea, or fatigue?

☐1 0 days
☐2 1-3 days
☐3 4-6 days

☐4 7-12 days

☐5 More than 12 days

☐6 Don't know

Section V -- Diabetes History

We would now like to ask you about the health care you have received recently.

Please answer every question by filling in the blank(s), circling the correct answer, or checking the correct box.

Resource Use

Q1. During the past 12 months, how many total visits to health care providers did you make? (fill in the blanks)

_____ visits in the past 12 months

---

a. When was the last time that you had an eye exam during which the doctor put drops in your eyes that made your pupils large? (You may have been unable to see enough to drive or had to wear dark glasses afterward.) (check one box)

☐1Within the last 12 months
☐2 1-2 years ago
☐3 2-3 years ago
☐4 More than 3 years ago
☐5 Never had this type of eye exam

---

b. My last visit with a **podiatrist** was: (check one box)

(A podiatrist is a physician who treats and takes care of people's feet)

☐1Within the last 12 months
☐2 1-2 years ago
☐3 2-3 years ago
☐4 More than 3 years ago
☐5 Never had a visit with a podiatrist

---

c. My last visit with a **dietitian (outside of our study)** was: (check one box)

☐1 Within the last 12 months
☐2 1-2 years ago
☐3 2-3 years ago
☐4 More than 3 years ago
☐5 Never had a visit with a dietitian

---

d. My last visit with a **diabetes educator (outside of our study)** was: (check one box)

☐1 Within the last 12 months
☐2 1-2 years ago
☐3 2-3 years ago
☐4 More than 3 years ago
☐5 Never had a visit with a diabetes educator

Sometimes people with diabetes are concerned about some of the issues listed below regarding their primary care doctor. How much have these things bothered you in the **past 2 months**?

On a scale of 1 to 6, check the correct box. The first box means the issue has not been a problem for you. The last box means that the issue has been a serious problem for you. The boxes in the middle mean some amount in between.

	Not a Problem		Moderate Problem			Serious Problem
1. I felt that my doctor did not know enough about diabetes and diabetes care.	☐1	☐2	☐3	☐4	☐5	☐6
2. I felt that my doctor did not give me clear enough directions on how to manage my diabetes.	☐1	☐2	☐3	☐4	☐5	☐6
3. I felt that I could not tell my doctor what was really on my mind.	☐1	☐2	☐3	☐4	☐5	☐6
4. I felt that my doctor did not take my concerns seriously enough.	☐1	☐2	☐3	☐4	☐5	☐6

Source: Inventory of Chronic Illness Care

5. I felt that my doctor did not really understand what it is like to have diabetes. ☐1 ☐2 ☐3 ☐4 ☐5 ☐6

6. I felt that I did not have a doctor who I could see regularly about my diabetes. ☐1 ☐2 ☐3 ☐4 ☐5 ☐6

Q2. When was the last time that you had the following blood tests?

a. My last **Hemoglobin A1c test** was: (check one box)
(This is also known as glycohemoglobin or glycosylated hemoglobin, a test that measures your average blood sugar level over the past couple of months)

☐1 Within the last 12 months ☐2 1-2 years ago ☐3 2-3 years ago ☐4 More than 3 years ago ☐5 Never had a Hemoglobin A1c Test

---

b. My last **Cholesterol blood test** was: (check one box)

☐1 Within the last 12 months ☐2 1-2 years ago ☐3 2-3 years ago ☐4 More than 3 years ago ☐5 Never had a cholesterol blood test

---

c. My last **Urine analysis** was: (check one box)
(Gave a urine sample to be tested by the health care provider, clinic, or laboratory)

☐1 Within the last 12 months ☐2 1-2 years ago ☐3 2-3 years ago ☐4 More than 3 years ago ☐5 Never had a urine analysis

---

Section VI - Self-Care

We would now like to ask you about your diabetes self-care.
Please answer every question by filling in the blank(s), circling the correct answer, or checking the correct box.

Blood Sugar Testing

Q1. Do you test your blood sugar? (check one box)

☐0 No ☐1 Yes → Q1a. On how many of the last SEVEN DAYS (that you were not sick) did you test your blood sugar?

☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7

If no, skip to the next page

Q1b. On how many of the last SEVEN DAYS (that you were not sick) did you test your blood sugar the number of times recommended your healthcare provider?

☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7

Q1c. On days that you test, how many times do you test your blood sugar?

