

2010

Evaluating outcomes related to diabetes in Toledo-Lucas County CareNet patients

Avishek Nagi
The University of Toledo

Follow this and additional works at: <http://utdr.utoledo.edu/theses-dissertations>

Recommended Citation

Nagi, Avishek, "Evaluating outcomes related to diabetes in Toledo-Lucas County CareNet patients" (2010). *Theses and Dissertations*. 919.
<http://utdr.utoledo.edu/theses-dissertations/919>

This Thesis is brought to you for free and open access by The University of Toledo Digital Repository. It has been accepted for inclusion in Theses and Dissertations by an authorized administrator of The University of Toledo Digital Repository. For more information, please see the repository's [About page](#).

A Thesis

entitled

Evaluating Outcomes Related to Diabetes in Toledo-Lucas County CareNet Patients

by

Avishek Nagi

Submitted to the Graduate Faculty in partial fulfillment of the requirements for the
Masters of Science Degree in Pharmaceutical Sciences

Dr. Monica Holiday-Goodman, Advisor

Dr. Varun Vaidya, Committee member

Dr. Gregory Stone, Committee member

Dr. Patricia Komuniecki, Dean
College of Graduate Studies

The University of Toledo

December 2010

Copyright 2010, Avishek Nagi

The document is copyright material. Under copyright law, no part of this document may be reproduced without the expressed permission of the author.

An Abstract of
Evaluating Outcomes Related to Diabetes in Toledo-Lucas County CareNet Patients

by

Avishek Nagi

Submitted to the Graduate Faculty in partial fulfillment of the requirements for
the Master of Science Degree in Pharmaceutical Sciences

The University of Toledo
December 2010

Diabetes is a leading cause of morbidity and mortality in the United States. The American Diabetes Association has put forth guidelines to screen and prevent the progression of diabetes. However, lack of access to adequate health care can hinder treatment options for individuals diagnosed with diabetes. A number of organizations help uninsured individuals by providing access to health care. Toledo Lucas County CareNet has provided healthcare access to uninsured residents since 2003. The presented study focused on evaluating outcomes related specifically to CareNet members diagnosed with diabetes. The objectives of this study were to determine the percentage of patients with Type 2 diabetes that reached ADA recommended guidelines in A1c, blood pressure (Systolic and Diastolic) values, and lipid levels (HDL and LDL), and to determine the factors related to goal attainment. The factors studied were age, gender, race/ethnicity, height, weight, tobacco use, and pharmacotherapy. The study design was a retrospective chart review. Patient charts of Toledo Lucas County CareNet clients were reviewed. Data were collected from three major health systems in Toledo, Ohio, where CareNet members receive medical services. The results showed 179 patients met the inclusion criteria out of 712 charts reviewed from the three respective health centers. Goal

attainment was observed in all clinical markers. About 62% of CareNet members in the study met goal in A1c, 60% of members met goal in systolic blood pressure, and 75% met goal in diastolic blood pressure. In regard to HDL, 40% of men met goal compared to 77% of women. Over 51% of members met goal in LDL value. T-test results for changes in A1c were significant for participants greater than 40 years of age compared to those less than 40 years of age. Similarly, ANOVA results showed significant results for changes in A1c in African Americans compared to other races. The regression analysis model explained about 21% of variance, and age was estimated to be the strongest predictor for A1c improvement. The findings for regression analysis were statistically significant at $p=0.036$. The overall model for diastolic blood pressure was $R=0.281$, $p=0.013$, which means that about 28% of variance was explained by the model. Gender and age were estimated to be significant predictors for diastolic blood pressure improvement. Males showed lower improvement in diastolic blood pressure compared to females. Results obtained in this study were consistent with the previous literature. In conclusion, the ADA guidelines for goal attainment for A1c, blood pressure values and lipid levels were met by the majority of CareNet patients with diabetes.

I dedicate this thesis to my family and the almighty, without their support and assistance this would not have been possible.

Acknowledgements

I would like to express my sincere gratitude to my major advisor, Dr. Monica Holiday-Goodman, for her guidance and support during the course of this thesis project and throughout my study at University of Toledo. I would also like to thank my committee members, Dr. Varun Vaidya, Dr. Gregory Stone, and Dr. Kim Schmude for their valuable suggestions. I would also like to express my sincere appreciation to Dr. Sharel Pinto and Prof. Robert Bechtol for their feedback.

I am thankful to Ms. Jan Ruma (Executive Director – CareNet Toledo Lucas County), and everyone for helping have access to the data. I sincerely thank all the faculty members at University of Toledo for helping me gain valuable knowledge and expertise to attain this Master’s degree.

I especially acknowledge all of my fellow graduate students in the Pharmacy Health Care Administration program. They have been extremely helpful and a joy to work and study with. Last but most important, I would like to thank my family and God for their love and constant support, without their help this thesis would not have been possible.

Contents

Abstract.....	iii
Acknowledgements.....	vi
Contents	vii
List of Tables	ix
List of Figures.....	xi
Chapter One	1
Introduction.....	1
Diabetes Prevalence.....	2
Guidelines for Diabetes Treatment.....	3
Management of diabetes complications.....	6
The Uninsured and Disparities in diabetes	8
Need for Research.....	9
Significance.....	10
Goal.....	10
Research Objectives.....	10
Research Questions:.....	11
Chapter Two.....	14
Literature review	14
Diabetes.....	14
Macrovascular complications in diabetes	15
Studies Related to Diabetes Treatment.....	19
Diabetes Self-management	21
The Uninsured and diabetes.....	22
Disparities in diabetes	26
SafetyNet in diabetes	31
Studies related to CareNet	32
Chapter Three.....	36
Methods.....	36
Study Design.....	36
Data Source.....	36
Data Collection	37
Inclusion and Exclusion criteria.....	37

Independent variables	37
Dependent Variable	37
Data Analysis	38
Chapter Four	39
Results.....	39
Data Screening.....	39
Study population.....	40
Descriptive Results	43
Exploring difference using Analysis of Variance results	51
Summary.....	60
Chapter Five.....	62
Discussion and Conclusion.....	62
Goal attainment among CareNet members.....	62
Effect of age, gender and race/ethnicity on goal attainment among CareNet members.....	63
Implications of the findings	65
Future Research	67
Conclusion	67
References:.....	69
Appendix IRB and Data Collection forms.....	83

List of Tables

Table 1.1: Criteria for the diagnosis of diabetes	4
Table 4.1a Demographic characteristic RACE/Ethnicity	40
Table 4.1b Demographic characteristic (Weight).....	41
Table 4.1c Demographic characteristic (BMI)	41
Table 4.1d Demographic characteristic (Number of Visits).....	42
Table 4.2: T-test results for change in A1c.....	52
Table 4.3: ANOVA results for change in A1c.....	52
Table 4.4: T-test results for change in systolic blood pressure.....	53
Table 4.5: ANOVA results for change in systolic blood pressure.....	53
Table 4.6: T-test results for change in diastolic blood pressure	54
Table 4.7: ANOVA results for change in diastolic blood pressure	54
Table 4.8: T-test results for change in HDL	55
Table 4.9: ANOVA results for change in HDL	55
Table 4.10: T-test results for change in LDL.....	56
Table 4.11: ANOVA results for change in LDL.....	56
Table 4.12: Regression results for change in A1c	57
Table 4.13: Regression results for change in Systolic Blood Pressure.....	58
Table 4.14: Regression results for change in Diastolic Blood Pressure	59

Table 4.15: Regression results for change in HDL.....	59
Table 4.16: Regression result for change in LDL.....	60

List of Figures

Figure 2.1 Cardiovascular mortality rate by total serum cholesterol level for men with and without diabetes in the Multiple Risk Factor Intervention Trial population.	17
Figure 2.2 Barriers to Health Care among Nonelderly, Adults, by Health Insurance Status, 2006	24
Figure 4.1 Flow chart showing goal attainment in A1c.....	44
Figure 4.2 Flow chart showing goal attainment in SBP	45
Figure 4.3 Flow chart showing goal attainment in DBP.....	47
Figure 4.4 Flow chart showing goal attainment in HDL female	48
Figure 4.5 Flow chart showing goal attainment in HDL male	50
Figure 4.6 Flow chart showing goal attainment in LDL.....	51

Chapter One

Introduction

CareNet is a public private partnership that helps provide access to healthcare to the uninsured low-income residents of Toledo-Lucas County.¹ In 2002, Mayor Jack Ford initiated the first step to help reduce the expensive burden on healthcare placed by the uninsured population of Lucas County.² At that time, spending on emergency care for the uninsured was more than \$15 million.² Also, it was estimated that more than 44,000 residents of Lucas County were uninsured.² As a result, in 2003, Mercy Health Partners, the city of Toledo, and ProMedica Health System founded the Toledo-Lucas County CareNet program to increase healthcare access for the uninsured population.² To help get the program started, each of the three organizations committed \$100,000, while \$80,000 was provided by other partners cumulatively, including the University of Toledo Health Science Campus (formerly known as the Medical College of Ohio), St. Luke's Hospital, Lucas County, and the City of Oregon.² Since 2003, the purpose of CareNet has been “to provide healthcare access to low-income residents of Toledo-

Lucas County who don't have health insurance and do not qualify for government provided healthcare".³ Currently, CareNet is comprised of primary care sites, hospitals and volunteer specialists. Since its inception, they have connected more than 16,000 uninsured individuals to medical services and currently 5,000 active members.¹ CareNet has partnered with Toledo Area Regional Transit Authority (TARTA) to provide free transportation to its members. The organization also has partnered with The Pharmacy Counter, a local independent pharmacy, to provide medications and durable supplies to its members at a lower cost, through the „We Care pricing' program.¹ Although, CareNet patients receive services for many diseases and conditions, those with chronic diseases such as diabetes can be spared severe long-term clinical and economic consequences if treatment goals are reached and maintained.

Diabetes Prevalence

The prevalence of diabetes has been increasing worldwide. The World Health Organization (WHO) estimates that there are approximately 180 million cases of diabetes worldwide, and has predicted that number to double by the year 2030.⁴ In the United States alone, nearly 24 million individuals have diabetes.⁵ Among those approximately 18 million cases are diagnosed, and 6 million cases are undiagnosed.⁵ Diabetes is a burden to our society. In 2006, Diabetes was estimated to be the seventh leading cause of death in the U.S.⁵ Also in 2007, the anticipated cost of diabetes care was \$174 billion, of which an estimated \$116 billion was allocated to direct medical costs, while \$58 billion was allocated to indirect costs, such as disability, work loss, and premature mortality.⁵ The American Diabetes Association (ADA) has classified

diabetes into four clinical diagnoses⁶: Type 1 diabetes, Type 2 diabetes, Gestational diabetes mellitus (GDM), and other specific types of diabetes due to other causes.

Even though different diagnoses of diabetes exist, Type 2 has been found to be the most prevalent among the adult population in the U.S. Adults diagnosed with Type 2 diabetes account for 90% to 95% of all cases, while Type 1 diabetes, which is mostly found in adolescents, teens, and young adults, accounts for only 5% to 10% of cases.⁶ The health impact associated with Type 2 diabetes has been devastating. Diabetes may lead to cardiovascular disease and even increased risk of mortality.⁵ Other complications such as stroke, high blood pressure, blindness, kidney disease, neuropathy, and amputations are also associated with diabetes.⁵ Guidelines and recommendations are available to prevent and manage diabetes.

Guidelines for Diabetes Treatment

The guidelines for diabetes care target several clinical markers to further reduce the complications of diabetes. Clinical markers include Hemoglobin A1c values, blood pressure (systolic and diastolic), and lipid levels. The ADA recommended guidelines for screening, diagnostic, and therapeutic treatment options for diabetes are described below.

Screening and Diagnosis

In many illnesses, there is a distinction between screening and diagnosis. In diabetes, however, no such distinction exists.⁷ Generally, patients who are diagnosed with diabetes must meet one of three types of diagnosis criteria (Table 1).⁷ The patient must either have a Fasting Plasma glucose (FPG) level ≥ 126 mg/dl; the patient may present with hyperglycemia symptoms and must have a plasma glucose concentration level

≥ 200 mg/dl; or the patient may present with a 2-hour plasma glucose level of ≥ 200 mg/dl during an oral glucose tolerance test (OGTT).⁷ While an OGTT is a more accurate way of detecting diabetes, it is poorly reproducible and difficult to perform in practice, whereas FGP is easier, less expensive, commonly used, and accepted by patients.⁷

Table 1.1: Criteria for the diagnosis of diabetes⁷	
1.	FPG ≥ 126 mg/dl (7.0 mmol/l). Fasting is defined as no caloric intake for at least 8 hrs. OR
2.	Symptoms of hyperglycemia and a casual (random) plasma glucose ≥ 200 mg/dl (11.1 mmol/l). Casual (random) is defined as any time of day without regard to time since last meal. The classic symptoms of hyperglycemia include polyuria, polydipsia, and unexplained weight loss. OR
3.	2-h plasma glucose ≥ 200 mg/dl (11.1 mmol/l) during an OGTT. The test should be performed as described by the World Health Organization using a glucose load containing the equivalent of 75-g anhydrous glucose dissolved in water.

To adequately manage diabetes, healthcare providers with expertise and specialization in diabetes care must work as a team. Such teams may include but are not limited to physicians, nurse practitioners, physician’s assistants, nurses, dietitians, pharmacists, and mental health practitioners.⁷ Similarly, patient education in self-management of diabetes is also an integral part of care.⁷

Two techniques, self-management of blood glucose (SMBG), and measurement of A1C, are primarily used for screening and management of diabetes.⁷ Findings from the ADA’s 2009 Position Statement, demonstrated SMBG was associated with reducing A1C in non-insulin treated patients. Because the results of SMBG have been shown to be user dependent, it becomes important to closely monitor patient’s techniques.⁷ The most

widely used technique for managing glycemic level is Hemoglobin A1C (HbA1c). In 2008, an Expert Committee on the Diagnosis of Diabetes was convened, comprised of the (ADA), the European Association for the Study of Diabetes, and the International Diabetes Federation. The joint committee recommended that A1C be considered the preferred diagnostic test for diabetes.⁷ Because of its strong predictive values for diabetes complications,^{8,9} and its ability to reflect average glycemic values over several months,¹⁰ the ADA recommends that testing for A1C be performed according to the following patient's clinical situation, their treatment regimen use, and the clinician's judgment⁷.

According to the guidelines, clinicians should:

- Perform the A1C test at least two times a year in patients who are meeting treatment goals (and who have stable glycemic control).
- Perform the A1C test quarterly in patients whose therapy has changed or who are not meeting glycemic goals.

Several landmark clinical trials have shown a reduction in A1C value to 7 or below 7, significantly decreasing microvascular^{9, 11, 12} and macrovascular complications,^{9, 11, 13} and events of cardiovascular disease (CVD).^{9, 14}

Another technique for management of diabetes is Continuous Glucose Monitoring (CGM), a measure of interstitial glucose. CGM is a sensor type device, which has been found to reduce patients' hypo- and hyperglycemic episodes, and may modestly improve glycemic control.⁷ Since CGM is an emerging technique to manage glycemic level, a patient's motivation to wear the device at all times needs to be considered.⁷

Treatment for Diabetes

It has been recommended that intervention at the time of diagnosis of diabetes should incorporate the use of metformin in combination with lifestyle changes such as Medical nutrition therapy and exercise.¹⁵ Meanwhile keeping an overall goal in mind, that is to achieve and maintain glycemic control, and to change intervention appropriately when therapeutic goals are not being met, is essential. To modify the treatment option, a practitioner should select a suitable medication from the recommended list of approved drugs.¹⁶

Another more important part of treatment is diabetes self-management education (DSME), which helps patients self-manage their complications. Since the 1990s, DSME has shifted from a didactic to a more patient-centered approach where patients are empowered to play a role in the joint decision-making process with their health care provider.⁷ Studies of DSME programs have demonstrated that improving patient's knowledge of diabetes care and self-care behavior have shown progress in outcomes, such as lower A1C level,¹⁷⁻²⁰ lowered self-reported weight,²¹ and improved quality of life.²²

Management of diabetes complications

Hypertension, Hyperlipidemia, and other cardiovascular conditions commonly coexist in patients with diabetes, leading to morbidity and mortality from cardiovascular disease (CVD).⁷ Studies have demonstrated that controlling for cardiovascular risk factors reduces the chances of CVD in people with diabetes.²³ The ADA has recommended managing diabetes complications in patients who smoke and in those who have the risk of hypertension and hyperlipidemia.⁷

Hypertension in diabetes

Patients who have systolic blood pressure ≥ 130 mmHg and diastolic blood pressure ≥ 80 mmHg have a diagnosis of hypertension. To manage hypertension, the ADA recommends bringing systolic blood pressure to < 130 mmHg and diastolic blood pressure to < 80 mmHg for patients with diabetes. The treatment plan for hypertension is more specific relative to different blood pressure values. It is recommended that patients with systolic blood pressures of 130-139 mmHg or a diastolic blood pressure of 80-89 mmHg should participate in lifestyle therapies such as diet and exercise for a maximum of 3 months, and if targets are not achieved, pharmacological agents may be added to bring down the pressure. Whereas, patients with systolic blood pressure ≥ 140 mmHg or diastolic blood pressure ≥ 90 mmHg, a case of severe hypertension, should be treated with pharmacologic agents in addition to lifestyle therapies. The recommended pharmacologic therapy should include either an ACE inhibitor or an angiotension receptor blocker (ARB). It is also advised to add a thiazide diuretic or loop diuretic in the patient's therapy depending on their glomerular filtration rate (GFR).⁷

Hyperlipidemia in diabetes

To control hyperlipidemia, the ADA recommends patient's LDL values should be < 100 mg/dl, HDL > 50 mg/dl, and triglycerides < 150 mg/dl. The ADA recommends statin therapy and lifestyle changes including increased exercise and decreased levels of saturated and trans fat intake.⁷

Smoking in diabetes

The ADA recommends that patients should be advised not to smoke, because smoking increases the risk of diabetes and worsens the condition in those who have diabetes. They also suggested that smoking cessation programs should be a routine component of any diabetes care plan.⁷

Achieving ADA recommended goals would likely result in improvements in clinical and humanistic outcomes for the CareNet members and economic benefit for CareNet, thereby, providing additional opportunities for funding to aid in the future growth of the program.

