A Thesis

Entitled

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

By

Gautam Partha

Submitted as partial fulfillment of the requirements for the Masters of Science Degree in Pharmaceutical Sciences, Administrative Pharmacy Option

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May 2012

An Abstract of

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Introduction: Hypertension is a chronic disease whose management has met with limited success in underserved and low-income populations. Understanding the different factors that help in meeting clinically recommended goals among members of a safety net organization can help in improving the process of care. Studying this population can also provide insight regarding some of the probable causes for lack of progress towards recommended goals.

Objective: To determine blood pressure goal attainment levels and the factors influencing them for hypertension patients in the Toledo-Lucas County CareNet population.

Methods: A retrospective, cohort study was carried out by reviewing patient charts. Eligible subjects were at least 18 years old and had to be enrolled as

CareNet members for a minimum duration of one year for the study period of 1st Jan 2003- 31st Dec 2008. Descriptive statistics were utilized to determine goal attainment. Chi square analysis was used to determine variables that had significantly different goal attainment. A binomial logit model was used to predict goal attainment. Goal attainment served as the dependent variable and was determined based on JNC-7 guidelines. Age, gender, race/ethnicity, BMI, tobacco use, number of primary care visits, and pharmacotherapy treatment were used as predictor variables.

Results: A total of 269 patients were included in the final analysis. 92 of these patients had diabetes. The overall goal attainment was found to be 42.39% in the patients with diabetes as co-morbidity and 60.45% among the members without diabetes as co-morbidity. Chi-square analysis found significant differences in goal attainment for the variables co-morbidity ($p=0.05$) and number of visits ($p<0.01$). Number of primary care visits between 6-10 times was found to significantly predict goal attainment (OR=3.705; CI: 1.670-8.218). Notable trends were observed for other variables but the effect was not found to be significant.

Conclusion: Goal attainment among CareNet members was found to be comparable to other studies and national statistics. Encouraging regular utilization of primary care services may further improve the clinical outcomes in a low-income population.

I dedicate this thesis to my parents and my late grandmother

Acknowledgements

I am extremely grateful to my major advisor, Dr. Monica Holiday- Goodman, for her constant guidance and support throughout my study at University of Toledo. I would like to express my tremendous gratitude to Dr.Sharrel Pinto, not only as an invaluable committee member, but also for all her advices and for providing me an opportunity to work in the PCOR lab. Thanks are also due to Dr.Vincent Mauro for all his helpful guidance towards this project as a committee member. I would like to thank Dr. Varun Vaidya and Prof. Robert Bechtol for all their support and guidance throughout my coursework. This project wouldn't have been possible without the help and the co-operation offered by Ms. Jan Ruma (Executive Director – CareNet) and all the staff at Promedica, Mercy St. Vincent and Toledo-Lucas County Health Department.

I sincerely thank all faculty members at University of Toledo for their constant assistance, Dr. Steven Martin (department chair) for providing me financial support, and the entire Pharmacy Practice office staff for their help throughout my master's program. I would specially acknowledge all of my fellow graduate students at the Pharmacy Health Care Administration program, who have been extremely helpful and a joy to work and study with. Finally, I would like to thank my family for their love and unconditional support which has given me confidence in pursuing all my endeavors.

Table of Contents

List of Tables

List of Figures

Chapter 1

Background

1.1 Hypertension

Hypertension (HTN) has been clinically defined as a condition of elevated blood pressure levels, both systolic and diastolic. With an ever increasing population being afflicted by the disease, it presents a major clinical and economic burden on the society.

1.2 Disease Statistics

Worldwide estimates show that as much as 1 billion individuals might be suffering from the disease and over 7.1 million deaths may be attributed to HTN.[1,2] The World Health Organization (WHO) has reported that suboptimal BP is the number one attributable risk factor for death across the world.[1] Similar to worldwide observations, HTN has been a major cause of morbidity and mortality in United States too. Almost 29% of the US population was diagnosed as being hypertensive in the years 2005-2006.[3] As the disease is nearly

asymptomatic in its early stages, a large population exists who are yet to be diagnosed with the disease.[4] Center for Disease Control and Prevention (CDC) estimates that nearly 28% of the US population are pre-hypertensive and are not being pharmacologically treated for the disease.[5] HTN has been associated with an increased risk for stroke, heart failure, myocardial infarction, and other serious cardiovascular and renal diseases. This risk is described as continuous, consistent and independent of other risk factors.[6] The combined effect of all these factors causes the economic burden to increase dramatically and was estimated to be $73.4 billion in 2009.[7] Healthy People 2010 identified the dangers posed by the disease and set a goal of 50 percent of patients reaching control figures (<140/90 mmHg or <130/80 mmHg) by 2010.[8]

1.3 Treatment Guidelines

Treatment of HTN has been governed by the widely accepted guidelines issued by the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC). The seventh report was issued by JNC in December 2003 and is commonly referred to as JNC-7. It defines normal blood pressure to be <120/80 mm Hg, where the former figure refers to the systolic blood pressure (SBP) and the latter to the diastolic blood pressure (DBP). These figures have been based on epidemiologic data and not on outcomes of any clinical trials.[9] JNC-7 introduced the category of pre-hypertensives and

individuals who had SBP value between 120-139 and DBP of 80-89 were included in this category. These patients are said to have a higher risk of eventually progressing into hypertension and this risk is stated to be twice that of people who are normotensives (blood pressure values <120/80 mm Hg).[10] The pre-hypertensive groups of patients are not required to have pharmacological treatment but are recommended lifestyle modifications for improving their BP levels. Patients are said to be in Stage 1 hypertension if they have SBP of 140-159 and DBP of 90-99. These patients are recommended to undergo pharmacological treatment. Thiazide diuretics are usually the first line of therapy. Other drugs and combinations may be given on an as needed basis. Stage 2 HTN patients have SBP values equal to or greater than 160 and DBP values greater than 100. These patients require an intensive therapy regimen of at least two drugs in most cases. The first line therapy of thiazide diuretics is usually combined with angiotensin converting enzyme (ACE) inhibitors, angiotensin receptor blockers (ARBs), beta blockers or calcium channel blockers. The pharmacological therapy is coupled with lifestyle modifications for both Stage 1 and Stage 2 HTN patients.