_____ (times / day)

Q1d. Do you keep a record of your blood Sugar test results? (check one box)

☐0 No ☐1 Yes ☐2 Only Unusual Values

Medication Use

Q1. Do you now take pills for your diabetes? (check one box)

☐0 No ☐1 Yes ⟶ Q1a. On how many of the last SEVEN DAYS did you take your recommended diabetes pills?

☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7

Q2. Do you now use insulin? (check one box)

☐0 No ☐1 Yes ⟶ Q2a. How many times during the day do you usually take your insulin? (check one box)

If no, skip to question 3.

☐1 Once a day (Take in **Morning**)

☐2 Once a day (Take in **Evening**)

☐3 Twice a day

☐4 Three times a day

☐5 Four or more times a day

☐6 I use an infusion pump

↓

Q2b. How long have you taken insulin?
___ ___ years

↓

Q2c. Have you taken insulin for as long as you had diabetes? (check one box)

☐0 No ☐1 Yes

↓

Q2d. On how many of the last SEVEN DAYS did you take your recommended diabetes insulin injections?

☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7

Q3. Are you currently taking medications for high cholesterol? (Check one box)

☐0 No
☐1 Yes
☐2 Don't know

Q4. Are you currently taking medication for high blood pressure? (Check one box)
☐0 No
☐1 Yes

Q5. Please list **all** medications you are currently taking.

Name of Medicine	**Dosage of Medicine**	**Times per day**
Example: Glucophage	500 mg	Once per day
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

Diet

Q1. How many of the last SEVEN DAYS have you followed a healthful eating plan?

☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7

Q2. On average, over the past month, how many DAYS PER WEEK have you followed your eating plan?

☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7

Q3. On how many of the last SEVEN DAYS did you eat five or more servings of fruits and vegetables?

☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7

Q4. On how many of the last SEVEN DAYS did you eat high fat foods such as red meat or full-fat dairy products?

☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7

Exercise

Q1. On how many of the last SEVEN DAYS did you participate in at least 30 minutes of physical activity? (Continuous activity, including walking)

☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7

Q2. On how many of the last SEVEN DAYS did you participate in a specific exercise session (such as swimming, walking, biking) other than what you do around the house or as part of your work?

☐1 ☐2 ☐3 ☐4 ☐5 ☐6 ☐7

Problem Areas in Diabetes Questionnaire (PAID)

Which of the following diabetes issues are currently a problem for you? Circle the number that gives the best answer for you. Please provide an answer for each question.

	Not a problem	Minor problem	Moderate problem	Somewhat serious problem	Serious problem
1. Not having clear and concrete goals for your diabetes care?	☐1	☐2	☐3	☐4	☐5
2. Feeling discouraged with your diabetes treatment plan?	☐1	☐2	☐3	☐4	☐5
3. Feeling scared when you think about living with diabetes?	☐1	☐2	☐3	☐4	☐5
4. Uncomfortable social situations related to your diabetes care (e.g. people telling you what to eat)?	☐1	☐2	☐3	☐4	☐5
5. Feelings of deprivation regarding food and meals?	☐1	☐2	☐3	☐4	☐5

6. Feeling depressed when you think about living with diabetes?	☐1	☐2	☐3	☐4	☐5
7. Not knowing if your mood or feelings are related to diabetes?	☐1	☐2	☐3	☐4	☐5
8. Feeling overwhelmed by your diabetes?	☐1	☐2	☐3	☐4	☐5
9. Worrying about low blood sugar reactions?	☐1	☐2	☐3	☐4	☐5
10. Feeling angry when you think about living with diabetes?	☐1	☐2	☐3	☐4	☐5
11. Feeling constantly concerned about food and eating?	☐1	☐2	☐3	☐4	☐5
12. Worrying about the future and the possibility of serious complications?	☐1	☐2	☐3	☐4	☐5
13. Feelings of guilt or anxiety when you get off track with your diabetes management?	☐1	☐2	☐3	☐4	☐5
14. Not “accepting” your diabetes?	☐1	☐2	☐3	☐4	☐5
15. Feeling unsatisfied with your diabetes physician?	☐1	☐2	☐3	☐4	☐5
16. Feeling that diabetes is taking up too much of your mental and physical energy every day?	☐1	☐2	☐3	☐4	☐5
17. Feeling alone with your diabetes?	☐1	☐2	☐3	☐4	☐5
18. Feeling that your friends and family are not supportive of your diabetes management efforts?	☐1	☐2	☐3	☐4	☐5
19. Coping with complications of diabetes?	☐1	☐2	☐3	☐4	☐5