The Uninsured and Disparities in diabetes

In the U.S, the redistribution of the human population to cities to live and to do business brought with it diversity, which has impacted the health of the population. Past literature has shown urbanization reflected social, economic, and technological changes, and along with it came threats to health and life.²⁴ Morbidity and mortality rates trended upward, and much of the impact was felt by poor people, primarily due to lack of resources.²⁴ The current situation similarly suggests that poor people may suffer devastating consequences, due to a lack of resources including access to health insurance.

In 2008, 46.3 million people were estimated to be without health insurance.²⁵ Health insurance status has had a great impact on those in poverty. Their inability to afford health insurance may delay the chances of detecting any illness or chronic conditions at an early stage.²⁶ Chronic diseases such as diabetes, hypertension, and cardiovascular complications are common among uninsured populations. A recent national study estimated that nearly one third, 11.4 million, adults in the United States had

at least one chronic condition, and of them 1.4 million people were without insurance and have diabetes.²⁷

Besides being affected by detrimental illness, low-income people suffer from a disproportionate number of health problems (i.e. a 'health disparity') when compared to other economic groups. Healthy People 2010 defines “health disparity as a difference that occur by gender, race or ethnicity, education or income, disability, living in rural localities, or sexual orientation.”²⁸ Every individual should receive quality health care, however differences persist. Studies have shown that disparities exist in those with lower income levels²⁹ and minority race/ethnicity status.³⁰ Similarly, the 2008 National Health Disparity Report indentified that African Americans and Hispanics experience greater gaps in diabetes care compared to their white counterparts.²⁶ Health disparities can be eliminated by reducing barriers of access to care and by providing services to uninsured low-income populations, in a manner similar to that of the Toledo-Lucas County CareNet program.

Need for Research

The lack of access to health care has a negative impact on patients who have been diagnosed with diabetes. There is strong evidence that health complications associated with the condition can be devastating for individuals with diabetes. On the contrary, proper management of diabetes may help reduce such complications. Therefore, it is important to assess the outcomes of diabetes in the CareNet population. In addition, no extensive review of the outcomes of Toledo-Lucas County CareNet patients regarding diabetes has been performed.

Significance

The results of this study may be useful in assessing the effectiveness of the CareNet program. Positive outcomes can further assist such programs in obtaining additional funding for development and expansion. Less effective outcomes may be used to further evaluate and improve the program for their members. Additionally, timely achievement of treatment goals can lead to a reduction in health care expenditures.

Goal

The main goal of this research is to evaluate diabetes-related outcomes and determine factors related to goal attainment for patients enrolled in the Toledo-Lucas County CareNet program.

The specific study objectives are:

Research Objectives:

Research Objective 1:

- a. To determine the percentage of CareNet patients that have met ADA recommended guidelines for hemoglobin A1c.
- b. To determine the percentage of CareNet patients that have met ADA recommended guidelines for systolic blood pressure.
- c. To determine the percentage of CareNet patients that have met ADA recommended guidelines for diastolic blood pressure.
- d. To determine the percentage of CareNet patients that have met ADA recommended guidelines for high density lipoprotein (HDL).

- e. To determine the percentage of CareNet patients that have met ADA recommended guidelines for low density lipoprotein (LDL).

Research Objective 2:

- a. To explore factors related to goal attainment for CareNet patients diagnosed with type 2 diabetes. Factors studied are age, gender, and race/ethnicity, height, weight, BMI, tobacco use, pharmacotherapy use and number of primary care visits.

Research Questions:

- a. What percentage of CareNet patients who are diagnosed with type 2 diabetes have met ADA recommended guidelines for hemoglobin A1c value (less than 7%) from the initial reading to the final reading?
- b. What percentage of CareNet patients who are diagnosed with type 2 diabetes have met ADA recommended guidelines for systolic blood pressure value (less than 130 mm Hg) from the initial reading to the final reading?
- c. What percentage of CareNet patients who are diagnosed with type 2 diabetes have met ADA recommended guidelines for diastolic blood pressure value (less than 80 mm Hg) from the initial reading to the final reading?
- d. What percentage of CareNet patients who are diagnosed with type 2 diabetes have met ADA recommended guidelines for HDL value (greater than 40 mmol/l for men and greater than 50 mmol/l for women) from the initial reading to the final reading?
- e. What percentage of CareNet patients who are diagnosed with type 2 diabetes have met ADA recommended guidelines for LDL value (less than 100 mmol/l) from the initial reading to the final reading?

Research Question 2:

- a. Does change in A1c from initial to final value differ by age, gender, race/ethnicity, height, weight, BMI, tobacco use, pharmacotherapy use and number of primary care visits?
- b. Does change in systolic blood pressure from initial to final value differ by age, gender, race/ethnicity, height, weight, BMI, tobacco use, pharmacotherapy use and number of primary care visits?
- c. Does change in diastolic blood pressure from initial to final value differ by age, gender, race/ethnicity, height, weight, BMI, tobacco use, pharmacotherapy use and number of primary care visits?
- d. Does change in HDL from initial to final value differ by age, gender, race/ethnicity, height, weight, BMI, tobacco use, pharmacotherapy use and number of primary care visits?
- e. Does change in LDL from initial to final value differ by age, gender, race/ethnicity, height, weight, BMI, tobacco use, pharmacotherapy use and number of primary care visits?
- f. Is there a relationship between change in A1c (initial value to final value) and other variables (age, gender, race/ethnicity, height, weight, BMI, tobacco use, pharmacotherapy use and number of primary care visits)?
- g. Is there a relationship between change in systolic blood pressure (initial value to final value) and other variables (age, gender, race/ethnicity, height, weight, BMI, tobacco use, pharmacotherapy use and number of primary care visits)?

- h. Is there a relationship between change in diastolic blood pressure (initial value to final value) and other variables (age, gender, race/ethnicity, height, weight, BMI, tobacco use, pharmacotherapy use and number of primary care visits)?
- i. Is there a relationship between change in HDL (initial value to final value) and other variables (age, gender, race/ethnicity, height, weight, BMI, tobacco use, pharmacotherapy use and number of primary care visits)?
- j. Is there a relationship between change in LDL (initial value to final value) and other variables (age, gender, race/ethnicity, height, weight, BMI, tobacco use, pharmacotherapy use and number of primary care visits)?

Chapter Two

Literature review

This chapter includes a brief review of the literature and major topics related to this study. The topics covered are diabetes, the uninsured and diabetes, disparities in diabetes, safety nets and studies related to similar programs.

Diabetes

Diabetes mellitus is a well-known chronic metabolic disorder negatively affecting the population of the United States. A total of 23.6 million people or 7.8% of the U.S population have diabetes. Among adults, males accounted for 12 million and female accounted for 11.5 million cases of diabetes; moreover, in 2007 about 1.6 million new cases of diabetes were diagnosed in people aged 20 years or older.⁶ People in the United States with diabetes also face financial burden. For 2007, the overall anticipated cost of diabetes care was \$174 billion, of which \$116 billion was allocated to direct medical costs, and \$58 billion was allocated to indirect costs, such as disability, work loss, and

premature mortality.⁶ The American Diabetes Association (ADA) has classified diabetes into four clinical classes:

- Type 1 diabetes (which results from β -cell destruction, usually leading to absolute insulin deficiency)
- Type 2 diabetes (which results from a progressive insulin secretory defect on the background of insulin resistance)
- Other specific types of diabetes due to other causes, e.g., genetic defects in β -cell function, genetic defects in insulin action, diseases of the exocrine pancreas and drug-or chemical-induced (such as in the treatment of AIDS or after organ transplantation)
- Gestational diabetes mellitus (GDM) (diabetes diagnosed during pregnancy)

However, the most common among is type 2 diabetes. Adults diagnosed with Type 2 diabetes account for 90% to 95% of the cases. Type 2 diabetes results when insulin resistance and impaired beta cell function occur simultaneously. The phenomenon of insulin resistance occurs when the target tissues, muscle cells, the liver and the lipids do not respond to the normal concentration of circulating insulin. To maintain normal blood glucose levels, the beta cells secrete increased amounts of insulin, which results in an excess level of circulating insulin in the blood. However, over time, beta cells are unable to maintain a high level of insulin output, consequently leading to the development of Type 2 diabetes.³¹

Macrovascular complications in diabetes

There are many complications associated with diabetes leading to morbidity and mortality, for example, macrovascular complications. Risk of macrovascular

complications can be partially explained by the adverse effect of diabetes and insulin resistance on lipids. Low levels of high-density lipoprotein cholesterol (HDL-C), elevated triglycerides, and small, dense low-density lipoprotein (LDL) particles have been abnormalities linked with type 2 diabetes and insulin resistance. Notably, the presence of small, dense LDL particles, which are more readily oxidized, is associated with worsening cardiovascular outcomes.³²

The Multiple Risk Factor Intervention Trial (MRFIT)³³ looked at the relationship of total serum cholesterol to cardiovascular disease (CVD) mortality in men with and without diabetes. The study included more than 360,000 men, ranging from 35-55 years of age. The follow up continued for 12 years. Researchers found that death rates resulting from CVD increased from the lowest serum cholesterol (<180 mg/dL) to the highest (\geq 280 mg/Dl) for men with and without diabetes. Also, death rates due to CVD were several times higher in patients with diabetes than those without diabetes (Fig 2.1). Moreover, for both men with and without diabetic complications, serum cholesterol level, systolic blood pressure, and cigarette smoking were also significant predictors of CVD mortality.³³

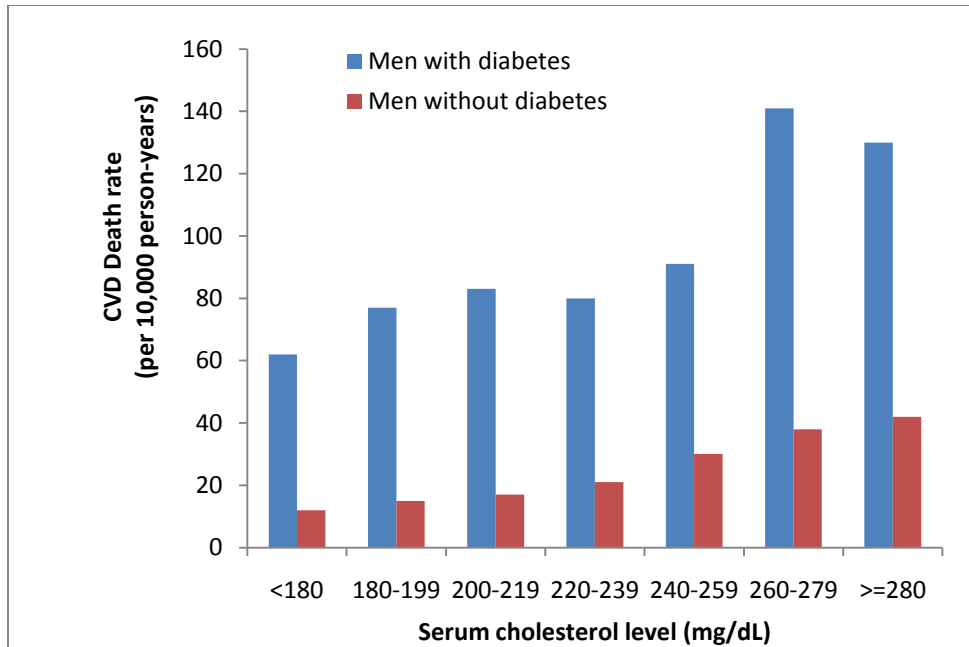


Figure 2.1: Cardiovascular mortality rate by total serum cholesterol level for men with and without diabetes in the Multiple Risk Factor Intervention Trial population.

A study by Kannel et al. examined the risk of cardiovascular disease among men and women with pre-disposed diabetes. They reported men with diabetes were 1.73 times more likely to have coronary heart disease (CHD), and 2.38 times more likely to die from it, when compared to men without diabetes. For women, the risk was even higher. Women with diabetes were 2.5 times more likely to have CHD and 3.6 times more likely to die from it.³⁴ Elevated lipid levels also contribute to macrovascular complication in those with diabetes. Uusitupa et al. conducted a prospective study over a 10-year period to observe cardiovascular morbidity and mortality in patients with newly diagnosed Type 2 diabetes and non-diabetic control subjects. They observed the effect of general risk factors, plasma insulin, urinary albumin excretion, lipoprotein abnormalities, and degree of hyperglycemia. The demographics characteristics obtained showed substantially higher rates of cardiovascular mortality in men and women with diabetes compared to

those without diabetes. Their analysis also revealed, age, LDL, triglycerides, smoking, and blood glucose had independent associations with cardiovascular mortality. The authors concluded that the indication of high LDL, triglycerides and/or other changes in lipoprotein composition, and consequences of long-term hyperglycaemia explained a higher chance of cardiovascular mortality risk among Type 2 diabetic patients.³⁵

Similarly, high blood pressure also has an impact on the development of cardiovascular disease in diabetes patients. Adler et al. conducted a study to evaluate the relationship between systolic blood pressure over time and the development of macrovascular and microvascular complications using the data from the UKPDS trial. The results of this prospective observational study revealed the risk of macrovascular and microvascular complications of type 2 diabetes was strongly associated with mean systolic blood pressure. For systolic blood pressure in the range of <120 mm Hg to \geq 160 mm Hg, there was found to be an increased incidence rate of myocardial infarction compared to microvascular complications. In addition, on average, every 10mm Hg reduction in systolic blood pressure was associated with reductions in the risk of complications related to diabetes by 12%, deaths related to diabetes by 15%, and microvascular complications by 13%. No threshold of risk was observed for any studied end points.³⁶

Likewise, a cohort-based study in a primary care setting investigated the relationship between glycemia and survival in patients who had been diagnosed with the disease for a longer periods of time. The participants were categorized into two groups, a younger-onset diabetic group (condition diagnosed younger than 30 or older) and an older-onset diabetic group (condition diagnosed when 30 years or older). Both groups

were followed for 8.3 years, and in both groups for younger-onset, and for older-onset, higher HbA1c was statistically significantly associated with mortality from diabetes.³⁷

Studies Related to Diabetes Treatment

Although diabetes cannot be cured completely, several studies show that diabetes can be managed and treated effectively. A study conducted by Stratton et al. determined the relationship between exposure to glycemia over time and the risk of macrovascular and microvascular complications in type 2 diabetes. A total of 3542 patients, from the UKPDS study were included in the analysis of relative risk. Their primary outcome was a collection of clinical values including endpoint or death related to diabetes. Secondary outcomes included myocardial infarction, stroke, amputation, and microvascular disease. The results revealed that any increase in the incidence rate for microvascular end points was greater with increasing glycemia, as compared to the increase in the incidence rate for myocardial infarction. At near normal concentrations of mean HbA1c, the risk of myocardial infarction was twice to three times that of a microvascular end point, and in the highest category of HbA1c concentration ($\geq 10\%$) the risks of myocardial infarction were also similar. In addition, mortality related to diabetes and all cause mortality were strongly associated with glycemia ($P < .0001$). Reduction in risk was associated with glycemic control. Each 1% reduction in updated mean HbA1c over 10 years was associated with a risk reduction of 21% for endpoints related to diabetes.³⁸

The Scandinavian Simvastatin survival study (4S) was designed to evaluate the effect of cholesterol lowering with simvastatin on mortality and morbidity in patients with coronary heart disease (CHD). A total of 4,444 patients were randomized to double-blind treatment with simvastatin or placebo. The study demonstrated that over the 5.4

years for median follow up, simvastatin had mean changes in total cholesterol lowered by 25%, low-density-lipoprotein cholesterol was lowered by 35%, and high-density-lipoprotein cholesterol was raised by 8%. Overall the study found that simvastatin treatment significantly reduced CHD morbidity and mortality compared to placebo.³⁹

Similarly, Pyorala et al. carried out a post hoc subgroup analysis on data from 202 diabetic patients and 4242 non-diabetic patients who previously had myocardial infarction or angina pectoris. Participants in the 4S were randomly assigned to double blind treatment with simvastatin 20mg day - 40mg day for 6-18 weeks. Over the 5.4-year median follow-up period, simvastatin treatment produced mean changes in serum lipids in diabetic patients similar to those observed in non-diabetic patients. The probability of not having a major CHD event within 6 years was 75.1% in patients with diabetes who were treated with simvastatin vs. 50.7% in the placebo group (P = .002). In patients without diabetes, the probability was 79.8% in those treated with simvastatin vs. 71.3% in the placebo group (P=.0001). The results strongly suggest that cholesterol lowering with simvastatin improves the prognosis of diabetic patients with CHD. The clinical benefit achieved by cholesterol lowering may be greater in diabetic patients than in those without the disease because of the greater absolute risk of CVD.⁴⁰