Such intensive treatments have been based on the benefits arising from various clinical trials. It has been shown that antihypertensive therapy has led to 35 to 40 percent reduction in incidences of stroke, 20 to 25 percent reduction of myocardial infarction and more than 50 percent reduction of heart failure cases.[11] Treatment leading to sustained reduction of 12 mmHg in SBP over one year has

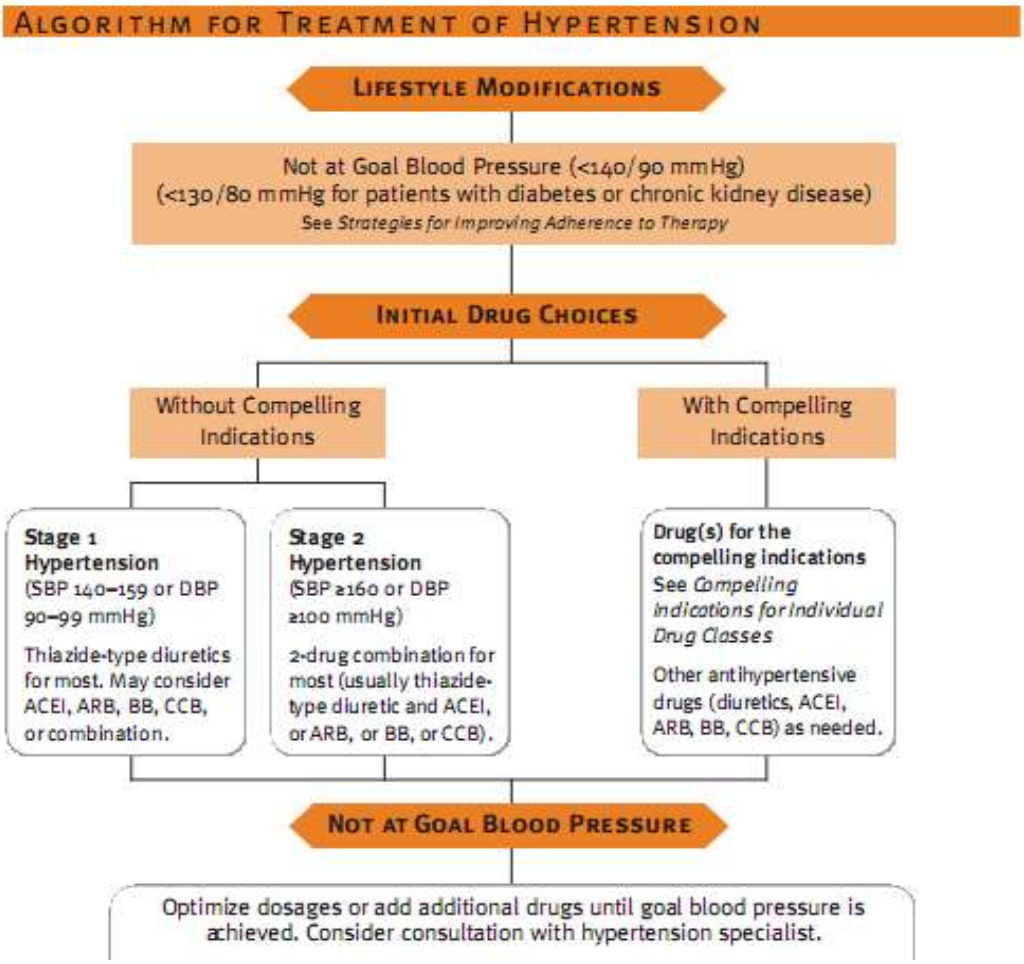
been estimated to prevent one death for every eleven patients suffering from Stage 1 hypertension and additional cardiovascular risk factors.

Once the patient has been identified as being hypertensive, JNC recommends evaluation by using three major objectives:

1. to assess lifestyle and identify other cardiovascular risk factors or concomitant disorders that may affect prognosis and guide treatment
2. to reveal identifiable causes of high BP
3. to assess the presence or absence of target organ damage and CVD.

The ultimate goal of the therapy is a reduction in cardiovascular and renal morbidity and mortality.