20. Feeling "burned out" by the constant effort needed to manage diabetes? ☐1 ☐2 ☐3 ☐4 ☐5

Attitudes Toward Diabetes – DES SF

	Strongly Disagree	Somewhat Disagree	Neutral	Somewhat Agree	Strongly Agree
In general, I believe that I:					
1. ...know what part(s) of taking care of my diabetes that I am **dissatisfied** with.	( )	( )	( )	( )	( )
2. ...am able to turn my diabetes goals into a workable plan.	( )	( )	( )	( )	( )
3. ...can try out different ways of overcoming barriers to my diabetes goals.	( )	( )	( )	( )	( )
4. ...can find ways to feel better about **having** diabetes.	( )	( )	( )	( )	( )
5. ...know the **positive** ways I cope with diabetes-related stress.	( )	( )	( )	( )	( )
6. ...can ask for support for having and caring for my diabetes when I need it.	( )	( )	( )	( )	( )
7. ...know what helps me stay motivated to care for my diabetes.	( )	( )	( )	( )	( )
8. ...know enough about myself as a person to make diabetes care choices that are right for me.	( )	( )	( )	( )	( )

Appendix M: Ancillary Tables

Table A1. Ten Processes of Change

Constructs	Description
Consciousness Raising	Finding and learning new facts, ideas, and tips that support the healthy behavior change
Dramatic Relief	Experiencing the negative emotions (fear, anxiety, worry) that go with unhealthy behavioral risks
Self-Reevaluation	Realizing that the behavior change is an important part of one's identity as a person
Environmental Reevaluation	Realizing the negative impact of the unhealthy behavior, or the positive impact of the healthy behavior, on one's proximal social and/ or physical environment
Self-Liberation	Making a firm commitment to change
Helping Relationships	Seeking and using social support for the healthy behavior change
Counter-conditioning	Substitution of healthier alternative behaviors and/or cognitions for the unhealthy behavior
Reinforcement Management	Increasing the rewards for the positive behavior change and/or decreasing the rewards of the unhealthy behavior
Stimulus Control	Removing reminders or cues to engage in the unhealthy behavior and/or adding cues to reminders to engage in the healthy behavior
Social Liberation	Realizing that social norms are changing in the direction of support the health behavior change

Source: (226)

Table A2. Study design and timeline (Phase I – Phase IV)

Month	3-6	7	8-10	8-19	20-22	23-26	47-53
	Dec 2000-Jan 2002	Aug. 2001	Oct 2001-April 2002	April 2002-April 2003	Jan 2003-June 2003	Oct 2002-June 2003	Oct 2004-May 2005
Group	Chart Review	Physician Education	Baseline assessment+ recruitment	Patient education	Chart Review	Follow-up assessment	2nd Follow-up a assessment
Physician+ Patient	X	X	X	X	X	X	X
Physician Only	X	X	X	------	X	X	X
Usual Care	X	------	------	------	X	X	X
Endocrine Clinic	X	------	------	------	X	------	-------

X=participation

Table A3. Measurement Timeline

Measure	Baseline (Oct 2001-June 2002)	12-Month Follow-Up (Oct 2002–Mar 2003)	36-Month Follow-Up (Oct 2004-May 2005)
Laboratory Measures (Height, Weight, Blood Pressure, HbA1c, HDLc, LDLc, Non-HDLc, Triglycerides, Microalbuminuria)	X	X	X
Modified Diabetes Care Profile	X	X	X
Diabetes Empowerment Scale	X	X	
Diabetes Knowledge Test	X	X	
Quality of Well-Being Index	X	X	X
Barriers to Diabetes Care Instrument	X	X	X
Diabetes Empowerment Scale Short-Form (DES-SF)			X
Summary of Diabetes Self-Care Activities Measure (SCSCA)			X
Problem Areas in Diabetes Survey (PAID)			X

Table A4. Performance Characteristics of the Cholestech LDX

	Cholestech LDX	McKeesport
Total Cholesterol		
N=	20	119
$\bar{x}$ (mg/dL)	244	200
SD (mg/dL)	8.6	42.6
CV (%)	3.5	21.3
HDL Cholesterol		
N=	20	119
$\bar{x}$ (mg/dL)	46	44
SD (mg/dL)	2.9	11.7
CV (%)	6.3	26.6
Triglycerides		
N=	20	119
$\bar{x}$ (mg/dL)	276	254
SD (mg/dL)	8.7	167.1
CV (%)	3.2	77.6

Table A5. Accuracy of Samples Assayed by a Quantitative Radioimmunoassay Method and by Micral Test Strips.