The Veteran Affairs HDL International Trail (VA-HIT) was the first large scale randomized double-blind trial to examine the role of therapy in raising low levels of HDL cholesterol and its impact on long-term support for cardiovascular benefits. The trial enrolled 2,531 men who had cardiovascular heart disease (CHD) and other lipoprotein complications. Approximately 25% of enrolled patients had a history of diabetes; subjects were either on gemfibrozil or placebo. After one year of therapy, significant

changes was observed in the levels of HDL cholesterol (6% increase), triglycerides (31% decrease), and total cholesterol (4% decrease); however, LDL cholesterol levels did not differ significantly between gemfibrozil and placebo. There was a 22% reduction in death or nonfatal myocardial infarction in the treatment group. In addition, VA-HIT was the first trial to reveal that higher HDL levels are associated with lower CHD risks.⁴¹

Holman et al. conducted a 10-year post intervention trial of newly diagnosed type 2 diabetes patients enrolled in the United Kingdom Prospective Diabetes Study.⁴² They compared results of patients on intensive therapy vs. conventional therapy (diet). The intensive therapy group was further classified into a sulfonylurea-insulin group and a metformin group. The results showed a decrease in micro-vascular complications and other diabetes related complications in the sulfonylurea-insulin group. In the metformin group, reduction in diabetes related complications and reduction in heart complications and death were also observed.⁴²

The ADVANCE trial randomly assigned a total of 11,140 type 2 diabetes patients to either an intensive therapy group (gliclazide) or to treatment with other diabetes medications. Researchers found that the intensive therapy group had an average HbA1c of 6.5%. The intensive group showed a reduced risk of macrovascular and microvascular complications of 10% compared to 21% in the control group. Therefore, intensive therapy was found to be the most effective option.⁴³

Diabetes Self-management

According to national guidelines, diabetes self-management (DSME) should be part of care for patients diagnosed with diabetes and thereafter as needed. Norris et al. conducted a meta analysis to evaluate the efficacy of DSME on A1c in adults with type 2

diabetes. They examined a total of 31 randomized control trial studies. Their findings show that, on average, the patients in the intervention groups had decreased HbA1c by 0.76% (95% CI 0.31-1.8) more than the control groups at the follow-up visit. Also, studies with intervention groups showed decreased HbA1c at one to three months and at ≥ 4 months of follow up; however, the effect diminished for long term follow up. Moreover, additional contact time between participants and educators also led to decreases in HbA1c levels. The meta analysis showed that every additional 23.6 hours of contact was associated with a 1% decrease in A1c.⁴⁴

Similarly, a study conducted by Waris et al. looked at evaluating the efficacy of patient self-managed education programs for chronic disease and reviewed the methodologies of the selected studies. Researchers selected 71 studies for this meta analysis. They found that studies involving diabetes patients in self-management education programs demonstrated reductions in HbA1c, and systolic blood pressure. The study indicated small benefit from self-management education programs for chronic conditions.⁴⁵

Diabetes is associated with several complications. Treatment from self-management and through medications such as metformin, sulfonylurea, insulin and other cholesterol lowering drugs can reduce the risk of morbidity and mortality in patients with diabetes. However, lack of insurance can be a barrier to access diabetes treatment.

The Uninsured and diabetes

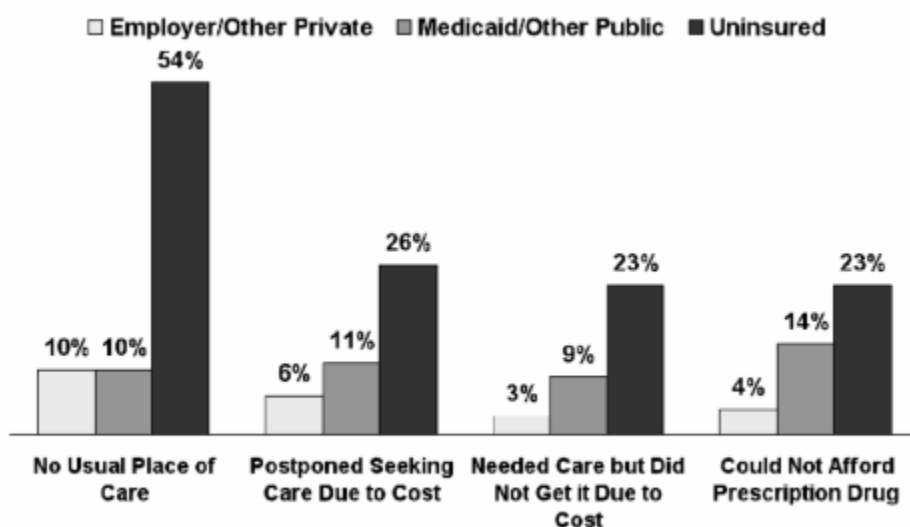
According to the Center for Disease Control and Prevention (CDC) *uninsured* is defined as

“ A person who did not have any private health insurance, Medicare, Medicaid, State Children's Health Insurance Program (SCHIP), state-sponsored or other

government-sponsored health plan, or military plan. A person was also defined as uninsured if he or she had only Indian Health Service coverage or had only a private plan that paid for one type of service such as accidents or dental care.”⁴⁶

Sky rocketing diabetes costs and lack of health insurance coverage is a large and growing problem for millions of American families. Approximately, 46 million people in the United States are living without health insurance. It is estimated that the inability to have access to health insurance is higher among people with lower incomes.² Low-paying jobs are less likely to offer health insurance as a benefit and the cost of health insurance leaves poorer individuals less likely to be able to afford it. Due to this reason, uninsured individuals often face difficulty in obtaining care for illness or injuries and as a consequence avoid non-urgent care. For instance, 2007 national health statistics show that about 54% of uninsured adults have no usual source of care compared to 10 percent of those with other types of coverage. Additionally, twenty six percent of uninsured adults said that they have postponed seeking care in the past year because of its cost, compared to about 6 percent of privately insured adults (Figure 2.2).⁴⁷

Barriers to Health Care Among Nonelderly Adults, by Health Insurance Status, 2006



Respondents who said usual source of care was the emergency room were included among those not having a usual source of care.
SOURCE: National Center for Health Statistics, Summary of Health Statistics for U.S. Adults: NHIS, 2006, CDC, 2007.

Figure 2.2: Barriers to Health Care among Nonelderly, Adults, by Health Insurance Status, 2006

Moreover, a study by Tu and Cohen, demonstrated overwhelming growth in the financial and health burden of chronic illness in both uninsured as well as privately insured patients. The key finding showed 51% or 5 million uninsured have reported being in fair or poor health compared to 29% of the privately insured. They also observed that many uninsured patients do not qualify for government options because of stringent requirements.⁴⁸

Inability to afford health insurance may delay the chances of detecting any illness or chronic conditions at an early stage.²⁶ Chronic diseases such as diabetes, hypertension, and cardiovascular complications are found to be common among the uninsured population. For example, Wilper et al. in their national study of Chronic Disease Prevalence and Access to Care in Uninsured U.S. Adults, observed that nearly one third (i.e., 11.4 million) of the uninsured adult population had at least one chronic condition. They estimated that 1.4 million of these patients have diabetes.²⁷ The Wilper study also

demonstrated that newly diagnosed uninsured individuals with a chronic condition had significantly fewer office-based visits and prescription medications, but significantly higher emergency room visits.⁴⁹

A study conducted by Cunningham demonstrated that many Americans face out-of-pocket health care expenses. The researcher used the Medical Expenditure Panel survey data for 2001-2005 and found that 39% of nonelderly adults with three or more chronic conditions had out-of-pocket expenses that exceeded 5% of income for two consecutive years.⁵⁰ Among low-income adults with two or more chronic conditions, 45% spent 5% of their income on out-of-pocket costs; additionally, 27% had persistently high financial burden accounting for 10% of their income.⁵⁰ Another study indicated the out-of-pocket spending among chronically ill patients increased by 45% over a ten-year period.⁵¹ Thus, the presence of co-morbidity increases the health care cost dramatically for chronically ill patients.

Comparing patients with no insurance, Medicaid, and private insurance, a study conducted by Hoffman and colleagues found worsening conditions in access and affordability of care in non-elderly adults with chronic conditions in the uninsured group. Examining data from the National Health Interview Survey (from 1997-2006), they determined that access to care in the uninsured group had deteriorated over time. About 34.4% of the uninsured group with chronic conditions did not have usual access to care compared to 5% in the insured group (4.7% private, and 5% for Medicaid). In addition, going without needed medical care due to cost was found to be four times higher in uninsured patients compared to insured. Further, lack of affordability of prescription drugs due to cost was found to be more likely in uninsured patients.⁵²

Likewise, Bowker et al. in a cross sectional study, reported patients without health insurance for self-monitoring supplies had poorer glycemic control. They observed that the mean difference in A1c values was 0.5% lower among the insured group compared to the uninsured group.⁵³

Providing health insurance to uninsured individuals may positively affect their health. In fact, literature shows having insurance improves health for previously uninsured individuals. A quasi-experimental longitudinal study conducted by McWilliams and colleagues looked at health effects of insurance coverage on previously uninsured individuals. They analyzed data from using the Health and Retirement Study, a nationally representative longitudinal study. The results show that having insurance improved health status for previously uninsured individuals, once they became eligible for Medicare. Researchers compared health trends among previously insured adults with previously uninsured adults for age 65 or older. They found that previously uninsured individuals with cardiovascular disease or diabetes reported significant improvement in summary health (differential change in annual trend, change in general health, mobility, agility, and adverse cardiovascular outcomes). By age 70, the expected difference in summary health between previously uninsured and insured adults with CVD or diabetes was reduced by 50%. They also found previously uninsured adults without CVD or diabetes had differential improvement in depressive symptoms but not in summary health or any other measure.⁵⁴

Disparities in diabetes

Evaluating health care disparities is an integral part of improving health care quality. The National Healthcare Quality Report (NHQR), and the National Healthcare

Disparities Report (NHDR) shows, Americans too often do not receive care that they need or they receive harmful care. In some instances, American receive suboptimal care compared to other nations. The NHDR AND NHQR both categorize quality of care into four dimensions: effectiveness, patient safety, timeliness, and patient centeredness. The 2008 NHDR reported disparities persist in health care quality and access. The findings on the measures of quality (the percentage of patients with a disease or condition who get recommended care) and access to care were lacking in all populations studied. For at least 60% of African Americans, Asians, American Indians/Alaska Natives (AI/ANs), Hispanics, and poor people, measures of quality of care either stayed the same or worsened. In addition, despite many Americans with access to primary and hospital care, barriers to getting health insurance or having trouble getting doctor's appointments exists.⁵⁵

The report also indentified that African Americans and Hispanics have gaps in diabetes related quality of health care compared to their white counter parts. From 2002 to 2005, they showed that the gap remained the same for three recommended services (HbA1c testing, retinal eye examination, and foot examination) between African American and White adults age 40 and over. However, a significant increase in the gap was found between Hispanics (33.8%) and non-Hispanic Whites (42.4%). Moreover, when comparing gaps in quality of care between poor, middle and high-income people, the gap was significantly lower for poor (30.3%), near-poor (28.5%), and middle-income people (38.4%) than for high-income people (52.6%). Further, the percentage of adults age 40 and over with diabetes who received three recommended services was lower for

people with less than a high school education (31.5%) and high school graduates (39.9%) than for people with at least some college education (47.7%).⁵⁶

The report also demonstrated that between 2003-2006, only 54.6% of adults with diagnosed diabetes had their HbA1c under optimal control. An increased gap was found between African Americans, Mexican Americans and Whites. The rate was significantly lower for African Americans (43.0%) and Mexican American, (37.6%) compared to Whites (60.5%).⁵⁷

Similarly, other studies also show that African Americans and Hispanics have poorly controlled HbA1c, compared to whites. For example, Boltri et al. determined the association between HbA1c and race/ethnicity in diagnosed and undiagnosed diabetes patients using the 1999-2000 National Examination Survey (NHANES). Four hundred ninety five subjects were identified as having diabetes, of these 292 (79.2%) were diagnosed with diabetes and 103 (20.8%) were undiagnosed. Researchers observed that Whites adults were older, had higher education and higher income. African Americans were more likely to be female and reported higher BMI. And more Hispanics had lower income, lower education and lower BMI. All participants had BMI levels in the obese range ($BMI \geq 30$). The study demonstrated fasting plasma glucose was lower in Whites (157 mg/dL, SE .17) and higher in African Americans (182 mg/Dl, SE .17). However, A1c values were found to be higher in Hispanics (8.2%, SE .3) than in Whites (7.6%, SE .2). The percentage of diagnosed persons with diabetes with HbA1c level $\geq 11\%$ for African Americans, Hispanic and Whites was 11.1%, 10.4% and 1.7% respectively. Whereas, the percentage of undiagnosed persons with diabetes with HbA1c level $\geq 7\%$ for African Americans, Hispanic and Whites was 39.3%, 60.5% and 37.8% respectively.⁵⁸

Gray et al. conducted a cross sectional study to assess the quality of diabetes care and intermediate clinical outcomes within a multiethnic population (African Americans, South Asian and white). The results of clinical outcomes showed that African Americans and south Asians groups were significantly less likely to meet treatment targets for blood pressure, HbA1c, and cholesterol, than the white groups. In addition, they found that African Americans had significantly poorer blood pressure and HbA1c control than the white group. The south Asian group had significantly poorer HbA1c control, but better cholesterol control than the white group.⁵⁹

The racial/ethnic disparity further persists between Hispanic and non-Hispanic whites. In a meta-analysis conducted by Kirk et al. data was collected on sample size, age, sex, A1C, geographical location, and study design. They included cross-sectional data and baseline data from clinical trials and cohort studies for Hispanics and non-Hispanic whites with diabetes. They excluded those studies that reported individuals <18 years of age or patients with pre-diabetes or gestational diabetes. They found that 73 out of the 495 studies had recorded A1c measures for Hispanics and non-Hispanic whites. In the final analysis, 11 combined studies revealed statistical significance in A1c between the two groups.⁶⁰

Missing medication doses and depression are also found to be more strongly associated with poor diabetes control among African Americans than in whites. Duru et al. conducted a case control study of patients with diabetes. They used data from the Translating Research into Action for Diabetes (TRIAD) survey. They observed whether modifiable risk factors were strongly associated with poor control of multiple intermediate outcomes among African Americans with diabetes than among whites with

diabetes. From the 764 patients that were selected, 56% of African Americans, and 34% of whites that had poor control. African Americans were more likely to have depression and to have missed a medication dose than whites.⁶¹

The literature also shows patients with chronic conditions have disparities in regard to income level,²⁹ race/ethnicity status,³⁰ and age.⁶² A recent study performed by Gregg et al. found that gaps were persistent among patients who were younger, healthier, had low income, had fewer years of diabetes, and relied on diet only to control their diabetes.²⁹ Selby et al. also found poorer control of diabetes was associated with being younger, female, African American and unmarried. Lower socioeconomic status, measured by education and household income was also strongly associated with poorer control of diabetes.⁶²

Similarly, Levene et al. conducted a study on racial/ethnic differences in self-monitoring blood glucose (SMBG). They assessed differences in SMBG based on income level, using the Behavioral Risk Factor Surveillance System data from 2000-2004. They found that Hispanics and African Americans were less likely to perform SMBG compared to whites. In addition, in the income level <\$20,000, Hispanics performed SMBG substantially less than African Americans.⁶³

Alternatively, one study reported contradictory evidence of racial/ethnic disparities in diabetes care. In a longitudinal observational study conducted by Karter and colleagues, a total of 62,432 diabetic patients were included, where 12% were Asians, 14% were African Americans, 10% were Latinos, and 64% were whites. All patients had uniform health care coverage. Their results revealed that Asians and Latinos had

significantly lower cardiovascular disease rates. They also found that African Americans had a significantly lower incidence rate of heart complications than whites.⁶⁴

The prevalence of diabetes, the growing number of uninsured and increase in health disparities may draw attention towards safety net health systems, who can provide cost-effective, sustainable services to uninsured patients suffering from diabetes.

SafetyNet in diabetes

The first objective of Healthy people 2020 is to “increase the proportion of persons with health insurance.”⁶⁵ Following this objective, health care safety nets play a critical role in providing access to care to uninsured citizens. Although there is no consistent definition of safety net, the Institute of Medicine explains a health care safety net as a concept that “conjures up the image of a tightly woven fabric of federal, state, and local programs stretched across the nation ready to catch those who slip through the health insurance system.”⁶⁶ In an article, Redlener and Grant also define safety net as a program that ensures “regardless of social or economic conditions, no citizen’s access to essential services falls below a certain level.”⁶⁷ Thus, a safety net health system is a net of organizations that helps vulnerable populations of the nation’s poor, uninsured individuals or most disadvantaged groups, by providing access to health care.