The recommended guidelines vary for those hypertensive patients that also have diabetes as a co-morbid condition. Vijan et al. conducted a review of published primary trials for hypertension control in diabetics and found that by setting aggressive blood pressure goals of 135/80 mmHg, hypertensives with type 2 diabetes avoided potential long term complications.[12] Following the publication of these recommendations, JNC-7 recommended an even more aggressive blood pressure control for diabetics and those with chronic kidney disease and set the blood pressure figures of less than 130/80 mmHg as being in control.[13] The recommended pharmacotherapy for these groups though did not differ when compared to patients without diabetes (when in same stage of the disease). An outline of the recommendations is provided in Figure 1-1:



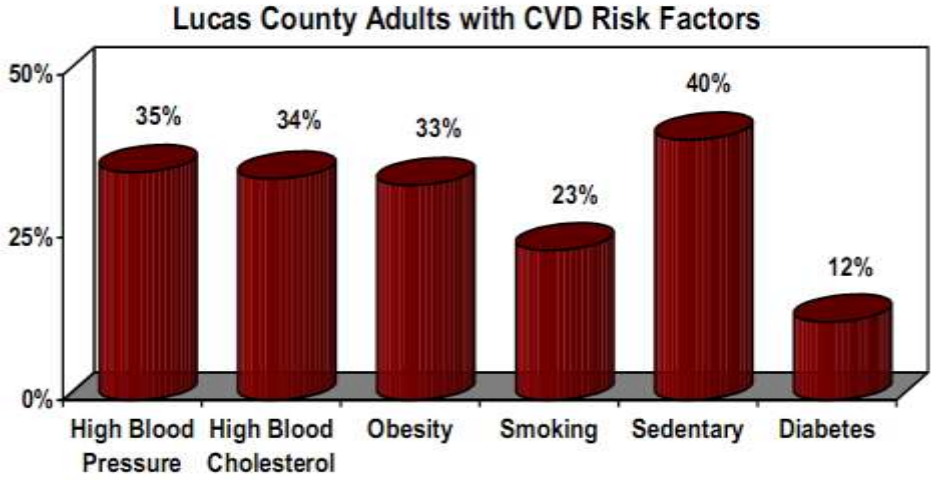
Source: Reference card for physicians from the JNC-7

Figure 1-1 Algorithm for treatment of Hypertension

1.4 CareNet

Toledo/Lucas County CareNet is a non-profit safety-net organization operative in Toledo,Ohio. A safety-net organization has been defined in literature as an organization that offers care to patients regardless of their ability to pay for services, and for which a substantial share of their patients are uninsured, Medicaid, or other vulnerable patients.[14] The need for an organization like CareNet is very important in a region like Lucas County where the number

of patients that have elevated blood pressure levels is higher than the national average. Such patients amount to 35% (Figure 1-2) in the Lucas County population, which is higher than the national average of 26% and state average of 27%.[15] Out of these, 46% of the patients have reported their income to be under $25,000. Therefore, these patients not only have a chronic condition but also may lack the resources to receive adequate and regular care.



Source: 2007 Lucas County Health Assessment

Figure 1-2 Cardiovascular risk factors among Lucas County adults

CareNet came into inception in 2003 at the behest of Mayor Jack Ford's initiative to provide access to care to the poor and the uninsured. To be a member of the organization, one has to meet certain inclusion criteria, such as being a citizen of Lucas County for at least six months and being ineligible for any other insurance or government coverage. Once a patient meets the eligibility criteria for being a part of the organization, they can gain access to primary care services being provided at various participating centers on a sliding fee scale.

Specialty care is provided by volunteer physicians on an as needed basis but may not always be guaranteed. Charges for emergency room care and daily room rates are waived, in case of hospitalization. In addition, transportation issues are taken care of by providing free bus service for medical appointments through collaboration with TARTA, the local bus service provider. Recently in 2008, the organization started a pharmacy benefits program so that members can have access to prescription drugs at reasonable rates compared to market prices.

1.5 Rationale

Since its inception in 2003, a large scale evaluation of the hypertensive population in the Toledo-Lucas County CareNet program has not been done so far. This study will help determine the current status of clinical outcomes in these patients. Identifying trends in clinical outcomes is very important for patients receiving care for chronic conditions such as hypertension. These patients can be spared severe long-term clinical and economic consequences if they are adherent to recommendations and reach established goals. Further, this study will help in characterizing the population utilizing the services. This characterization is important for the organization as it helps the caregivers in improving the process of care for the patients.

1.6 Significance

The results of the study will help CareNet in determining the progress made by their members towards goal attainment. Demonstrating improvements in clinical outcomes as a result of improved access to care is important for a chronic condition like hypertension because of the potential long-term cost savings and improved health for the patient. CareNet is an organization that is run primarily on charitable funding. Therefore, highlighting any improvement in clinical outcomes can also help them gain funding, which will help increase their reach to needy patients. CareNet can also utilize the study to characterize the hypertensive population utilizing their services which will allow caregivers to suitably tailor the care which is currently being provided. Further, the results of the study can help identify patient sub-groups that are either performing well or lagging in terms of achieving goal. Identifying these sub-groups will help CareNet to explore potential areas of improvement or in determining populations that require additional care.

1.7 Goal

To determine blood pressure goal attainment levels and the factors influencing them for hypertension patients in the CareNet population.

1.8 Objectives

1. To determine the percentage of CareNet patients with only hypertension, who attain the goals for systolic and diastolic blood pressure based on recommended guidelines.
2. To determine the percentage of hypertensive CareNet patients with diabetes as a co-morbidity, who attain the goals for systolic and diastolic blood pressure based on recommended guidelines.
3. To identify differences in patient characteristics based on their ability to attain goal.
4. To identify the effect of age, gender, race/ethnicity, BMI, tobacco use, pharmacotherapy use,co-morbidity and number of primary care visits on goal attainment in hypertensive patients.

1.9 Research Questions

1. What percentage of CareNet patients diagnosed with hypertension reached the treatment goal for systolic and diastolic blood pressure by the end of the study period?
2. What percentage of hypertensive CareNet patients with diabetes as co-morbidity reached the treatment goal for systolic and diastolic blood pressure by the end of the study period?