		RIA Method Albumin Concentration (mg/dL)	
Micral Test Strips		≥ 20	< 20
Albumin Concentration (mg/dL)	≥ 20	193	15
	< 20	13	243

N= 464
Accuracy = 94%
Sensitivity = 93.7%
Specificity = 94.2%

Table A6. Within Group Power Analyses for Primary and Secondary Outcomes by Study Group, Baseline to 12-Month Follow-up (α=0.05, β=0.8)

Outcome	CCM		PROV		UC	
	Difference Detected	Power	Difference Detected	Power	Difference Detected	Power
HbA1c (%)	0.7	86%	0.02	5%	0.2	14%
Non-HDL mg/dl	10.4	23%	2.2	6%	1.4	6%
HDL mg/dl	5.5	98%	1.3	21%	3.6	66%
Systolic BP mm/Hg	0.7	5%	1.6	8%	3.3	18%
Diastolic BP mm/Hg	0.3	5%	1.9	20%	0.1	5%
Quality of Well-Being Score	0.9	17%	1.8	64%	0.5	15%
Diabetes Knowledge Score	5.9	47%	2.1	15%	1.4	11%
Diabetes Empowerment Score	0.3	67%	0.03	6%	0.004	5%

*All calculations based on the change in values from baseline to 12-month follow-up

Table A7. Between Group Power Analyses for Primary Outcomes between CCM and UC, 12-Month Follow-up (α=0.05, β=0.8)

Outcome	CCM	UC	
	Follow-up value	Follow-up value	Power
HbA1c (%)	7.0	6.8	13%
Non-HDL mg/dl	143.3	148.7	9%
HDL mg/dl	44.5	47.4	21%
Systolic BP mm/Hg	141.8	143.3	6%
Diastolic BP mm/Hg	73.3	70.0	22%
Quality of Well-Being Score	20.4	19.8	57%
Diabetes Knowledge Score	61.9	70.0	12%
Diabetes Empowerment Score	4.0	3.9	8%

*All calculations based on 12-month follow-up values

Table A8. Between Group Power Analyses to Detect Clinically Significant Differences in the Primary Outcomes between the Chronic Care Model Group and the Usual Care Group, 12-Month Follow-up (α=0.05, β=0.8)

Outcome	Clinically Significant Difference *	Power to Detect Clinically Significant Differences in Outcomes between CCM (n=27) and UC (n=46)
HbA1c (%)	0.5	40.4%
	1.0	93%
	1.5	99.9%
Non-HDL mg/dl	5	8.5%
	10	20%
	15	37.8%
Systolic BP mmHg	3	9.8%
	5	18.6%
	8	39.8%
	10	56.6%
	15	89.1%

Table A9. Associations Between Patient Characteristics and Sustained Improvements in Metabolic Outcomes at 36-Month Follow-up

	HbA1c		Non-HDLc		Systolic Blood Pressure		Diastolic Blood Pressure	
	OR	**95%CI**	**OR**	**95% CI**	**OR**	**95% CI**	**OR**	**95% CI**
Age (years)	0.96	(0.89, 1.0)	1.0	(0.95, 1.1)	1.0	(0.03, 1.1)	0.99	(0.93, 1.1)
Duration (years)	0.97	(0.89, 1.1)	0.96	(0.88, 1.1)	1.0	(0.93, 1.1)	1.0	(0.93, 1.1)
Sex (% male)	0.7	(0.2, 2.5)	1.0	(0.27, 3.7)	0.29	(0.08, 1.1) *	0.51	(0.14, 1.8)
Race (%Non-White)	2.1	(3.2, 14.5)	0.39	(0.04, 3.8)	0.56	(0.08, 3.8)	1.0	(0.15, 6.8)
Insulin use (yes:no)	0.51	(0.51, 2.7)	0.22	(0.04, 1.5)	-----	----------	0.43	(0.08, 2.2)
Smoker (yes:no)	1.1	(0.3, 3.8)	1.1	(0.28, 4.0)	0.83	(0.24, 2.9)	0.6	(0.17, 2.2)
Socio-economic position (high:low)	0.54	0.13, 2.2)	0.2	(0.05, 0.9) †	1.5	(0.37, 6.0)	0.44	(0.11, 1.8)
Self-monitor blood glucose (yes:no)	2.8	(0.23, 33.8)	3.8	(0.32, 46.7)	0.43	(0.04, 5.1)	3.3	0.27, 39.7)
WHO10 Subscale 1	0.93	(0.76, 1.1)	0.97	(0.79, 1.2)	1.1	(0.88, 1.3)	1.0	(0.82, 1.2)
WHO10 Subscale 2	0.93	(0.78, 1.1)	0.98	(0.81, 1.2)	1.1	(0.91, 1.3)	1.0	(0.82, 1.2)
WHO10 Total Score	0.96	(0.87, 1.1)	0.99	(0.89, 1.1)	1.0	(0.95, 1.1)	1.0	(0.91, 1.1)
Problem Areas In Diabetes (PAID) Score	1.0	(0.98, 1.0)	1.0	(0.97, 1.1)	0.99	(0.96, 1.0)	0.98	(0.96, 1.0)
CCM group	1.9	(0.45, 7.7)	1.0	(0.24, 4.4)	1.9	(0.47, 7.3)	5.0	(0.92, 27.1) *
PROV group	1.1	(0.28, 4.4)	1.3	(0.3, 5.3)	0.43	(0.11, 1.8)	0.34	(0.08, 1.4)