Safety nets in the United States are neither secure nor uniform. Depending upon the number of uninsured, the local health care market and other circumstances, safety nets differ from state to state, and community to community. Safety net providers are a combination of community health centers (CHC), public hospitals, clinics, or health systems.⁶⁶

Similarly, CareNet is a kind of safety net program in the Toledo Lucas County area. With a purpose to provide healthcare access to low-income residents of Toledo-Lucas County who are uninsured and do not qualify for government provided healthcare, since its inception, CareNet has connected more than 16,000 uninsured, low-income residents to medical homes and vital medical care. Currently, CareNet has about 5000 active members and includes 15 primary care sites, 8 hospitals and 150 volunteer specialists. CareNet provides healthcare services to its registered members, those who meet eligibility requirements, on a sliding fee scale. Through the CareNet passport, an identification card, CareNet members can access services such as primary, emergency, outpatient, inpatient and specialty care; as well as city bus transportation for medical visits. In 2008, CareNet provided services to over 6,400 Lucas County residents, each with an income of 200% or less of federal poverty guidelines and with no access to any other health insurance.¹

Studies related to CareNet

Research shows that the uninsured low-income population is more likely to rely on a health care safety net. Forrest and Whelan reported that uninsured persons or those with Medicaid are most likely to visit a patchwork of community health centers, hospital outpatient departments and physicians for primary care. This study used three nationally representative surveys, The National Ambulatory Medical Care Survey (NAMCS), The National Hospital Ambulatory Medical Care Survey (NHAMCS), and the Bureau of Primary Health Care's 1994 Survey of Visits to Community Health Centers. They contrast primary care visits made to community health centers, physicians' offices, and hospital outpatient departments. They found 65.4% of primary care visits were made to

community health centers, 43.0% to hospital outpatient departments, and 18.5% to physicians' offices.^{67, 68}

Safety net programs comparable to CareNet may improve health outcomes for uninsured minorities. For example, Philis-Tsimikas et al. looked at the impact of a community based program called The Project Dulce diabetes case management program. The program enrolled low-income uninsured diabetes patients, who were managed by nurse and peer educators. The results of this prospective longitudinal study revealed that after one year in Project Dulce, diabetes patients had significant improvements in HbA1c, total cholesterol, LDL cholesterol, and diastolic blood pressure, which were significantly better than in the control group.⁶⁹

A study by Gilmer et al. evaluated the cost-effectiveness of Project Dulce by comparing four cohorts: those that were uninsured, those that were covered by County Medical Services, those covered by Medi-Cal coverage (California's Medicaid Program), and those with private insurance. This was a simulation study, in which researchers found that diabetes case management may be cost-effective and also projected clinical outcomes among all four cohorts can improve. However, the greatest improvement was projected for the uninsured cohort. The age difference was also found to be lower in the uninsured group, indicating early preventive measures can be beneficial in the long run.⁷⁰

It has been shown that safety nets are committed to providing care to minority populations, but may also represent one approach to reducing disparities. Eisert et al. showed the impact of safety net organizations. The analysis of this retrospective longitudinal study was conducted under Denver Health, an urban safety net serving 150,000 patients annually. From ten Denver health associated community health centers,

medical charts were randomly selected for 4795 patients between 1999-2001 and were reviewed. HbA1c measurement had been obtained in the last 12 months for 77% of the study patients, and for 70% of African Americans and Hispanic patients. The results indicated the quality of care exceeded the benchmark and no inequalities in care were found.⁷¹

Research also shows, however, that not all uninsured healthcare needs are being met by safety net. A study by Becker indicated that safety nets are inadequate to provide care to uninsured adults. Findings were based on interviews of 176 uninsured people with chronic illness. Major findings revealed that individuals delay health care because of the cost. In addition, they are often under medicated. Moreover, patients reported more negative experiences with safety net health care compared to private health care. Furthermore, patients also felt discriminated against because of being uninsured. These experiences resulted, for some, in feelings of alienation and avoidance of the health care system.⁷²

A study conducted by Dalton et al. examined how the safety net in Michigan responded to the health care needs of their uninsured population with diabetes and/or mental illness. In a multiple-site case study design, data was collected through interviews of key informants in five Michigan community sites. Patterns and themes were identified, and compared across communities and by organizational type. Their findings showed safety nets were managing to meet the needs of uninsured diabetics but were having great difficulty caring for the uninsured with mental illness. In terms of specialty care, ophthalmology, podiatry, endocrinology, and nephrology for diabetes was obtainable, but referrals for such care were found to rely on a loose network of volunteer physicians and

dependent on the area's clinical directors' ability to encourage area physicians to help. Formal affiliation of clinics with health systems was also found to be the key to easier access to specialist care. On the other hand, mental health services for uninsured patients are severely limited. Very few providers were willing to provide uncompensated mental health care services. The authors concluded that the safety net for Michigan's uninsured population with diabetes and mental illness is weak. Additionally, processes including referrals and care coordination are of poor quality in some communities.⁷³

Thus, safety nets are an important part of the health care system that helps, especially low-income uninsured patients, to have access to care. Studies have shown the effectiveness of safety net programs in diabetes care, and others have shown the need for improvement in safety net care.

Chapter Three

Methods

This chapter describes the methodology used in the study. The method is broken down in to the following topics: study design, data source, study time period, inclusion and exclusion criteria, independent and dependent variable, and data analysis. The methodology stems from the research questions mentioned in Chapter One.

Study Design

The study desing was a longitudinal retrospective chart review. The charts of diabetes patients who were active members of CareNet from January 1, 2003 to December 12, 2008 were reviewed.

Data Source

Patients' charts from Mercy Health Partners, ProMedica, and the Toledo/Lucas County Health Department, were used as the data source. Formal approval from IRB was obtained from The University of Toledo, Mercy Health Partners and ProMedica. No such formal approval process exists for Toledo-Lucas County Health Department.

Data Collection

Data was collected from January 2010 through June 2010. All data was collected in a standard data collection form (Appendix A) by the researcher. Collected data was input into an Excel spreadsheet by the researcher. Patients' charts for those patients who were enrolled for minimum 12 calendar months were reviewed.

Inclusion and Exclusion criteria

To have been included in the study, patients had to be age 18 or older, receiving treatment for a minimum of one calendar year, and diagnosed with Type 2 diabetes. Pregnant females with gestational diabetes, children, and patients with Type 1 diabetes were excluded.

Independent variables

The individual variables included in the study were: Age (continuous variable), Gender (categorical variable), Ethnicity/Race (categorical variable), date of enrollment in CareNet (continuous variable), Height (continuous variable), Weight (continuous variable), Tobacco Use (categorical variable), pharmacotherapy treatment (categorical variable), and the number of Primary care visits within the last 12 months (categorical variable).

Dependent Variable

Hemoglobin A1C (continuous variable), systolic and diastolic blood pressure values (continuous variable), LDL levels(continuous variable), and HDL levels (continuous variable), were the primary measures to determine improvement in diabetes status.

Data Analysis

To determine the number of patients that reached ADA recommended guidelines for A1c, descriptive statistics (mean, median, standard deviation, and proportion) were used. To examine the relationship between A1c and other independent variables, regression analyses were used. To determine the differences between A1c and other independent variables, t-test and ANOVA were used. All analyses were conducted in SPSS version 17.

Chapter Four

Results

This chapter describes the results obtained in the study. The results section is broken down into Data screening, Descriptive results, Analysis of variance results, and Regression results, for each respective clinical marker. The descriptive results will correspond to Research Objective One. Exploring differences using Analysis of variance results will correspond to Research Objective Two, and exploring relationships using regression results will also correspond to Research Objective Two.

Data Screening

To check for normality assumption, skewness and kurtosis for changes in each clinical variable (A1c, SBP, DBP, HDL and LDL) was obtained using SPSS. If the skewness and kurtosis values were between ± 1 , data was considered normally distributed. If that was not the case, data was further screening for univariate outliers. To do this, a standardized z-scores were obtained using the descriptive option in SPSS. Those cases with standardized z-score exceeding ± 2.5 were manually eliminated. This decision was

concurrent with Meyers and colleagues' suggestion.⁷⁴ After correction, skewness and kurtosis were obtained again to examine normality

Study population

A total of 179 patients out of 712 charts reviewed from the three health centers met the inclusion criteria for data analysis. Distribution by the three health center was as follows: 61 cases were from the Mercy system, 58 cases were from ProMedica, and 60 cases were from the Toledo/Lucas County Health Department. Descriptive results for the demographic characteristics of this population are presented in Tables 4.1a-4.1d below:

Table 4.1a Demographic characteristic RACE/Ethnicity

Independent variable	Number of Cases	Percentage %
RACE (N=151)	n	of N
African American	72	48%
White	56	37%
Asian	11	7%
Hispanics	12	8%

Table 4.1b Demographic characteristic (Weight)

Independent variable Weight (N=147)	Number of Cases	Percentage % of N
130-160lbs	12	8%
161-190lbs	12	8%
191-220lbs	28	19%
221-250lbs	28	19%
251-280lbs	32	22%
281-310lbs	14	9.5%
311-340lbs	12	8%
341-370lbs	2	1.4%
371-400lbs	7	5%

Table 4.1c Demographic characteristic (BMI)

Independent variable BMI (N=89)	Number of Cases	Percentage % of N
Underweight = <18.5	2	2.2%
Normal weight = 18.5–24.9	12	14%
Overweight = 25–29.9	11	12%
Obesity = BMI of 30 or greater	64	79%

Table 4.1d Demographic characteristic (Number of Visits)

Independent variable	Number	Percentage % of
Number of Visits (N=171)	of Cases	N
1-3 visits	42	25%
4-6 visits	43	25%
7-9 visits	28	16.4%
10-12 visits	27	16%
13-15 visits	11	6.4%
16-18 visits	7	4.1%
19-21 visits	4	2.33%
22-24 visits	3	1.8%
25-27 visits	3	1.8%
28-30 visits	3	1.8%

A subgroup analysis for each independent variable is discussed individually below: Age was coded as a dichotomous variable (0 as less than or equal to forty years old and 1 as greater than forty years old). This distinction is important for clinical significance because cardiovascular risk increases after age forty⁷. In the study population 70% of patients were older than 40. Gender was coded as dichotomous variable (0 for female, and 1 for male). In the study 57% (96) of patients were female. Race was coded as a categorical variable (1 for Alaskan Native, 2 as American Indian, 3 as Asian, 4 as African Americans, 5 as Pacific Islander, 6 as White, 7 as Hispanic and 8 as others). Body Mass Index (BMI) was coded as categorical variable according to the criteria set by the National Heart Lung and Blood Institute.⁷⁵ (1 as underweight, 2 as

normal weight, 3 as overweight, and 4 as obese). Weight was coded categorically at thirty pound increments difference. Tobacco use was coded as a dichotomous variable (0 for no tobacco use and 1 for tobacco use). Slightly more than 50% (56) of the sample were tobacco users. Pharmacotherapy use was also coded as dichotomous variable (0 for diabetes medications use only, 1 for both diabetes and hypertension medication). In this population, 40% (68) of patients were only on diabetes medications, and 60% (102) of patients were on both hypertension and diabetes medication. The number of visits was coded as a categorical variable, 1 as 1-3 visits, 2 as 4-6 visits, 3 as 7-9 visits, 4 as 10-12 visits, 5 as 13-15 visits, 6 as 16-18 visits, 7 as 19-21 visits, 8 as 22-24 visits, 9 as 25-27 visits and 10 as 28-30 visits.

Descriptive Results

Goal attainment in A1c:

As shown in the Figure 4.1 below, A1c values were available for 164 patients. In twenty-three cases, either the beginning or ending A1c value was missing. Therefore the number of cases used in the analysis was 141. A1c data was further classified into two groups: 1) those with an initial A1c <7 and, 2) those with an initial A1c \geq 7. The number of patients whose initial A1c level was less than seven were fifty-four. Of those patients with an initial A1c <7, upon review of their last recorded A1c value, 42 patients improved or remained the same. Four patients' A1c value worsened but they were still within goal. Eight patients' A1c value increased to below goal.

Eighty seven patients had an initial A1c \geq 7. Of those patients with an initial A1c \geq 7, upon review of their last recorded A1c value, 42 patients improved to goal. Twenty-two patients' A1c value improved but stayed below goal. Twenty-three patients'

A1c value either increased to below goal or stayed below goal. Overall, 62% of the sample met the ADA recommended A1c goal at the last recorded reading.

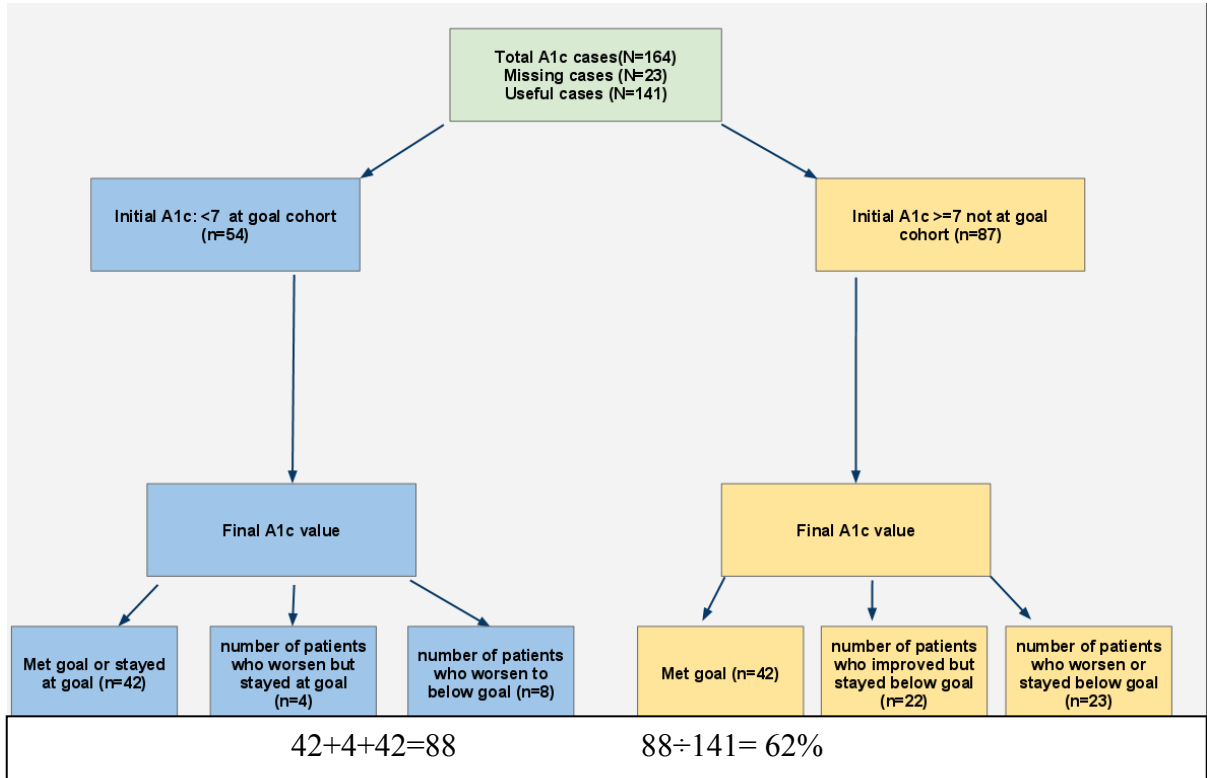


Figure 4.1 Flow chart showing goal attainment in A1c

Goal attainment in Systolic Blood Pressure:

As shown in the Figure 4.2 below, systolic blood pressure values were available for 179 patients. In nine cases, either the beginning or ending systolic blood pressure value was missing. Therefore the number of cases used in the analysis was 170. Systolic blood pressure data was further classified into two groups: 1) those with an initial systolic blood pressure < 130, and 2) those with an initial systolic blood pressure ≥ 130 . The number of patients whose initial systolic blood pressure level was <130 was forty-four. Of those patients with an initial systolic blood pressure <130, upon review of their last

recorded systolic blood pressure value, 36 patients improved or remained the same. Four patients' systolic blood pressure value worsened but they were still within goal. Four patients' systolic blood pressure value increased to below goal.

One hundred twenty six patients had an initial systolic blood pressure ≥ 130 . Of those patients with an initial systolic blood pressure ≥ 130 , upon review of their last recorded systolic blood pressure value, 62 patients improved to at goal. Twenty-two patients' systolic blood pressure value improved but did not reach goal. Forty-two patients' systolic blood pressure value either increased to below goal or did not reach goal. Overall, 60% of the sample met ADA recommended systolic blood pressure goal at the last recorded reading.