3. What are the differences in patient characteristics based on goal attainment?
4. What is the effect of age, gender, race/ethnicity, BMI, tobacco use, pharmacotherapy use, co-morbidity and number of primary care visits on goal attainment in hypertensive patients?

Chapter 2

Literature review

There are several factors that play a role in determining outcomes for patients with hypertension. Evidence exists in literature that points towards how each of these factors can limit the outcomes for patients that suffer from hypertension.

2.1 Effect of Lack of Insurance

Lack of insurance has been an imposing problem in this country. Over 45 million individuals were reported to lack insurance of any kind in 2008. Locally, Ohio had reported 12.9% uninsured individuals for the year 2007/08 which was close to a percentage increase for the same figure from the previous years.[16] The problem of lack of insurance is compounded by the poor health status that is characteristic of the population.

An estimated 11.4 million uninsured Americans of working age reported that they suffer from cardiovascular disease, hypertension, diabetes, hypercholesterolemia, pulmonary disease or cancer.[17] Literature has shown that not only is prevalence a problem but uninsured patients suffering from these chronic diseases also have adverse outcomes compared to their insured peers. A longitudinal epidemiological study of risk factors titled The Atherosclerosis Risk in Communities Study(ARIC) followed approximately 16,000 patients aged 45-64 who mostly belonged to minority communities. These patients reported to the investigators for at least one visit in 3 years for a total of 4 visits following their inclusion. They reported their insurance status while their cardiovascular outcomes such as incidents of myocardial infarction, stroke etc. were documented. The study findings showed that the patients that were uninsured at least once were more likely to have cardiovascular risk factors such as diabetes or hypertension.[18] The risk of mortality was also found to be higher for people who are uninsured compared to privately insured patients with stroke (a condition that has been shown to be of increased prevalence in hypertensive patients). In another study done by Mcwilliams et al, publicly available data from the Health and Retirement Study (HRS), was used to determine the mortality and prevalence of chronic conditions among similar cohorts, who differed just in their insurance status. The study focused on two major groups; while one group was privately insured, the other group lacked any form of insurance coverage. They found that a higher adjusted mortality was seen in near elderly patients

who lacked health insurance and/or had diabetes, hypertension, or heart disease. The interplay of age, presence of a chronic condition and lack of insurance was evident in this study which resulted in adverse outcomes for the patients. The problem of access to care was therefore a major issue that plagued the uninsured population.[19]Another study corroborating the statement was conducted by Ayanian et al who did a nationwide telephone survey with a sample size of over 100,000 patients between 18-64 years of age. The respondents were classified based on the duration of insurance they have had. These groups were then compared by the prevalence of chronic conditions such as hypertension and hyperlipidemia and other factors that influenced them. In this study, long-term uninsured (uninsured for greater than a year) and short-term uninsured patients were found to have lack of access to physician in times of need. The barrier was found to be majorly due to cost issues and sub-group analysis showed that this was highest for women, blacks, the unemployed and those with low incomes.[20]

Looking specifically at hypertensive patients using National Health and Nutrition Examination Surveys (NHANES) conducted from1999 through 2002, Duru et al found that people lacking any form of insurance had the lowest rate of reporting antihypertensive medication treatment.[21] Moreover, the uninsured in the study had lower odds of BP control when compared to the insured population. They reported that the lower odds are more likely to cause issues of treatment intensification rather than treatment initiation between the two

groups. The differences in outcomes seen among the uninsured and insured was particularly evident in a study done by Brooks et al. using over 6,000 patients aged 19-64 from the Framingham Heart Study (FHS). Both the insured and uninsured in this population were found to have similar levels of prevalence for hypertension and elevated LDL levels. But the proportion of uninsured patients that reached the recommended control level was lower and they had higher rates of poor health and mortality, when compared to the patients having insurance.[22]

As seen across all these studies, uninsured patients therefore not only gain access to lower amounts of health care services but this may also impact their clinical outcomes. According to national guidelines, varying levels of clinical outcomes require varying treatment and if the desired clinical outcomes are not being obtained then it requires treatment intensification. As shown in the literature, the differences in outcomes based on insurance status makes it necessary to determine how these issues influence clinical outcomes in a safety-net population like CareNet.

2.2 Programs for the uninsured

Research has shown that care directed specifically towards the uninsured population has resulted in the improvement of clinical outcomes. Stroebel et al used a chronic care model for treatment of an uninsured population in a free medical clinic where care was provided with the help of volunteer physicians.

The patients were followed up for as long as possible to a maximum period of 22 months. For all the patients that had been diagnosed with hypertension, 64% improved at least a stage at the end of the study period.[23]Another study that utilized elements of a chronic care model was carried out at a Geriatric Ambulatory Practice at Boston Medical Center, which is Boston's safety net hospital. The study focused on diabetes and cardiovascular diseases and on patients aged greater than 65. A significant improvement in clinical measures was seen for all disease states and was found to be independent of frequency of the visits.[24] Mcwilliams et al followed the basic clinical services utilization of a group of elderly adults aged 60-64 who did not have any or continuous insurance coverage and who later became eligible for Medicare. The hypertensive population in this study had a significant increase in the utilization of cholesterol screening services after gaining Medicare coverage.[25] Although clinical outcomes were not measured in this study, the results show the benefits that hypertensive individuals with greater cardiovascular risk can gain.