----- Validity of model unknown, * $p<0.1$, † $p<0.05$

Table A10. Associations Between Diabetes Empowerment Scale Short Form Scores and Sustained Improvements in Metabolic Outcomes at 36-Month Follow-up

	HbA1c		Non-HDLc		Systolic Blood Pressure		Diastolic Blood Pressure	
	OR	**95% CI**	**OR**	**95% CI**	**OR**	**95% CI**	**OR**	**95% CI**
Diabetes Empowerment Scale Total Score	0.7	(0.36, 1.4)	0.86	(0.44, 1.7)	2.2	(10, 4.6) †	1.4	(0.73, 2.7)
…know what parts of diabetes I am dissatisfied with…	1.0	(0.6, 1.7)	0.98	(0.55, 1.8)	1.4	(0.8, 2.4)	1.1	(0.64, 1.9)
…turn my diabetes goals into a workable plan…	0.75	(0.45, 1.3)	0.86	(0.51, 1.4)	1.6	(0.95, 2.8) *	1.0	(0.64, 1.7)
…try different ways of overcoming barriers to diabetes goals…	0.88	(0.54, 1.5)	0.84	(0.5, 1.4)	2.1	(1.1, 4.0) †	0.99	(0.6, 1.6)
…find ways to feel better about having diabetes…	0.59	(0.34, 1.0) *	0.73	(0.43, 1.2)	1.7	(0.99, 2.9) *	0.97	(0.6, 1.6)
…know positive ways to cope with diabetes related stress…	0.77	(0.45, 1.3)	0.84	(0.49, 1.4)	1.6	(0.93, 2.9) †	1.6	(0.91, 2.6)
…can ask for support for having and caring for diabetes…	0.89	(0.56, 1.4)	0.87	(0.53, 1.4)	1.3	(0.83, 2.2)	1.1	(0.66, 1.7)
…know what helps me to stay motivated…	0.8	(0.48, 1.3)	0.95	(0.58, 1.6)	1.7	(1.0, 3.0) *	1.4	(0.83, 2.2)

Table A10
continued

…know enough about myself to make diabetes care choices that are right for me…	0.79	(0.45, 7.7)	0.97	(0.58, 1.6)	2.1	(1.1, 3.8) †	1.5	(0.92, 2.6)

* p<0.1, † p<0.05

Table A11. Associations Between Summary of Diabetes Self Care Activities Measure Scores and Sustained Improvements in Metabolic Outcomes at 36-Month Follow-up