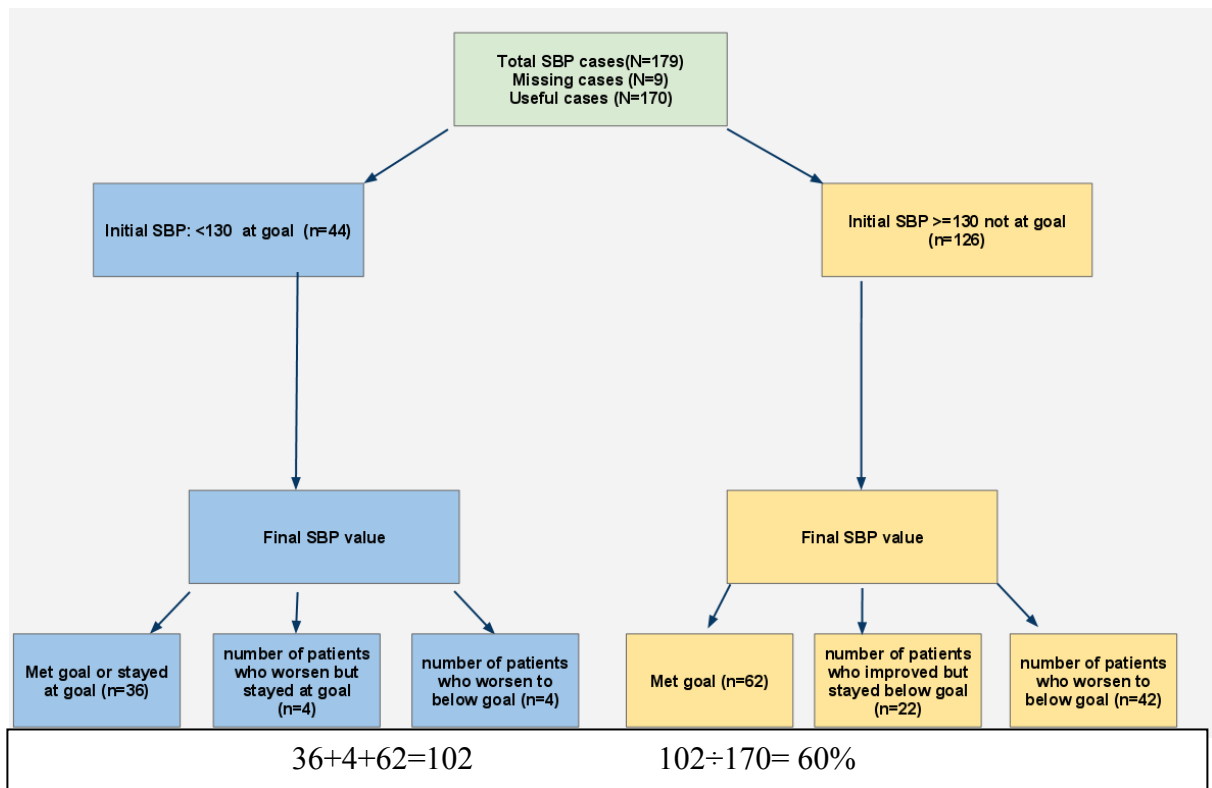


Figure 4.2 Flow chart showing goal attainment in SBP

Goal attainment in Diastolic Blood Pressure:

As shown in the Figure 4.3 below, diastolic blood pressure values were available for 175 patients. In eight cases, either the beginning or ending diastolic blood pressure value was missing. Therefore the number of cases used in the analysis was 167. Diastolic blood pressure data was further classified into two groups: 1) those with an initial diastolic blood pressure <80 , and 2) those with an initial diastolic blood pressure ≥ 80 . The number of patients who's initial diastolic blood pressure level was <80 was forty-six. Of those patients with an initial diastolic blood pressure <80 , upon review of their last recorded diastolic blood pressure value, 22 patients improved or remained the same. Eight patients' diastolic blood pressure value worsened but they were still within goal. Sixteen patients' diastolic blood pressure value increased to below goal.

One hundred twenty one patients had an initial diastolic blood pressure ≥ 80 . Of those patients with an initial diastolic blood pressure ≥ 80 , upon review of their last recorded diastolic blood pressure value, 56 patients improved to at goal. Seventeen patients' diastolic blood pressure value improved but did not reach goal. Forty-eight patients' diastolic blood pressure value either increased to below goal or did not reach goal. Overall, 51% of the sample met ADA recommended diastolic blood pressure goal at the last recorded reading.

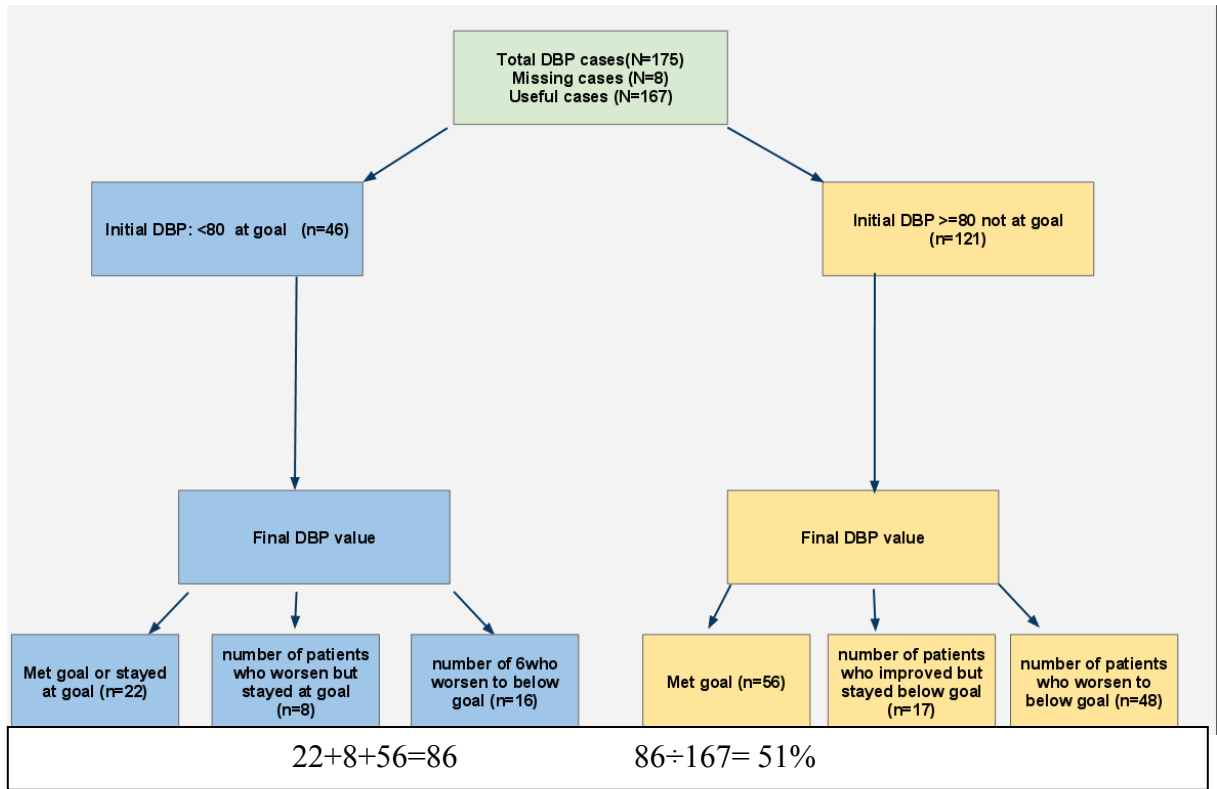


Figure 4.3 Flow chart showing goal attainment in DBP

Goal attainment in HDL for female subjects:

As shown in the Figure 4.4 below, HDL values were available for 91 female patients. In 33 cases, either the beginning or ending HDL value was missing for females. Therefore the number of cases used in the analysis was 58. HDL values for females were further classified into two groups: 1) those with an initial HDL value >50 , and 2) those with an initial HDL value ≤ 50 . The number of female patients who's initial HDL level was >50 was ten (n=10). Of those patients with an HDL value >50 , upon review of their last recorded HDL value, 7 patients improved or remained the same. Three patients' HDL value worsened but they were still within goal. None of the patients' HDL value decreased to below goal.

Forty-eight female patients had an initial HDL value ≤ 50 . Of those patients with an initial HDL value ≤ 50 , upon review of their last recorded HDL value, 13 patients improved to at goal. Ten female patients' HDL value improved but did not reach goal. Twenty-five female patients' HDL value either increased to below goal or did not reach goal. Overall, 40% of the female sample met ADA recommended HDL goal at the last recorded reading.

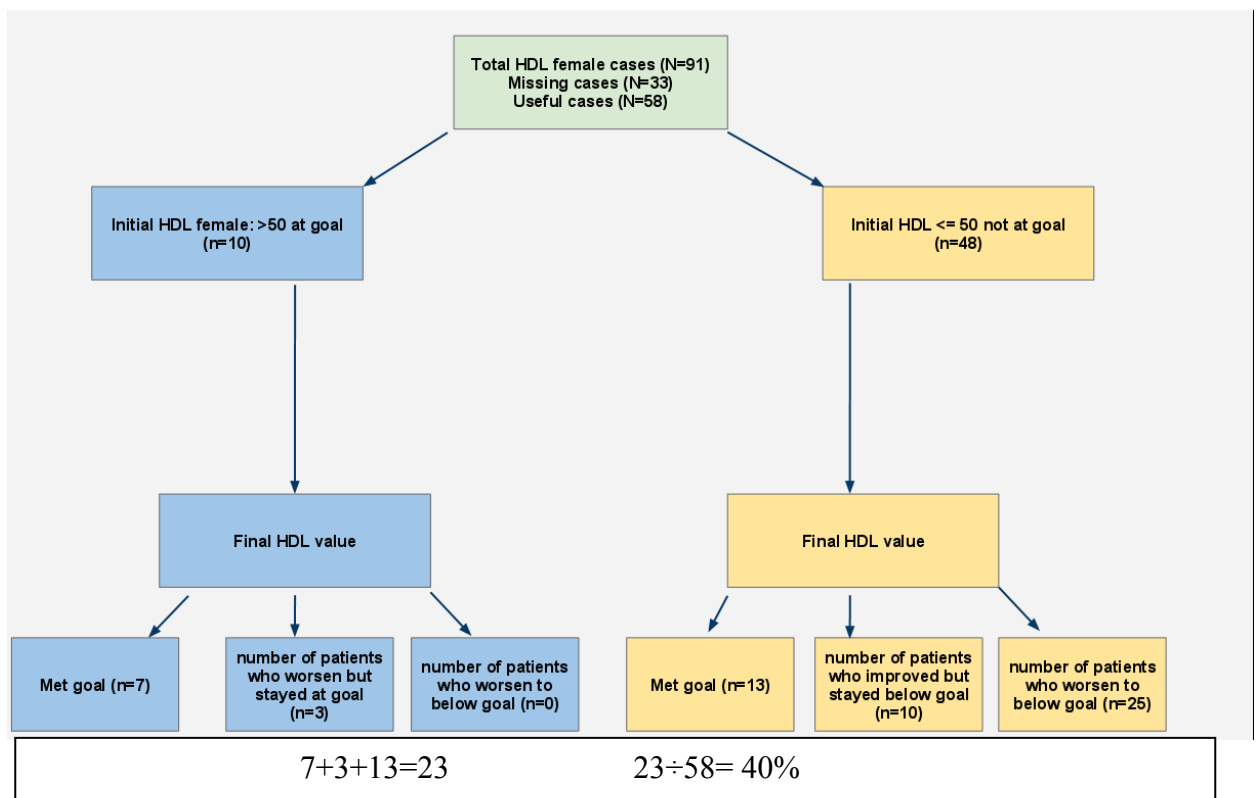


Figure 4.4 Flow chart showing goal attainment in HDL for female subjects

Goal attainment in HDL in male subjects:

As shown in the Figure 4.5 below, HDL values were available for 64 male patients. In 33 cases, either the beginning or ending HDL value was missing. Therefore the number of cases used in the analysis was 31. HDL values for males were further

classified into two groups: 1) those with an initial HDL value >40 , and 2) those with an initial HDL value ≤ 40 . The number of male patients whose initial HDL level was >40 was fifteen. Of those patients with an HDL value >40 , upon review of their last recorded HDL value, 12 patients improved or remained the same. Three patients' HDL value worsened but they were still within goal. None of the patients' HDL value worsened to below goal.

Sixteen male patients had an initial HDL value ≤ 40 . Of those patients with an initial HDL value ≤ 40 , upon review of their last recorded HDL value, nine male patients improved to at goal. Three male patients' HDL value improved but did not reach goal. Four male patients' HDL value either increased to below goal or did not reach goal. Overall, 77% of the male sample met the ADA recommended HDL goal at the last recorded reading.

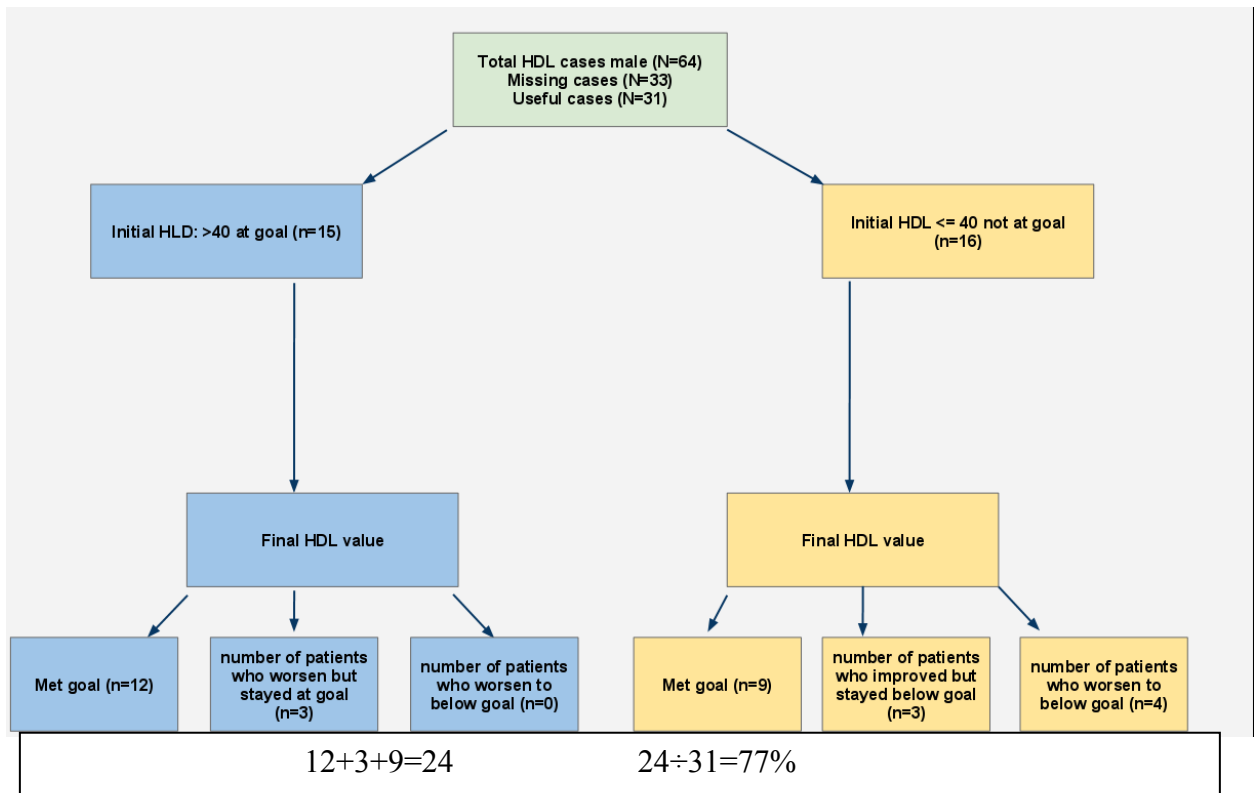


Figure 4.5 Flow chart showing goal attainment in HDL for male subjects

Goal attainment in LDL:

As shown in Figure 4.6 below, LDL values were available for 140 patients. In 39 cases, either the beginning or ending LDL value was missing. Therefore the number of cases used in this was 101. LDL values were further classified into two groups: 1) those with an initial LDL value <100, and 2) those with an initial LDL value ≥100. The number of patients whose initial LDL level was <100 was thirty-three. Of those patients with an LDL value <100, upon review of their last recorded LDL value, 25 patients improved or remained the same. Four patients' LDL value worsened but they were still within goal. Four patients' LDL value increased to below goal.

Sixty-eight patients had an initial LDL value ≥100. Of those patients with an initial LDL value ≥100, upon review of their last recorded LDL value, 23 patients

improved to at goal. Eleven patients' LDL value improved but did not reach goal. Thirty-four patients' LDL value either increased to below goal or did not reach goal. Overall, 51.5% of the sample met the ADA recommended LDL goal at the last recorded reading.