Not all programs directed towards uninsured have been successful in improving the clinical outcomes. Landon et al conducted a study aimed at assessing the impact of the Health Disparities Collaboratives as a part of the US Health Resources and Services Administration (HRSA) community health centers. The program was designed to improve care in community health centers which serve mostly the uninsured, minority and the low-income group population. While improvement in other disease states was observed, they found

that quality of care and clinical outcomes did not improve for hypertensive patients at the sites that received the intervention.[26]

2.3 Effect of Race/Ethnicity

Understanding the race/ethnicity related disparities in clinical outcomes is especially important when trying to determine the effectiveness of a safety-net because minorities tend to be major users of these services. Findings from a national ambulatory care settings survey showed that over 65% of the patients treated in urban safety net ambulatory care settings are members of ethnic minority communities.[27] This high percentage may also be likely due to the fact that minority populations are more likely to be uninsured than whites.[28]

Race/ethnicity has been found to influence the clinical outcomes for hypertension patients. Hypertension in African-Americans has been characterized by an earlier onset, greater prevalence, harder to control, and leads to far more end-organ damage compared to their white counterparts.[29]In a study by Davis et al, hypertension was found to cause four to five times greater potentially preventable hospitalizations in African-Americans compared to whites.[30]In another study by Baumann et al, medical records were reviewed for an urban community health center and the researchers found that a disproportionately lower number of African-Americans were able to lower their systolic and diastolic blood pressures below the guideline specified hypertensive

values.[31] The study shows that even in presence of access to care, disparities might be evidenced in the form of clinical outcomes.

2.4 Effect of other variables

There are many environmental, genetic and lifestyle choices that effect the clinical outcomes for a hypertensive patient. Several well-known epidemiological studies have identified risk factors for hypertension. One such major study was conducted in Framingham, Massachusetts and is known as the Framingham Heart Study. Some major findings of the study points toward the role of gender, weight gain and elevated cholesterol levels as some indicators of clinical outcomes. Men have been found to be more likely to have elevated blood pressure levels compared to females. A 10% gain in relative weight has been found to increase the systolic blood pressure levels by 6.5 mmHg.[32] In a study done in a population of minority youth, SBP was found to be significantly greater in obese patients compared with the lean controls.[33] The role of smoking in elevating the blood pressure levels has also been well documented in literature. In one of the earlier studies, Regalado et al demonstrated that smoking should be avoided in any hypertensive patient because it can markedly increase the risk of secondary cardiovascular complications and enhance the progression of renal insufficiency.[34] Therefore, clinical outcomes for hypertension are also influenced by the patient's physical state and the lifestyle habits that he/she is following.

2.5 Summary

The management of chronic diseases needs attention in low income, uninsured populations because they are more prone to adverse health outcomes.[18] Safety net organizations have been providing care to uninsured, low-income populations and have been found to provide good quality care in various disease conditions.[35,36]The management of hypertension, a major chronic disease has been met with limited success. Analyzing the trends in goal attainment of safety net organizations is therefore warranted to ensure proper management and determining focus on needy sub-groups within the population.

Chapter 3

Methods

3.1 Study Design

The study is a retrospective, cohort study carried out by reviewing patient charts.

3.2 Study Subjects and Settings

The subjects for this study were patients who had been enrolled in Toledo-Lucas County CareNet. They would have utilized primary care services at the clinics of participating sites i.e. Lucas County Health Department, Mercy Health Partners and Promedica. Since its inception, there have been an estimated 16,000 CareNet members. As the exact number of patients with hypertension was not known, while determining the sample size, the proportion of hypertension patients seen in an earlier, smaller-scale study done by CareNet was used. Based on that estimate, to make the study generalizable to all CareNet enrollees, it was determined that patient chart review should be carried out for 712 CareNet patients.[37] As the study involved the use of human subjects, an approval from

the Institutional Review Board (IRB) was required from the University of Toledo, Mercy Health Systems and Promedica. In the absence of any formal IRB for the Lucas County Health department, formal approval to get access to the patient charts was obtained from the Director of the organization.

3.3 Inclusion Criteria

The subjects were male and female adults aged 18 years or older who have been diagnosed with hypertension with or without any co-morbid condition. They needed to be enrolled in the program for at least a duration of 12 months between the study period of January 1st, 2003 to December 31st,2008.

3.4 Exclusion Criteria

Subjects not meeting the inclusion criteria were excluded from the study.

3.5 Data Collection

Patient chart reviews were conducted at clinics of The Lucas County Health Department, Mercy Health Partners and Promedica. Chart reviews were done for one clinic each from Lucas County Health Department and Promedica, while three clinics of Mercy Health Partners participated. These clinics were chosen on the evidence that the major volume of CareNet patients visit them. A data collection form, which had been approved by each health system, was used to collect data. No patient identifier information was collected. As the study was done in concurrence with other studies that were looking at different goals and

objectives for different disease states, the data collection form contained several variables that were eventually not used for this particular study.

Once the approval was obtained from each individual organization, the data collection process was initiated at the Promedica clinic in February 2010 followed by chart reviews at Lucas County Health Department and Mercy Health Partners. The researcher requested an approximated number of patient charts from each site based on the volume of CareNet patients that each clinic receives. The data collection process varied based on the individual health system as described below.

3.5.1 Promedica

Staff at the Promedica clinic gave the researcher access to the patient charts and a list of CareNet patients that met the inclusion criteria for the study. As the charts might be not present on the day of chart review, due to prior patient appointments or other related issues, the researcher was required to request another list, if the desired number of charts was not met from the first round of chart review. As the desired numbers of charts were reviewed during the first round of chart review, no further lists were requested.