	HbA1c		Non-HDLc		Systolic Blood Pressure		Diastolic Blood Pressure	
	OR	**95% CI**	**OR**	**95% CI**	**OR**	**95% CI**	**OR**	**95% CI**
How many of the last 7 days have you followed a healthful eating plan?	1.0	(0.73, 1.5)	1.0	(0.69, 1.5)	1.1	(0.75, 1.5)	1.6	(1.0, 2.4) †
On average, over the past month, how many days per week have you followed your eating plan?	1.2	(0.8, 1.7)	1.1	(0.78, 1.5)	1.2	(0.8, 1.7)	1.5	(1.0, 2.3) †
How many of the last 7 days did you eat 5 or more servings of fruits and vegetables?	0.9	(0.66, 1.2)	1.1	(0.78, 1.5)	0.94	(0.69, 1.3)	1.2	(0.88, 1.7)
On how many of the last 7 days did you eat high fat foods such as red meat or full-fat dairy products?	1.4	(0.92, 2.0)	1.3	(0.89, 1.9)	1.2	(0.81, 1.6)	1.4	(0.94, 2.1)
Exercise	0.93	(0.65, 1.3)	0.99	(0.68, 1.5)	1.0	(0.73, 1.4)	1.1	(0.77, 1.6)
Blood Sugar Testing	0.81	(0.57, 1.2)	0.94	(0.66, 1.3)	0.94	(0.68, 1.3)	1.3	(0.9, 1.8)

* $p<0.1$, † $p<0.05$

Table A12. Associations Between Patient Characteristics and Sustained Improvements in Quality of Well-Being and Diabetes Empowerment Scores at 36-Month Follow-up

	Quality of Well-Being Total Score		Diabetes Empowerment Scale Total Score	
	OR	**95%CI**	**OR**	**95% CI**
Age (years)	1.0	(0.98, 1.1)	0.95	(0.88, 1.0)
Duration (years)	1.0	(0.97, 1.1)	1.0	(0.97, 1.1)
Sex (% male)	0.8	(0.28, 2.3)	1.5	(0.5, 4.6)
Race (% Non-White)	6.4	(0.67, 61.4)	2.1	(0.22, 20.4)
Insulin use (yes:no)	0.33	(0.09, 1.3)	0.7	0.16, 3.0)
Smoker (yes:no)	0.67	(0.23, 1.9)	0.38	(0.12, 1.2) *
Socio-economic position (high:low)	0.54	(0.16, 1.8)	2.2	(0.65, 7.4)
Self-monitor blood glucose (yes:no)	1.4	(0.18, 10.8)	0.47	(0.06, 3.6)
WHO10 Subscale 1	------	--------	1.2	(0.98, 1.4) *
WHO10 Subscale 2	------	--------	1.1	(0.94, 1.3)
WHO10 Total Score	------	--------	1.1	(0.98, 1.2)
PAID Score	0.98	(0.95, 1.0)	0.96	(0.92, 1.0) *
Summary of Diabetes Self-Care Activities Measure				
How many of the last 7 days have you followed a healthful eating plan?	1.1	(0.8, 1.6)	1.2	(0.85, 1.8)
On average, over the past month, how many days per week have you followed your eating plan?	1.1	(0.78, 1.6)	1.3	(0.84, 1.9)
How many of the last 7 days did you eat 5 or more servings of fruits and vegatbles?	1.1	(0.84, 1.5)	1.3	(0.93, 1.8)
On how many of the last 7 days did you eat high fat foods such as red meat or full-fat dairy products?	1.3	(0.97,1.8) *	.95	(0.7, 1.3)
Exercise	1.1	(0.77, 1.3)	1.3	(0.93, 1.8)
Blood Sugar Testing	1.0	(0.9, 2.7	1.1	(0.81, 1.4)
CCM group	2.5	(0.69, 9.1)	0.41	(0.1, 1.7)
PROV group	0.87	(0.28, 2.7)	1.0	(0.31, 3.3)

* $p<0.1$, † $p<0.05$

Table A13. Associations Between Diabetes Empowerment Scale Short Form Scores and Sustained Improvements in Quality of Well-Being Scores at 36-Month Follow-up

	Quality of Well-Being Total Score	
	OR	**95% CI**
Diabetes Empowerment Scale Total Score	1.6	(0.9, 2.7)
…know what parts of diabetes I am dissatisfied with…	0.92	(0.59, 1.4)
…turn my diabetes goals into a workable plan…	1.2	(0.74, 1.8)
…try different ways of overcoming barriers to diabetes goals…	1.3	(0.82, 2.0)
…find ways to feel better about having diabetes…	1.1	(0.69, 1.7)
…know positive ways to cope with diabetes related stress…	1.4	(0.87, 2.3)
…can ask for support for having and caring for diabetes…	1.1	(0.75, 1.7)
…know what helps me to stay motivated…	1.5	(0.94, 2.3) *
…know enough about myself to make diabetes care choices that are right for me…	1.3	(0.83, 2.0)

*** p<0.1, † p<0.05**

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