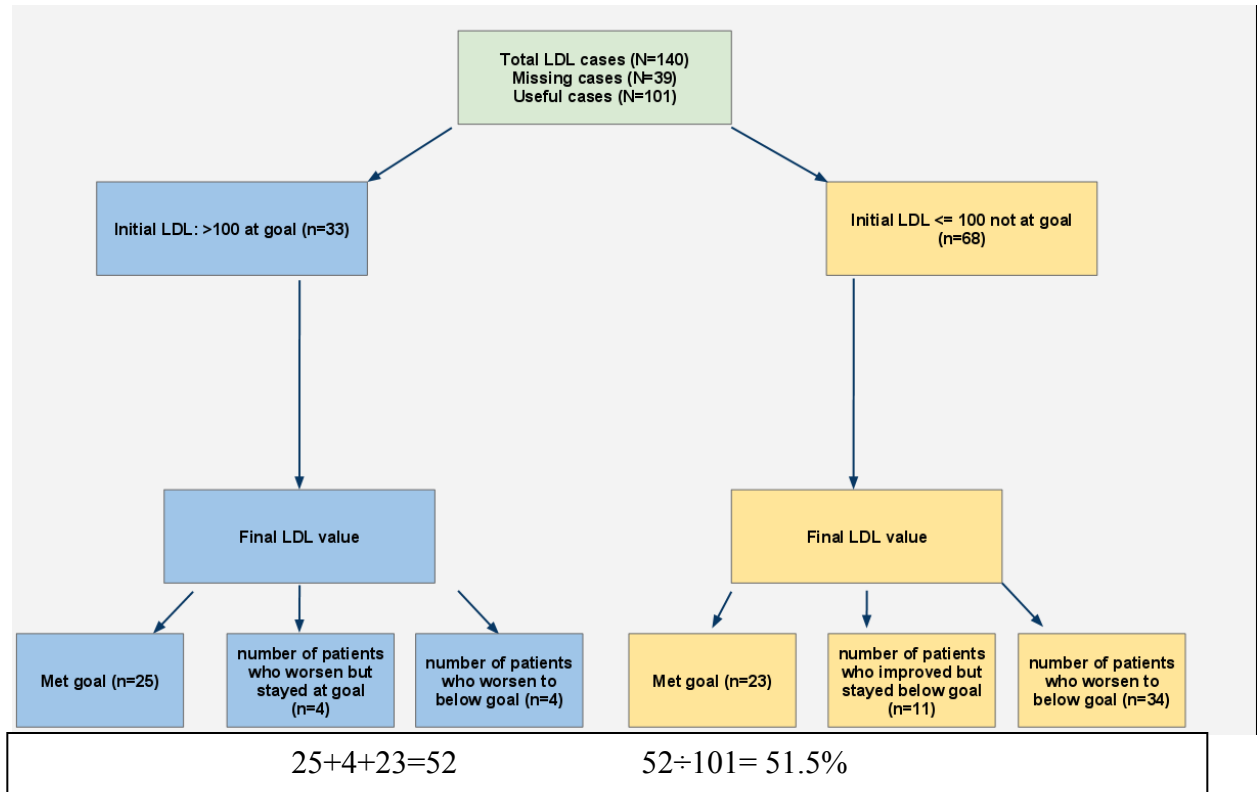


Figure 4.6 Flow chart showing goal attainment in LDL

Exploring difference using Analysis of Variance results

Group differences for change in A1c:

The change in A1c was calculated by subtracting the initial A1c value from the ending A1c value. The results (Tables 4.2-4.3) obtained in this population showed group difference in regards to Age, and Race/ethnicity. The calculated t-test ($t(79) = 3.304$, $p=0.001$) was significant for subjects older than 40 years old compared to those less than 40. The over 40 group had a higher improvement in A1c represented by a mean of 0.609 and standard deviation of 1.048. The mean change in A1c for patients ≤ 40 was 0.1059,

standard deviation=0.694. Similarly, ANOVA results ($F(5,136)=3.464$, $p=0.006$) were significant for Race/Ethnicity. African Americans had greater improvement in A1c value represented by the mean 0.610 and standard deviation (1.003), compared to the mean change in A1c for White of 0.5796, with a standard deviation of 0.8751. All tests were significant at $alpha\ 0.05$. No significant group difference was observed in other variables.

Table 4.2: T-test results for change in A1c.

Number of patients N=140			
Variables	<u>Mean change (SD)</u>	Statistics	P Value
		t	
Age(>40 years)	0.609 (1.048)	$t = 3.304$	0.001
Gender (female)	0.5101 (1.018)	$t = 0.352$	0.725
Tobacco use (no)	0.6222 (1.134)	$t = 1.276$	0.205
Pharmaco-therapy use (co morbid therapy)	0.498 (1.043)	$t = 0.681$	0.498

Table 4.3: ANOVA results for change in A1c.

Number of patients N=140			
Variables	<u>Mean Change (SD)</u>	Statistics	P Value
		F	
Number of visits (28-30visits)	1.750 (1.626)	$F = 1.883$	0.066
RACE(African Americans)	0.610 (1.003)	$F = 3.464$	0.006
Weight(160-190 lbs)	0.876 (0.940)	$F = 3.178$	0.060
BMI(obese)	0.666 (1.010)	$F = 2.253$	0.087

Group differences for change in Systolic Blood Pressure:

The change in systolic blood pressure was calculated by subtracting the initial systolic blood pressure value from the ending systolic blood pressure value. The results (Tables 4.4-4.5) obtained in this population showed no significant group difference in regard to the study variables.

Table 4.4: T-test results for change in systolic blood pressure.

Number of patients N=170			
Variables	<u>Mean Change (SD)</u>	Statistics	P Value
		t	
Age(>40 years)	12.87 (17.59)	$t = 1.940$	0.055
Gender (female)	12.32 (16.28)	$t = 0.760$	0.450
Tobacco use (no)	14.60 (16.694)	$t = 0.377$	0.710
Pharmaco-therapy use (co morbid therapy)	11.88 (17.752)	$t = 0.763$	0.450

Table 4.5: ANOVA results for change in systolic blood pressure.

Number of patients N=170			
Variables	<u>Mean Change (SD)</u>	Statistics	P Value
		F	
Number of visits (28-30visits)	14.58 (18.93)	$F= 1.350$	0.223
RACE(Whites)	13.14 (16.175)	$F= 1.035$	0.400
Weight(250-280 lbs)	18.00 (22.51)	$F= 1.062$	0.391
BMI(overweight)	15.00 (12.55)	$F= 2.196,$	0.093

Group differences for change in Diastolic Blood Pressure:

The change in diastolic blood pressure was calculated by subtracting the initial diastolic blood pressure value from the ending diastolic blood pressure value. The results (Tables 4.6-4.7) obtained in this population showed no significant group difference in regard to the study variables.

Table 4.6: T-test results for change in diastolic blood pressure

Number of patients N=167			
Variables	<u>Mean Change (SD)</u>	Statistics	P Value
		t	
Age(>40 years)	5.16 (15.057)	$t= 1.581$	0.116
Gender (female)	4.48 (15.227)	$t = 0.156$	0.876
Tobacco use (yes)	6.47 (14.853)	$t = 0.547$	0.586
Pharmaco-therapy use (co morbid therapy)	4.770 (15.541)	$t = 0.859$	0.394

Table 4.7: ANOVA results for change in diastolic blood pressure

Number of patients N=167			
Variables	<u>Mean Change (SD)</u>	Statistics	P Value
		F	
Number of visits (28-30visits)	21.00 (15.556)	$F= 1.077$	0.382
RACE(Pacific Islander)	10.50 (12.124)	$F= 1.649$	0.151
Weight (370-400 lbs)	15.00 (18.703)	$F= 2.188$	0.230
BMI(overweight)	8.43 (14.787)	$F= 1.335$	0.268

Group differences for change in HDL:

The change in HDL was calculated by subtracting the initial HDL value from the ending HDL value. The results (Tables 4.8-4.9) obtained in this population showed no significant group difference in regards to the study variables.

Table 4.8: T-test results for change in HDL

Number of patients N=89			
Variables	<u>Mean Change (SD)</u>	Statistics	P Value
		t	
Age(<40 years)	-2.80 (8.094)	$t = 0.891$	0.376
Gender (female)	-1.23 (8.257)	$t = 0.379$	0.706
Tobacco use (no)	-2.59 (7.236)	$t = 1.810$	0.075
Pharmaco-therapy use (diabetes meds only)	-3.56 (8.974)	$t = 1.098$	0.275

Table 4.9: ANOVA results for change in HDL

Number of patients N=89			
Variables	<u>Mean Change (SD)</u>	Statistics	P Value
		F	
Number of visits (19-21visits)	-4.00 (4.243)	$F= 0.656$	0.729
RACE(African Americans)	-1.76 (7.921)	$F= 0.956$	0.418
Weight (370-400 lbs)	-2.08 (8.703)	$F= 1.013$	0.305
BMI(obese)	-1.67 (6.982)	$F= 2.062$	0.135

Group difference for change in LDL:

The change in LDL was calculated by subtracting the initial LDL value from the ending LDL value. The results (Tables 4.10-4.11) obtained in this population showed no significant group difference in regard to the study variables.

Table 4.10: T-test results for change in LDL

Number of patients N=101			
Variables	<u>Mean Change (SD)</u>	Statistics	P Value
		t	
Age(>40 years)	17.096 (26.42)	$t = 1.773$	0.079
Gender (female)	17.390 (25.67)	$t = 1.650$	0.960
Tobacco use (no)	19.322 (31.97)	$t = 1.191$	0.111
Pharmaco-therapy use (diabetes meds only)	15.886 (24.30)	$t = 0.351$	0.509

Table 4.11: ANOVA results for change in LDL

Number of patients N=101			
Variables	<u>Mean Change (SD)</u>	Statistics	P Value
		F	
Number of visits (19-21 visits)	33.30 (17.68)	$F = 1.268$	0.269
RACE(Asian)	24.77 (7.23)	$F = 1.805$	0.134
Weight (370-400 lbs)	15.00 (8.70)	$F = 1.188$	0.590
BMI(obese)	25.42 (42.90)	$F = 0.915$	0.406

Regression results for change in A1c:

Table 4.12 shows the results for regression analysis for change in A1c and other independent variables. The type of regression used was stepwise regression, and all variables were used in the model together. The findings show the overall model was significant, $R=0.209$, $p=0.036$. About 21% of variance was explained by the model, and Age was estimated to be the strongest predictor for A1c improvement.

Table 4.12: Regression results for change in A1c

<u>Independent Variables</u>	<u>Standardized Coefficient</u>	<u>p-value</u>
Age	0.331	0.006*
Gender	-0.007	0.957
Tobacco use	-0.026	0.816
Pharmaco-therapy use	0.044	0.702
Number of visits	0.112	0.318
RACE	-0.007	0.978
Weight	0.145	0.355
BMI	0.183	0.230
Constant	-1.809	0.082
R-square	0.209	0.036*

$p<0.05^*$

Regression results for change in Systolic Blood Pressure:

Table 4.13 shows the results for regression analysis for change in systolic blood pressure and other independent variables. The type of regression used was stepwise regression, and all variables were used in the model together. The findings show the overall model with, $R=0.148$, $p=0.119$, however was not found to be significant.

Table 4.13: Regression results for change in Systolic Blood Pressure

<u>Independent Variables</u>	<u>Standardized Coefficient</u>	<u>p-value</u>
Age	0.078	0.532
Gender	-0.143	0.271
Tobacco use	-0.076	0.493
Pharmaco-therapy use	0.178	0.180
Number of visits	-0.077	0.490
RACE	0.100	0.380
Weight	0.155	0.375
BMI	0.076	0.634
Constant	-8.477	0.511
R-square	0.148	0.119

Regression results for Diastolic Blood Pressure:

Table 4.14 shows the regression analysis for change in diastolic blood pressure and other independent variables. The type of regression used was stepwise regression, and all variables were used in the model together. The findings show in the overall model with, $R=0.281$, $p=0.013$, 28% of variance was explained by gender and age. Males had lower improvement in diastolic blood pressure, compared to females. Those that were older than 40 had greater improvement compared to subjects less than 40. Other variables did not predict improvement in diastolic blood pressure. Results were found to be significant at *alpha 0.05* level.

Table 4.14: Regression results for change in Diastolic Blood Pressure

<u>Independent Variables</u>	<u>Standardized Coefficient</u>	<u>p-value</u>
Age	0.265	0.034*
Gender	-0.392	0.003*
Tobacco use	0.193	0.072
Pharmaco-therapy use	0.079	0.517
Number of visits	-0.071	0.551
RACE	0.193	0.120
Weight	0.208	0.172
BMI	-0.057	0.711
Constant	-8.607	0.034
R-square	0.281	0.013*

P<0.05*

Regression results for HDL:

Table 4.15 shows the regression analysis for change in HDL and other independent variables. The type of regression used was stepwise regression, and all variables were used in the model together. The findings show the overall model with, R=0.132, p=0.542, was not found to be significant. Study variables did not predict an improvement in HDL.

Table 4.15: Regression results for change in HDL.

<u>Independent Variables</u>	<u>Standardized Coefficient</u>	<u>p-value</u>
Age	0.272	0.064
Gender	-0.060	0.715
Tobacco use	0.073	0.611
Pharmaco-therapy use	0.123	0.398
Number of visits	-0.101	0.485
RACE	0.056	0.712
Weight	0.211	0.720
BMI	0.032	0.870
Constant	-6.332	0.342
R-square	0.132	0.542

Regression results for change in LDL

Table 4.16 shows the regression analysis for change in LDL and other independent variables. The type of regression used was stepwise regression, and all variables were used in the model together. The findings shows the overall model with, $R=0.127$, $p=0.592$, was not found to be significant. Study variables did not predict improvement in LDL.

Table 4.16: Regression result for change in LDL

<u>Independent Variables</u>	<u>Standardized Coefficient</u>	<u>p-value</u>
Age	0.128	0.382
Gender	-0.066	0.679
Tobacco use	-0.040	0.790
Pharmaco-therapy use	-0.045	0.758
Number of visits	-0.039	0.791
RACE	-0.139	0.367
Weight	-0.109	0.120
BMI	-0.194	0.331
Constant	19.059	0.342
R-square	0.127	0.592

Summary

A total of 179 charts were reviewed from the three respective health centers. Goal attainment was observed in the majority of CareNet members in most clinical markers. Sixty-two percent of CareNet member met goal in A1c value. Sixty percent of members met goal in systolic blood pressure value, 51% of members met diastolic blood pressure goal. Forty percent of female member met HDL goal, 77% of male members met goals in HDL and over 51% of members met goal in LDL value. In addition, age (over 40), and race/ethnicity (African Americans) predicted improvement in A1c values and diastolic

blood pressure value; whereas, males showed a lower improvement in diastolic blood pressure compared to females.

Chapter Five

Discussion and Conclusion

This chapter covers the discussion and conclusion based on the results obtained in this study. The chapter is divided into the following subheadings: goal attainment among CareNet members, effect of age, gender and race/ethnicity on goal attainment among CareNet members, implications of the findings, study limitation, future research and conclusion.

Goal attainment among CareNet members

In this study, goal attainment was assessed among CareNet members with diabetes. The results showed 60% of CareNet members met A1c goal, 58% met goal in systolic blood pressure values, 51% of CareNet members met diastolic blood pressure goal, 40% of female patients met HDL goal, whereas, 77% of male patients met HDL goal. LDL goal was met by 51.5% of CareNet members. Previous studies measuring goal attainment using the nationally representative sample National Health and Nutrition Examination Survey (NHANES), have shown consistent findings in A1c value,⁷⁵ blood pressure,⁷⁶ and lipid profile⁷⁶ compared to our study. A study published by Coon and

Zulkowaski determined adherence to ADA diabetes guidelines in a rural health setting. They found 47% of patients met ADA recommended A1c goal, 29% of patients met systolic blood pressure goal, 79% of patients met diastolic blood pressure, 26% of patients met LDL goal, and 40% of both males and females met the recommended goal for HDL.⁷⁷

One distinction was observed with goal attainment in regards to HDL values in the present study population. A high percentage of male patients met the HDL goal compared to females. The fact that a greater numbers of male patients were at goal at baseline for HDL might explain the high percentage of males meeting goal in this study. This result was particularly surprising because females tend to have a higher HDL values due to differences in sex hormone response.⁷⁸ It is possible that as the number of observations increase, the results would be more predictable. It is also important to note that in this sample there were some CareNet members that were not successful at meeting goal, which may be due to the fact that many of these patients started with a high values to begin with. This should be a concern for CareNet, as these patients might be more vulnerable to other serious diabetes complications.

Effect of age, gender and race/ethnicity on goal attainment among CareNet members

A within group difference was found for the variable age. Those patients who were older than 40 had greater improvement in A1c than those who were younger. This finding was consistent with a previous study conducted by Gilmer et al. which compared an uninsured cohort with insured groups, who received nurse managed diabetes services. They found that those less than 40 were less likely to have an improved diabetes related outcome.⁷⁹ The mean change in A1c was found to be higher for patients older than 40,

compared to those 40 and younger. When comparing ranges in both groups, the patients who were older than 40 started with higher A1c values to begin with compared to the younger patients. Accordingly, younger patients may require more attention to improve their diabetes outcome, because it may become increasingly difficult to further bring down A1c value if they already are closer to goal. Another study conducted by Kirk et al., observing goal attainment to national guidelines in diabetes patients, found similar findings to present study. Those in the age range of 65 year or older had improvements in glycemic control, blood pressure control, and lipid control. This indicates that older individuals seem to have a greater potential, in terms of improving their diabetes outcome as compared to younger ones. As the risk factors for heart disease increases with age, careful attention should be paid to older CareNet patients with diabetes.⁸⁰

Likewise, group differences in A1c were also found among African Americans and others. One study conducted by Feathers et al. looked at the effect of community-based diabetes intervention on risk factors for diabetes complications among African Americans and Latinos with type 2 diabetes. They found that those individuals who were African Americans had higher A1c levels compared to their White counterparts.⁸⁰ When comparing African Americans and Whites in the present study, the two groups were found to have similar values for change in A1c; however, the range value for African Americans were slightly higher. In addition, the fact that patients greater than 40 years old and African Americans formed the majority in their respective demographic groups (age and race/ethnicity) may have contributed to the observed statistically significant effect.