3.5.2 Toledo Lucas County Health Department

As identifying specific patients that met the inclusion criteria for the study was not possible at this site, a list of all the patients that were enrolled in CareNet was provided to the researcher by the staff. The researcher went through the patient charts for all CareNet patients and scanned each chart to determine if they met the inclusion criteria or not. If the CareNet patient met the inclusion criteria, his/her patient chart was kept in a separate pile for data extraction. This process was continued until the required number of patient charts were reviewed.

3.5.3 Mercy Health Partners

Mercy has a centralized database of patient appointments which contains information such as age, sex, ICD-9 codes, race/ethnicity etc. Therefore, the researcher used this tool to identify CareNet patients that met the inclusion criteria, before starting the patient chart review. A list of these patients was created and provided to the onsite staff, who then provided the charts, if available, for the data extraction process. The process was carried on until the desired numbers of patient charts were reviewed.

The entire data were compiled together and arranged based on the health system. Every subject was provided a unique study ID during the data collection process. This study ID was used to consolidate the data and enter them into Microsoft Excel. After suitable cleaning of the data in Excel, the data were further

imported into SPSS for all the analysis. During the entire process, only the researcher and the principal investigator had access to the de-identified data.

3.6 Data Analysis

Descriptive analysis was used for characterizing the study population and to determine how many patients fell into the category of being at goal and not being at goal when they start in the program and the last recorded time-point. Another analysis was run to determine how many patients reached goal anytime during the program to identify those patients that may have reverted back to out of control, after reaching control at some point. A chi square analysis was used for answering the second research question to identify within group differences based on categorical study variables and to determine if belonging to a certain group had an effect on goal attainment. A binomial logistic regression was used to answer the third research question. Attainment of clinical goal served as the dependent variable while age, gender, race/ethnicity, BMI, tobacco use, number of primary care visits, and pharmacotherapy treatment were used as predictor variables.

Chapter 4

Results

This chapter describes the results obtained in the study. The results section is broken down into descriptive results, chi-square analysis results , and binomial logistic regression results. The descriptive results will correspond to research objective one. Exploring differences using chi-square analysis results will correspond to research objective two, and predicting goal attainment using regression results will also correspond to research objective three.

4.1 Demographic Characteristics

The total number of hypertensive patients that were found in the patient chart review was 301. The majority of these patients came from Promedica Health Systems (n=126), followed by Mercy (n=110) and Toledo/Lucas County Health Department (n=65). Out of the 301 patients that met the inclusion criteria, 269 were eventually included in the analysis due to the presence of relevant clinical values noted in the chart.

The following is the breakdown of the demographic characteristics for the entire population. As not all variables might have been documented in the patients' charts, therefore, the individual sample sizes for each variables may not equal the overall sample size of 269. For example, gender could only be determined for 264 patients as this information was missing in 5 of the patient charts. In Table 4.1 below, the number in brackets for each variable therefore indicates the actual sample size for the variable.

Table 4.1 Demographic characteristics for patients with hypertension and co-morbid condition in the CareNet population

PATIENT CHARACTERISTICS	**n**	%
CO-MORBIDITY	(269)	100
Present	92	34.2
Absent	177	65.8
GENDER	(264)	100
Male	122	46.2
Female	142	53.8
AGE	(262)	100
<=40	30	11.2
40-49	86	32.0
50-59	112	41.6

>60	34	12.6
RACE/ETHNICITY	(238)	100
White	73	30.7
African American	119	50.0
Asian	30	12.6
Others	16	6.7
TOBBACO USE	(195)	100
Yes	106	54.4
No	89	45.6
NO.OF VISITS	(269)	100
1-5	125	46.47
6-10	91	33.83
11-15	31	11.52
>15	22	8.18
BMI	(131)	100
Underweight = <18.5	2	1.5
Normal weight = 18.5–24.9	20	15.3
Overweight = 25–29.9	30	22.9
Obesity = BMI of 30 or greater	79	60.3
PHARMACOTHERAPY	(269)	100

No medications	123	45.7
Monotherapy	54	20.1
Multiple medications	92	34.2

As national guidelines for attaining goal differ based on the co-morbidity state of the patient, the overall population groups were broken down into two based on whether they had diabetes as a co-morbid condition or they did not have diabetes as a co-morbid condition. The former group was comprised of 105 patients and the latter group was comprised of 196 patients. The two groups were then analyzed to determine goal attainment.

4.2 Descriptive Analysis

4.2.1 Goal attainment for overall blood pressure: Patients with diabetes

There were 105 patients in the overall population that had diabetes as a co-morbid condition. For this group it was required that they attain the clinical values of less than 130/80 mmHg to be considered to be at goal. Of these 105 patients, 92 (87.6%) had their clinical values documented which could be used for analysis. This group was further broken down into patients that were already at goal to begin with (n=31, 33.69%) and patients that were not at goal at baseline in the study (n=61, 66.31%). Figure 1 details the goal attainment for these two groups.