The regression results for A1c and diastolic blood pressure showed a statistically significant relationship in age and gender. Improved A1c was found to be greater in the age group of 40 and above. Past studies have shown that with increased age, improvement in diabetes and improvement in heart complications was observed.^{79,81}

Statistically significant improvement in diastolic blood pressure was found to be greater in the age group of individuals above 40 years old. This finding was consistent with pre existing literature on blood pressure control. Literature has shown that diastolic blood pressure decreases with age.⁸² However, a negative beta value was observed with gender and DBP, which means in the CareNet population males were less likely to show improvement in DBP as opposed to females. Results similar to our study for the effect of gender was not observed in the past literature, but elevated blood pressure is a cause of concern as there is some evidence that male with high blood pressure tend to have greater likelihood of heart complications.⁸³ It is also possible that unlike men, females were more likely to attend every primary care appointment. Reflectively, we found that females had a greater number visits, (104) compared to males who had only 67 primary care visits. In addition, the literature shows that as the number of missed appointments increases, diabetes outcomes tend to worsen.⁸⁴

Implications of the findings

Based on the objectives of this study, the majority of CareNet members reached ADA recommended goals, and a statistically significant improvement was observed in A1c and diastolic blood pressure value. Improvement was observed across all diabetes clinical markers, which translates to success for CareNet and its members. The findings are encouraging for CareNet, because they can use these results to make improvements to

their current program, and obtain additional funding for future growth. For those members that didn't meet ADA recommended goals, CareNet would need to look closely at these groups; especially, those patients with higher values at the beginning of a treatment. Statistically significant findings in older age would also have a clinically meaningful interpretation, because these groups of individuals are at a greater risk of cardiovascular complications.⁷ Improvement in this age group is a good sign for CareNet. This indicates that the care provided by CareNet has been beneficial for its members, and the members are taking full advantage of the services, especially the older members. However, this also means that in this population CareNet needs to look closer at younger patients, in order to improve their outcomes in the future. Key decisions, such as helping or assisting its members to keep doctor's appointments, may help to produce better outcomes in the future. Moreover, this study could also add valuable results to the literature on safety net organizations, which may further diabetes care to the uninsured populations.

Study limitation

In this study, there were several possible limitations. First, due to the low sample size it was difficult to estimate significant effects of other factors on goal attainment. The missing data due to patients not showing-up for doctor's appointment would be a possible reason for the low sample. Such incomplete information may not be useful for analysis. To combat such an issue, a suggestion would be to have a standard data form to record patient's information across all health care systems. This would make all useful information available in one document. Second, it is also possible that some information may not be available, since all records were paper based. Having electronic medical

records would make everything available in a secure and one location. Third, having no access to date of visits due to the Health Insurance Portability and Accountability Act of 1996 (HIPPA), which protects patient's personal health information, limited our ability to determine the exact enrollment time frame for the patients. The only possibility for estimating the time frame was through the patient's number of visits. Finally, the findings cannot be generalized, except for programs with similar group characteristics, because the nature of the study design was retrospective chart review.

Future Research

Future research should include a cohort group, in which a group of CareNet diabetes patients would be compared to a control group (not CareNet members) with similar characteristics. Although, this would mean more steps in terms of the IRB approval process, having this design would certainly make the study stronger. In addition, including some additional variables such as waist circumference in addition to BMI, would also be a more appropriate predictor of effectiveness of diabetes treatment. Also, using a more comprehensive data source, possibly at the state level, would be beneficial in terms of generalizability leading to a stronger study design.

Conclusion

Goal attainment in the majority of CareNet members diagnosed with diabetes was observed across most clinical markers (i.e., A1c, DBP, SBP, HDL and LDL). A statistically significant relationship was found with age, gender, and race/ethnicity in terms of goal attainment. CareNet can use this valuable information to make

improvements to their program and help their resources grow in order to encourage their members to continue to achieve better health outcomes.

References:

1. CareNet Annual Report. 2008. Available at: <http://www.toledocarenet.org/news.html>
2. Luke, Shockman. "Uninsured to get free health care" The Blade 28 August. 2002:
Available at:
<http://news.google.com/newspapers?nid=1350&dat=20020828&id=14UUAAAIBAJ&sjid=0QMEAAAIBAJ&pg=6753,3978869>
3. CareNet. 2008. Available at: http://www.toledocarenet.org/about_us.html.
4. World Health Organization. Diabetes. 2008. Available at:
<http://www.who.int/mediacentre/factsheets/fs312/en/>
5. American Diabetes Association. All about Diabetes. 2009. Available at:
<http://www.diabetes.org/diabetes-basics/diabetes-statistics/>
6. National Institute of Diabetes and Digestive and Kidney Diseases. National Diabetes Statistics, 2007 fact sheet. Bethesda, MD: U.S. Department of Health and Human Services, National Institutes of Health, 2008.

7. "Standards of medical care in diabetes--2009." *Diabetes Care* 32 Suppl 1 (2009), S13-61.
8. Knowler, WC., et al. "Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin." *New England journal of medicine* 346.6 (2002), 393-403.
9. Stratton, IM., et al. "Association of glycaemia with macrovascular and microvascular complications of type 2 diabetes (UKPDS 35): prospective observational study." *BMJ: British Medical Journal* 321.7258 (2000), 405-12.
10. Sacks, DB., et al. "Guidelines and recommendations for laboratory analysis in the diagnosis and management of diabetes mellitus." *Clinical Chemistry* 48.3 (2002), 436-72.
11. "The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. The Diabetes Control and Complications Trial Research Group." *New England journal of medicine* 329.14 (1993), 977-86.
12. Patel, A., et al. "Intensive blood glucose control and vascular outcomes in patients with type 2 diabetes." *New England journal of medicine* 358.24 (2008), 2560-72.
13. Holman, RR., et al. "10-year follow-up of intensive glucose control in type 2 diabetes." *New England journal of medicine* 359.15 (2008), 1577-89.

14. Duckworth W: VADT results. Presented at the 68th Annual Meeting of the American Diabetes Association, 6–10 June 2008, at the Moscone Convention Center, San Francisco, CA
15. Nathan, DM., et al. "Medical management of hyperglycemia in type 2 diabetes: a consensus algorithm for the initiation and adjustment of therapy: a consensus statement of the American Diabetes Association and the European Association for the Study of Diabetes." *Diabetes Care* 32.1 (2009), 193-203.
16. List of drugs. Available at: www.ndep.nih.gov/media/Drug_tables_supplement.pdf
17. Norris, SL., et al. "Self-management education for adults with type 2 diabetes: a meta-analysis of the effect on glycemic control." *Diabetes Care* 25.7 (2002), 1159-71.
18. Gary, TL., et al. "Meta-analysis of randomized educational and behavioral interventions in type 2 diabetes." *Diabetes Educator* 29.3 (2003), 488-501.
19. Ellis, SE., et al. "Diabetes patient education: a meta-analysis and meta-regression." *Patient Education and Counseling* 52.1 (2004), 97-105.
20. Warsi, A., et al. "Self-management education programs in chronic disease: a systematic review and methodological critique of the literature." *Archives of Internal Medicine* 164.15 (2004), 1641-9.

21. Norris, SL., MM. Engelgau, and KM Narayan. "Effectiveness of self-management training in type 2 diabetes: a systematic review of randomized controlled trials." *Diabetes Care* 24.3 (2001), 561-87.
22. Steed, L., D. Cooke, and S Newman. "A systematic review of psychosocial outcomes following education, self-management and psychological interventions in diabetes mellitus." *Patient Education and Counseling* 51.1 (2003), 5-15
23. Gaede, P., et al. "Effect of a multifactorial intervention on mortality in type 2 diabetes." *New England journal of medicine* 358.6 (2008), 580-91.
24. Grob GN. *The Deadly Truth: A History of Disease in America*. Cambridge: Harvard University Press, 2002.
25. DeNavas-Walt, Carmen, Bernadette D. Proctor, and Jessica C. Smith, U.S. Census Bureau, Current Population Reports, P60-236, *Income, Poverty, and Health Insurance Coverage in the United States: 2008*, U.S. Government Printing Office, Washington, DC, 2009.
26. 2008 National Healthcare Quality & Disparities Reports. Agency for Healthcare Research and Quality, Rockville, MD. Available at:
www.ahrq.gov/qual/nhqr08/nhqr08.pdf.

27. Wilper, AP., et al. "A national study of chronic disease prevalence and access to care in uninsured U.S. adults." *Annals of Internal Medicine* 149.3 (2008), 170-6.
28. Carter-Pokras, O. and C Baquet. "What is a 'health disparity'?" *Public health reports (Washington, D.C. : 1974)* 117.5 (2002), 426-34.
29. Gregg, EW., et al. "Characteristics of insured patients with persistent gaps in diabetes care services: the Translating Research into Action for Diabetes (TRIAD) study." *Medical Care* 48.1 (2010), 31-7.
30. Banerjee, D.; Perry, M.; Tran, D.; Arafat, R. "Self-reported Health, Functional Status and Chronic Disease in Community Dwelling Older Adults: Untangling the Role of Demographics." *Journal of Community Health: The Publication for Health Promotion and Disease Prevention*, 2009.
31. Drexler AJ. Lessons learned from landmark trials of type 2 diabetes mellitus and potential applications to clinical practice. *Postgrad Med.* 2003;Spec No:15-26.
32. Lamarche B, Tchernof A, Moorjani S, et al. Small, dense low-density lipoprotein particles as a predictor of the risk of ischemic heart disease in men. Prospective results from the Québec Cardiovascular Study. *Circulation.* 1997;95(1):69-75.

33. Stamler J, Vaccaro O, Neaton JD, Wentworth D. Diabetes, other risk factors, and 12-yr cardiovascular mortality for men screened in the Multiple Risk Factor Intervention Trial. *Diabetes Care*. 1993;16(2):434-444.
34. Kannel WB, D'Agostino RB, Wilson PW, Belanger AJ, Gagnon DR. Diabetes, fibrinogen, and risk of cardiovascular disease: the Framingham experience. *Am. Heart J.* 1990;120(3):672-676.
35. Uusitupa MI, Niskanen LK, Siitonen O, Voutilainen E, Pyörälä K. Ten-year cardiovascular mortality in relation to risk factors and abnormalities in lipoprotein composition in type 2 (non-insulin-dependent) diabetic and non-diabetic subjects. *Diabetologia*. 1993;36(11):1175-1184.
36. Adler AI, Stratton IM, Neil HA, et al. Association of systolic blood pressure with macrovascular and microvascular complications of type 2 diabetes (UKPDS 36): prospective observational study. *BMJ*. 2000;321(7258):412-419.
37. Moss SE, Klein R, Klein BE. Long-term incidence of lower-extremity amputations in a diabetic population. *Arch Fam Med*. 1996;5(7):391-398.
38. Stratton IM, Neil HA, et al. Association of systolic blood pressure with macrovascular and microvascular complications of type 2 diabetes (UKPDS 36): prospective observational study. *BMJ*. 2000;321(7258):412-419.

39. Randomised trial of cholesterol lowering in 4444 patients with coronary heart disease: the Scandinavian Simvastatin Survival Study (4S). *Lancet*. 1994;344(8934):1383-1389.
40. Pyörälä K, Pedersen TR, Kjekshus J, et al. Cholesterol lowering with simvastatin improves prognosis of diabetic patients with coronary heart disease. A subgroup analysis of the Scandinavian Simvastatin Survival Study (4S). *Diabetes Care*. 1997;20(4):614-620.
41. Duckworth W, Abraira C, Moritz T, et al. Glucose control and vascular complications in veterans with type 2 diabetes. *N. Engl. J. Med*. 2009;360(2):129-139.
42. Implications of the United Kingdom Prospective Diabetes Study. *Diabetes Care*. 2002;25(90001):28S-32.
43. Waeber B, de la Sierra A, Ruilope LM. The ADVANCE trial: clarifying the role of perindopril/indapamide fixed-dose combination in the reduction of cardiovascular and renal events in patients with diabetes mellitus. *Am J Cardiovasc Drugs*. 2009;9(5):283-291.
44. Norris SL, Jack L et al. The effectiveness of family interventions in people with diabetes mellitus: a systematic review.

Diabet Med 2005; 22:1295–305.

45. Warsi A, Wang PS, LaValley MP, Avorn J, Solomon DH. Self-management education programs in chronic disease: a systematic review and method-ological critique of the literature. Arch Intern Med.2004;164:1641-1649.

46.CDC Features - Uninsured Americans: Newly Released Health Insurance Statistics. Available at: <http://www.cdc.gov/features/uninsured/> [Accessed July 2, 2010].

47. Rowland D, Shartzer A. America's uninsured: the statistics and back story. J Law Med Ethics. 2008;36(4):618-628, 607.

48. Tu HT, Cohen GR. Financial and health burdens of chronic conditions grow. Track Rep. 2009;(24):1-6.

49. Hadley J. Insurance coverage, medical care use, and short-term health changes following an unintentional injury or the onset of a chronic condition. JAMA. 2007;297(10):1073-1084.

50. Cunningham PJ. Chronic burdens: the persistently high out-of-pocket health care expenses faced by many Americans with chronic conditions. Issue Brief (Commonw Fund). 2009;63:1-14.

51. Paez KA, Zhao L, Hwang W. Rising out-of-pocket spending for chronic conditions: a ten-year trend. *Health Aff (Millwood)*. 2009;28(1):15-25.
52. Hoffman C, Schwartz K. Eroding access among nonelderly U.S. adults with chronic conditions: ten years of change. *Health Aff (Millwood)*. 2008;27(5):w340-348.
53. Bowker SL, Mitchell CG, Majumdar SR, Toth EL, Johnson JA. Lack of insurance coverage for testing supplies is associated with poorer glycemic control in patients with type 2 diabetes. *CMAJ*. 2004;171(1):39-43.
54. McWilliams JM, Meara E, Zaslavsky AM, Ayanian JZ. Health of previously uninsured adults after acquiring Medicare coverage. *JAMA*. 2007;298(24):2886-2894
55. Boltri JM, Okosun IS, Davis-Smith M, Vogel RL. Hemoglobin A1c levels in diagnosed and undiagnosed African Americans, Hispanic, and white persons with diabetes: results from NHANES 1999-2000. *Ethn Dis*. 2005;15(4):562-567.
56. Gray J, Millett C, Saxena S, et al. Ethnicity and quality of diabetes care in a health system with universal coverage: population-based cross-sectional survey in primary care. *J Gen Intern Med*. 2007;22(9):1317-1320.

57. Kirk JK, Passmore LV, Bell RA, et al. Disparities in A1C levels between Hispanic and non-Hispanic white adults with diabetes: a meta-analysis. *Diabetes Care*. 2008;31(2):240-246.
58. Boltri JM, Okosun IS, Davis-Smith M, Vogel RL. Hemoglobin A1c levels in diagnosed and undiagnosed African Americans, Hispanic, and white persons with diabetes: results from NHANES 1999-2000. *Ethn Dis*. 2005;15(4):562-567.
59. Gray J, Millett C, Saxena S, et al. Ethnicity and quality of diabetes care in a health system with universal coverage: population-based cross-sectional survey in primary care. *J Gen Intern Med*. 2007;22(9):1317-1320.
60. Kirk JK, Passmore LV, Bell RA, et al. Disparities in A1C levels between Hispanic and non-Hispanic white adults with diabetes: a meta-analysis. *Diabetes Care*. 2008;31(2):240-246.
61. Duru OK, Gerzoff RB, Selby JV, et al. Identifying risk factors for racial disparities in diabetes outcomes: the translating research into action for diabetes study. *Med Care*. 2009;47(6):700-706.
62. Selby JV, Swain BE, Gerzoff RB, et al. Understanding the gap between good processes of diabetes care and poor intermediate outcomes: Translating Research into Action for Diabetes (TRIAD). *Med Care*. 2007;45(12):1144-1153.

63. Levine DA, Allison JJ, Cherrington A, et al. Disparities in self-monitoring of blood glucose among low-income ethnic minority populations with diabetes, United States. *Ethn Dis.* 2009;19(2):97-103.
64. Karter AJ, Ferrara A, Liu JY, et al. Ethnic disparities in diabetic complications in an insured population. *JAMA.* 2002;287(19):2519-2527.
65. Healthy People 2020 - View Objective. Available at:
<http://www.healthypeople.gov/hp2020/Objectives/ViewObjective.aspx?Id=11&TopicArea=Access+to+Health+Services&Objective=AHS+HP2020%e2%80%931&TopicAreaId=10> [Accessed January 24, 2010].
66. America's Health Care Safety Net: Intact but Endangered. Available at:
http://books.nap.edu/openbook.php?record_id=9612&page=47 [Accessed July 2, 2010].
67. Redlener I, Grant R. America's Safety Net and Health Care Reform -- What Lies Ahead? *N Engl J Med.* 2009;361(23):2201-2204.
68. Forrest CB, Whelan EM. Primary care safety-net delivery sites in the United States: A comparison of community health centers, hospital outpatient departments, and physicians' offices. *JAMA.* 2000;284(16):2077-2083.