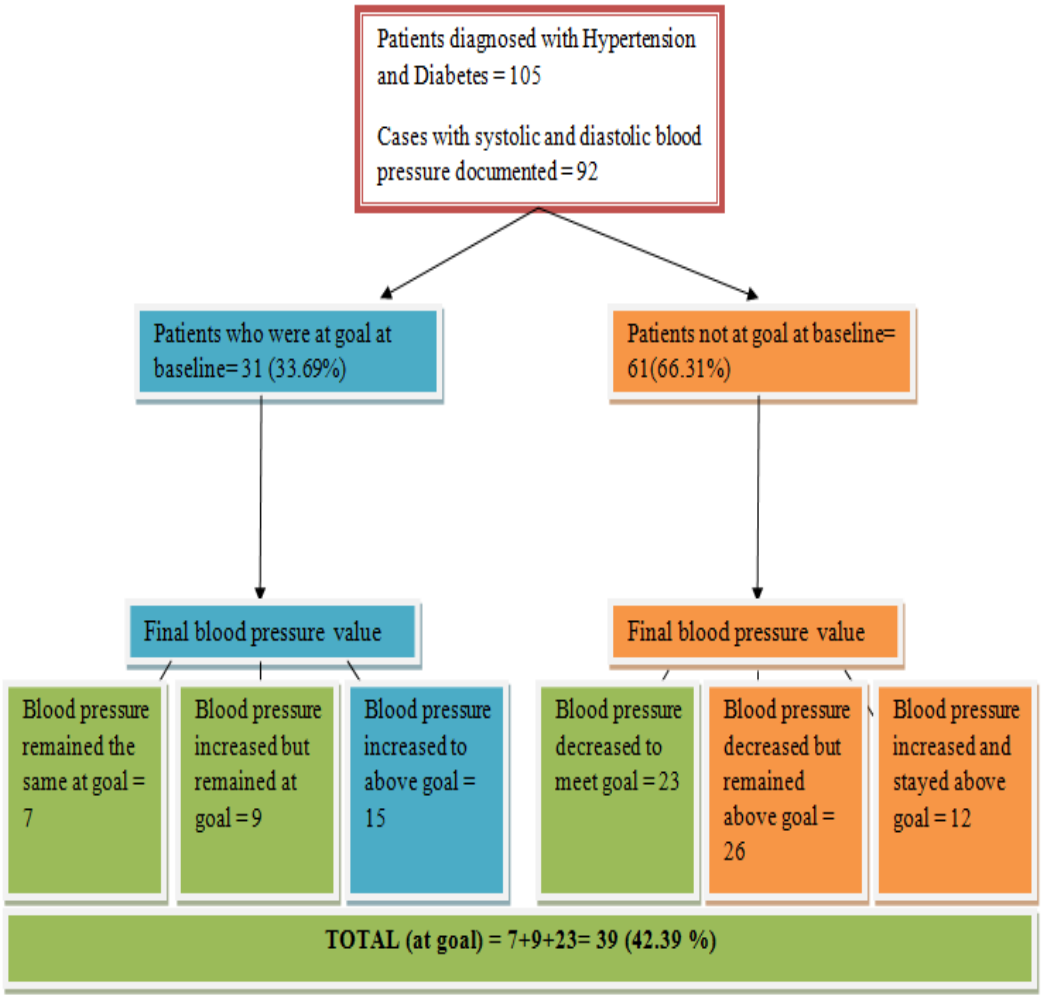


Figure 4-1 Goal attainment for CareNet patients having diabetes as co-morbid conditions

To determine the changes in clinical outcomes over the entire duration of the study period, a line graph was drawn. The mean value of systolic and diastolic blood pressure for all the participants that completed a particular visit were plotted on the x-axis vs. the visit number on y-axis. Therefore, if 200 patients had documented values on their first visit, the means of their systolic

and/or diastolic values were plotted against the first visit point on y-axis. Figure 4-2 shows this data.

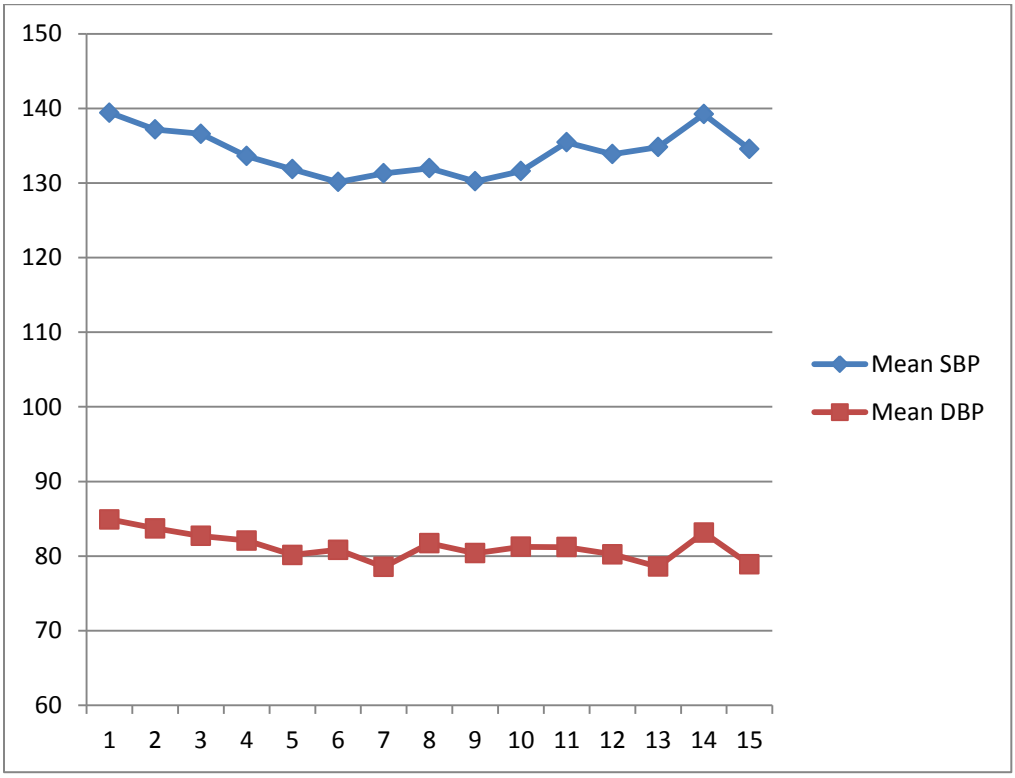


Figure 4-2 Trend of change in systolic and diastolic blood pressure values at each visit for CareNet patients