69. Philis-Tsimikas A, Walker C, Rivard L, et al. Improvement in diabetes care of underinsured patients enrolled in project dulce: a community-based, culturally appropriate, nurse case management and peer education diabetes care model. *Diabetes Care*. 2004;27(1):110-115.
70. Gilmer TP, Roze S, Valentine WJ, et al. Cost-effectiveness of diabetes case management for low-income populations. *Health Serv Res*. 2007;42(5):1943-1959.
71. Eisert SL, Mehler PS, Gabow PA. Can America's urban safety net systems be a solution to unequal treatment? *J Urban Health*. 2008;85(5):766-778.
72. Becker G. Deadly inequality in the health care "safety net": uninsured ethnic minorities' struggle to live with life-threatening illnesses. *Med Anthropol Q*. 2004;18(2):258-275.
73. Dalton VK, Jacobson PD, Konig M, Holman PP. Community responses to diabetes and mental health care for the uninsured population in Michigan. *J Health Care Poor Underserved*. 2009;20(1):98-106.
74. Meyers L, et al. *Applied Multivariate Research*. Sage Publishing, 2006.
75. National Heart Lung and Blood Institute. 2010. Available at: <http://www.nhlbisupport.com/bmi/>

76. INZUCCHI SE, REED JW. Achievement of ADA Guidelines Among US Adults With Diabetes: NHANES. 2007;43(3):469-477.
77. Coon P, Zulkowski K. Adherence to American Diabetes Association Standards of Care by Rural Health Care Providers. *Diabetes Care*. 2002;25(12):2224-2229.
78. Texasheart. 2010. <http://www.texasheart.org/HIC/Topics/HSmart/women.cfm>
79. Gilmer TP, Roze S, Valentine WJ, et al. Cost-effectiveness of diabetes case management for low-income populations. *Health Serv Res*. 2007;42(5):1943-1959.
80. Kirk JK, Huber KR, Clinch CR. Attainment of goals from national guidelines among persons with type 2 diabetes: a cohort study in an academic family medicine setting. *N C Med J*. 2005;66(6):415-419.
81. Two Feathers J, Kieffer EC, Palmisano G, et al. Racial and Ethnic Approaches to Community Health (REACH) Detroit Partnership: Improving Diabetes-Related Outcomes Among African American and Latino Adults. *Am J Public Health*. 2005;95(9):1552-1560.
82. Kirk JK, Huber KR, Clinch CR. Attainment of goals from national guidelines among persons with type 2 diabetes: a cohort study in an academic family medicine setting. *N C Med J*. 2005;66(6):415-419.

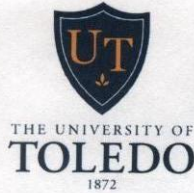
83. Wingfield D, Grodzicki T, Palmer AJ, Wells F, Bulpitt CJ. Transiently elevated diastolic blood pressure is associated with a gender-dependent effect on cardiovascular risk. *J Hum Hypertens.* 2005;19(5):347-354.

84. Schectman JM, Schorling JB, Voss JD. Appointment Adherence and Disparities in Outcomes Among Patients with Diabetes. *J Gen Intern Med.* 2008;23(10):1685-1687.

Appendix A

Institutional Review Board (IRB) Approval Documents

The documents attached below include individual Institutional Review Board (IRB) approval letters from University of Toledo IRB, Mercy IRB and Promedica IRB, in that precise order. In addition, the last page in this appendix contains the standard data collection form.



The University of Toledo
Department for Human Research Protections
Biomedical Institutional Review Board
Center for Creative Education Building – Room 0106
3025 Arlington Avenue, Toledo, Ohio 43614-2570
Phone: 419-383-6796 Fax: 419-383-3248
(FWA00010686)

TO: Monica Holiday-Goodman, Ph.D.
UT Department of Pharmacy Practice

FROM: Roland Skeel, M.D., Chair
Deepak Malhotra, M.D. Vice Chair
Gregory Siegel, R.Ph., J.D., Chair Designee
UT Biomedical Institutional Review Board

SIGNED: _____ **DATE** 2/18/2010

SUBJECT: IRB # 106532
TITLE: Clinical Outcomes Related to Diabetes, Hypertension and Mammogram
Screening in Toledo Lucas County CareNet Patients

The above research received **final approval** by the Chair and Director of Regulatory Compliance of the Institutional Review Board as an **expedited review** (category #5). Signed and dated Consent and Authorization for Use and Disclosure of Protected Health Information remains waived. It was determined that this waiver for signed consent/authorization for use and disclosure of protected health information form will not adversely affect the rights and welfare of the participants whose data is being collected. The full board will be notified of this action at its meeting on 03/18/2010.

Please note: The Lucas County Health Department and Promedica locations are the **only** sites currently approved as Performance Sites. We have not yet received a copy of the approval from Mercy Health Partners and therefore it cannot yet be approved as a performance site. You will need to submit an amendment to the IRB once you have received the approval documentation from Mercy Health Partners.

Items Included for Review:

- IRB Expedited Research Application
- CareNet Data Collection Tool (assigned version date 09/18/2009)
- Toledo Lucas County CareNet Board of Directors letter of agreement and understanding regarding the proposed project.
- Promedica IRB Approval Memo (dated 02/02/2010)

APPROVAL DATE: 02/17/2010

EXPIRATION DATE: 02/16/2011

Please read the following attachment detailing Principal Investigator responsibilities.



Mercy St. Anne Hospital
Mercy St. Charles Hospital
Mercy St. Vincent Medical Center
Mercy Children's Hospital
Mercy Defiance Hospital
Mercy Tiffin Hospital
Mercy Willard Hospital
Mercy Medical Partners

Research Oversight & Education
Mercy St. Vincent Medical Center
2213 Cherry St.
Toledo Ohio, 43608
Fax: (419) 251-0835
Research Compliance & IRB Coordinators
Adult IRB
(419) 251-3585
Pediatric IRB
(419) 251-2962

Honingford, Becky: Clinical Outcomes Related to Diabetes, Hypertension, and Mammogram Screening in Toledo Lucas County CareNet Patients (IRB# 0210102)

4/15/2010

The Designated Reviewer, on behalf of the Adult Institutional Review Board (IRB) of the St. Vincent Mercy Medical Center, reviewed and approved the following application materials.

- Research Summary Form dated 03/18/2010.
- Protocol.
- CareNet Data Collection Form.
- Request for a waiver of informed consent [45 CFR §46 116(d)(1-4)].
- Request for a waiver of Authorization for Release of Protected Health Information [45 CFR 164.512(i)(2)]

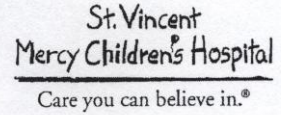
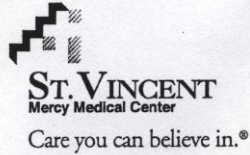
This study has been approved with the approval period ending **03/14/2011**.

This study was reviewed by the less than full IRB review process (expedited) for Category 5: Research involving materials that have been collected, or will be collected solely for non-research purposes. (IRB; Research Categories List; Expedited Review Procedure, [FR Doc. 98-29749])

It is the Reviewer's understanding that the research presents **no more than minimal risk to human subjects** [45 CFR §46. 101(i) / 21 CFR 56.101(i)] and the identification of the subjects and/or their responses **will not** place them at risk of criminal or civil liability, or be damaging to the their financial standing, employability, insurability

The Designated Reviewer has reviewed the required criteria for a waiver of informed consent [45 CFR §46 116(d)(1-4)] and **has waived the requirement to obtain informed consent.**

The Designated Reviewer has reviewed the required criteria for a waiver of Authorization for Release of Protected Health Information [45 CFR 164.512(i)(2) / MHP Regional Policy



Waiver of Authorization for Use and Disclosure of Protected Health Information (PHI) for Purposes of Research

This form must be filled out on a computer. The answer fields are shaded (or).

Research Title and Contact Information		
Research Oversight and Education and the IRB use the phone, fax, pager, postal address and email information to send the PI and/or the Contact Person approval letters, stamped consent forms, applications, etc. The contact information must be current and used regularly by the PI or Contact Person. Please notify ROE in writing if any contact information changes.		
Date:	IRB Number: (Assigned by RO&E)	
3/30/2010		
Research Title:		
Clinical Outcomes Related to Diabetes, Hypertension, and Mammogram Screening in Toledo Lucas County CareNet Patients		
Contact Information		
Principal Investigator: (Must be a St. Vincent employee or on the St. Vincent medical or hospital staff.)		
Ms. Becky Honingford		
Institution/Organization:	Email:	
Mercy	Becky Honingford@mhsnr.org	
Department, Section, Unit:	Phone:	Pager:
Mercy Physician Enterprise	(419) 251-2376	419-539-0495
Address:	Fax:	
Mercy St. Vincent Family Care Center 2213 Franklin Ave, Toledo, Oh 43608	419-251-2393	
Contact Person: (If not the Principal Investigator)		
Dr. Monica Holiday-Goodman		
Institution/Organization:	Email:	
The University of Toledo	MHolida@utnet.utoledo.edu	
Department, Section, Unit:	Phone:	Pager:
College of Pharmacy, Pharmacy Practice.	419-530-1968	
Address:	Fax:	
2801 Bancroft Toledo, Ohio 43606		

Source(s) of the Data

List all sources of records from which data will be collected. The SVMMC IRB cannot grant permission for data collection to be conducted at non-SVMC sites/sources.

Possible Sources – this is not an exhaustive list:

Billing records,	Hospital/medical records (in and out patient),
Lab, pathology, and/or radiology samples/results,	Mental Health records,
Physician/clinic records,	PHI previously collected for research purposes,
Questionnaires/Interviews,	MRI scans, X-rays, etc,

SVMC Site/Department	Title/Type of Database/Data Source	Time Period for Data Collection
Mercy St. Vincent Family Care Center 2213 Franklin Ave (SV)	Hospital Medical Record	01/01/2003-12/31/2008
Gandy Mercy Family Medicine 2200 Jefferson Ave (SV)	Hospital Medical Record	01/01/2003-12/31/2008
Navarre Family Medicine 2702 Navarre, Suite 206 (SV)	Hospital Medical Record	01/01/2003-12/31/2008

Add rows to table as needed. To add a row, place cursor in the last cell of the last row of the table and press [Tab].

Data to be Collected from the Source(s)

List all information collected including any information to be used to link information to the individual or to the individual's record(s). Attach a data collection form.

List all Source(s) Stated Above	Specific Information Being Collected from this Source.
Hospital Medical Record	Age, Gender, Ethnicity/Race, Height, Weight, Tobacco Use, A1c, Blood Pressure, HDL/LDL, Pharmacotherapy treatment, Number of Primary care visits in last 12 months, Marital status, Family history of breast cancer, Date mammogram performed and Date of enrollment in CareNet

Add rows to table as needed. To add a row, place cursor in the last cell of the last row of the table and press [Tab].

Research Title:
Clinical Outcomes Related to Diabetes, Hypertension, and Mammogram Screening in Toledo Lucas County CareNet Patients

Principal Investigator's Assurance Statement

I certify that the information provided in this application is complete and correct.

I understand that as Principal Investigator, I have the ultimate responsibility for the conduct of the research, the ethical performance of the project, the protection of the rights and welfare of human subjects, the privacy of their protected health information, and strict adherence to any stipulations imposed by the St. Vincent Mercy Medical Center IRB.

I agree to comply with all IRB and Institutional policies and procedures, as well as with all applicable Federal, State, and local laws regarding the protection of human subjects in research and the protection of the privacy of their individually identifiable health information.

I understand that the approval of this request for waiver of authorization for use and disclosure of PHI is contingent upon my agreement to the following:

- 1) This waiver of authorization for use or disclosure of PHI is sought solely for the purpose of this particular research project and includes only the PHI as described in the research protocol approved by the IRB;
- 2) The PHI for which waiver of authorization for use or access is being sought is necessary for the research purpose stated in the research protocol;
- 3) A copy of IRB approval of waiver of authorization will be presented to the appropriate personnel responsible for the source(s) from which PHI is sought prior to information being used from that source;
- 4) As Principal Investigator I am responsible for maintaining all research related information associated with this waiver, along with a copy of the waiver, in a secure location for a minimum of six (6) years for purposes of tracking of disclosures and, at the request of the individual whose data were disclosed, provide an accounting of such disclosures going back six (6) years prior to the date of the request;
- 5) Collection of information for the research purpose stated in the research protocol will not occur prior to the IRB assigned approval date and will not continue after the IRB assigned expiration date; and
- 6) Approval of this waiver of authorization may be revoked by the IRB at any time.

Signature of Principal Investigator

Name: Ms. Becky Honingford Date: 3/30/10

Note: A copy of the IRB approval letter and this form in its entirety with the IRB approval stamp must be presented to the appropriate SVMMC personnel before access to or release of any information from any SVMMC database/medical record.

IRB Use Only

Attach SVMMC IRB Approval for Waiver of Authorization Signature Page here as last page.
(SVMMC IRB Approval for Waiver of Authorization for Use and Disclosure of Protected Health Information (PHI) for Purposes of Research)

Application for Full Waiver of Authorization

When appropriate, a Waiver of Authorization can be granted from the PHS IRB for studies in which patients are not sought to authorize the use or disclosure of their Protected Health Information (PHI). (This application for a Waiver of Authorization is only part of the submission forms. Also required are the PHS IRB forms for Full board or Expedited review submission, the research protocol, and the data collection tools for the study).

RESEARCHER / PRINCIPAL INVESTIGATOR		Date: 1-20-10
Printed Name: Sue Ohler		
Degree(s): MSN		Institution: The Toledo Hospital
Affiliation to ProMedica Health System: Employee		
Department: Northwest Ohio Hemophilia Center		Position: Project Director of Hemophilia, Project Director of Pediatric Ambulatory, CareNet Coordinator
Mailing Address: 2150 West Central Avenue		City/State/Zip: Toledo, Ohio 43606
Phone: 419-291-7884	Pager: 419-534-8326	Fax: 419-479-3258 E-mail: Sue.Ohler@ProMedica.org

SUB-INVESTIGATORS or RESEARCH COORDINATORS (who will have access to PHI)			
Name	Degree(s)	Institution/Department & Affiliation to ProMedica Health System	Phone
Megan Kaun	PhD	Flower Hospital & University of Toledo College Pharmacy/Pharmacy/Employee	419-472-5575
Erin Taylor	BSN	Toledo Hospital/Adult Internal Medicine/Employee	419-291-8729
Dr. Monica Holiday-Goodman	PhD	University of Toledo College of Pharmacy/Pharmacy Practice	419-530-1968
Gautam Partha	N/A	University of Toledo College of Pharmacy/Graduate Student	419-530-1969
Avishek Nago	N/A	University of Toledo College of Pharmacy/Graduate Student	614-403-8607

Study Title: Clinical Outcomes Related to Diabetes, Hypertension and Mammogram Screening in Toledo Lucas County CareNet Patients

Funding Source for the study (if any): Unfunded

The HIPAA Privacy Rule [45 CFR 164 section 512(l)] requires that the following eight conditions must be satisfied in order to grant a waiver of individual authorization for research uses of PHI.

Waiver of Authorization: How does your research meet the following criteria?

- The research presents no more than minimal risk to the participants:**
 The risk involved with the study is minimal. Patient chart reviews will be conducted and there will be no patient identifiers recorded. Only demographic and clinical outcomes will be collected from the patient chart reviews.
- The waiver will not adversely affect the rights and welfare of the participants:**

Researchers will visit the performance site to do patient chart reviews. Therefore, the patient charts will not be removed from the performance sites. No patient identifier information will be collected. Confidentiality assured by HIPPA compliance training of researchers.

3. The research cannot be practicably carried out without the Waiver: (include why patients could not be consented or why the information can not be completely de-identified):

This study is a retrospective, cross-sectional study on Carenet subjects. It would be impractical to contact all patients and data is de-identified.

4. The project could not be conducted without use of PHI: (also include your sources of PHI; e.g. TTH hospital records, billing records, radiology results, etc.)

Chart and lab review required to determine outcome.

5. The privacy risks are reasonable relative to the anticipated benefits of research:

The risk involved with this study is minimal as de-identified data will be collected through patient chart reviews. Knowing the clinical outcomes of study participants can lead to the design of interventions that will improve health outcomes of all Care Net patients and also lead to improved quality of life. Also, proof of improved outcomes among their patients can facilitate grant eligibility for CareNet.

6. There is an adequate plan to protect identifiers from improper use and disclosure:

Students collecting data will go through confidentiality training assured by HIPPA compliance with the Volunteer Office at Toledo Hospital and only de-identified data will be collected.

7. There is an adequate plan to destroy the identifiers at the earliest opportunity, or justification for retaining identifiers:

Patient identifiers will not be collected as per UT's CareNet Data Collection form.

8. Investigator's Assurance:

I verify that my research team will collect only information essential to the study as described in this submission and I will not re-use or disclose protected health information to any other person or entity, except as required by law, research oversight, or those uses outlined above.

Signature of Researcher / Principal Investigator

1-20-2010
Date

Anytime you are disclosing protected health information (PHI) without patient authorization as part of a research project, you need to be tracking these disclosures. This would include reviewing a medical chart by a non-hospital employee.

If you are going to be disclosing PHI of 49 or less subjects (without their authorization), you will need to record the names of those individuals whose information has been disclosed for the research study. This list then needs to be forwarded to the Information Management Department.

If you are going to be disclosing the PHI of 50 or more subjects (without their authorization), you will need to provide the Information Management Department with the study title, principal investigator, a brief description of the study, and contact information if there are any questions.

Waiver of Authorization: How does your research meet the following criteria?

- 1. The research presents no more than minimal risk to the participants.
The risk involved with the study is minimal. Patient chart reviews will be conducted and there will be no patient identifiers recorded. Only demographic and clinical information will be collected from the patient chart reviews.*
- 2. The waiver will not adversely affect the rights and welfare of the participants.*

CareNet_Data_collection_form

D H M

	M	F						
Gender								
Age								
Race/ Ethnicity								
Height								
Weight								
Tobacco	V	X						
A1c								
BP systolic								
BP diastolic								
HDL								
LDL								
Marital_status	M	S						
Date_of_Enrollment_CareNet								
#Primary_Care_Visit_12months								
Date_Mammogram_performed								
Family_History_Breast_cancer								
Pharmacotherapy_Treatment								

Code	Race	Code	Race	Code	Marital status code
1	Alaskan Native	5	Pacific Islander	M	Married
2	American Indian	6	White	S	Single
3	Asian	7	Hispanic		
4	Black	8	Others		