An analysis was also run to determine if the patients attained goal anytime during the study period. The average value of systolic and diastolic blood pressure for all the participants that completed a particular visit were plotted on y-axis vs. the visit number on y-axis. Therefore, if 200 patients had documented values on their first visit, the average of their systolic and/or diastolic values were plotted against the first visit point on y-axis.Therefore, it might have happened that patients attained goal after the first few visits but later

on, they might have regressed back to values that were out of goal range. It was found that 69 or 65.7% of patients managed to meet goal at some point during the study period. The number of patients that met goal at any point during the study period was higher than the number of patients that were at goal by the end of the study period by almost 25%.

Table 4.2 Goal attainment anytime during the study period for patients with diabetes as co-morbid condition

	Frequency	Percent
Patients attaining Goal	69	65.7
Patients not attaining Goal	36	34.3
Total	105	100.0

4.2.2 Goal attainment for overall blood pressure: Patients without diabetes

Among the patients who did not have diabetes as a co-morbid condition, the guidelines recommend a value of less than 120/80 mmHg to be considered at goal. When compared to the group that had diabetes, this group of patients had a greater proportion of patients that were within control range to begin with (n=117, 66.10%). Of these 117 patients, 77 patients were able to maintain their clinical values and remain at goal at their final recorded value in the study. A small group of these patients had an increase in their clinical values (n=10), but

were still at goal when their final clinical markers were evaluated. Of those patients that were not at goal at baseline (n=60, 33.90%), 50% (n=30) attained goal by the final point of clinical measurement. Overall, desired outcomes in this group were achieved by 107 patients or 60.45% of the group that was followed. The breakdown is represented diagrammatically in Figure 4-3 below.

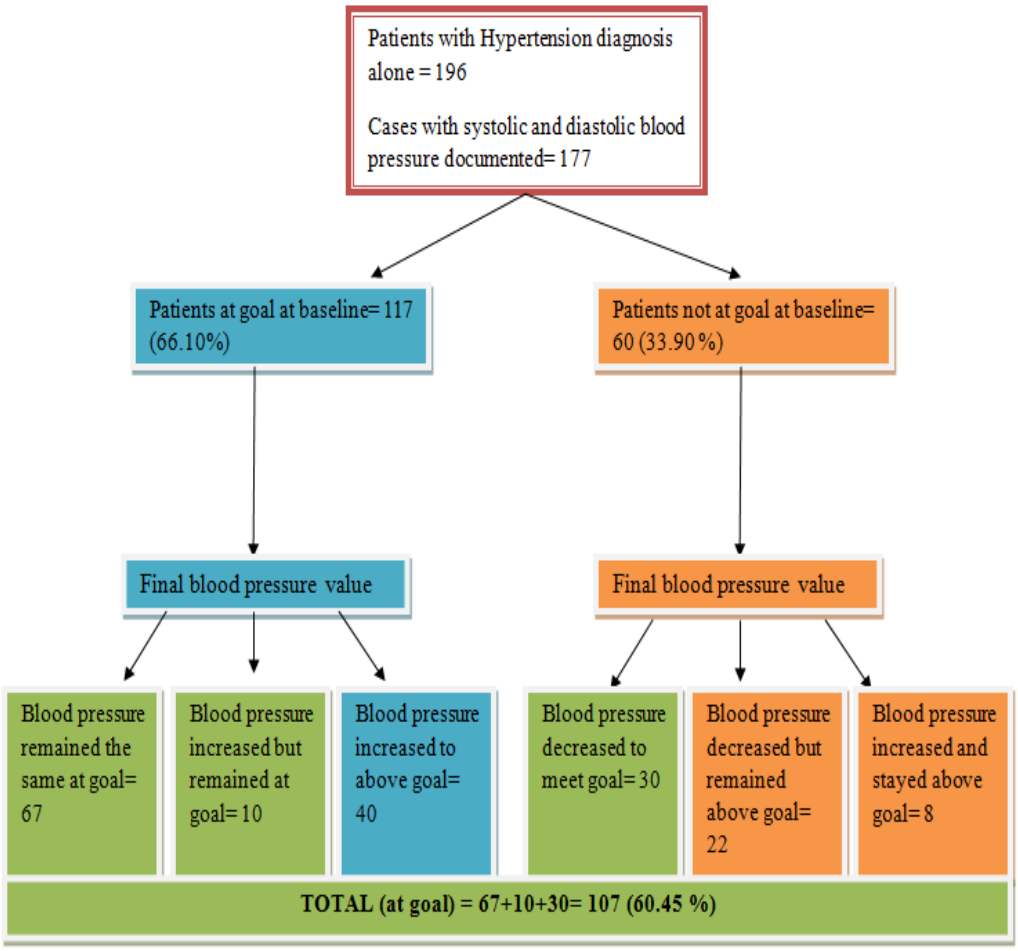


Figure 4-3 Goal attainment for CareNet patients not having diabetes as co-morbid condition

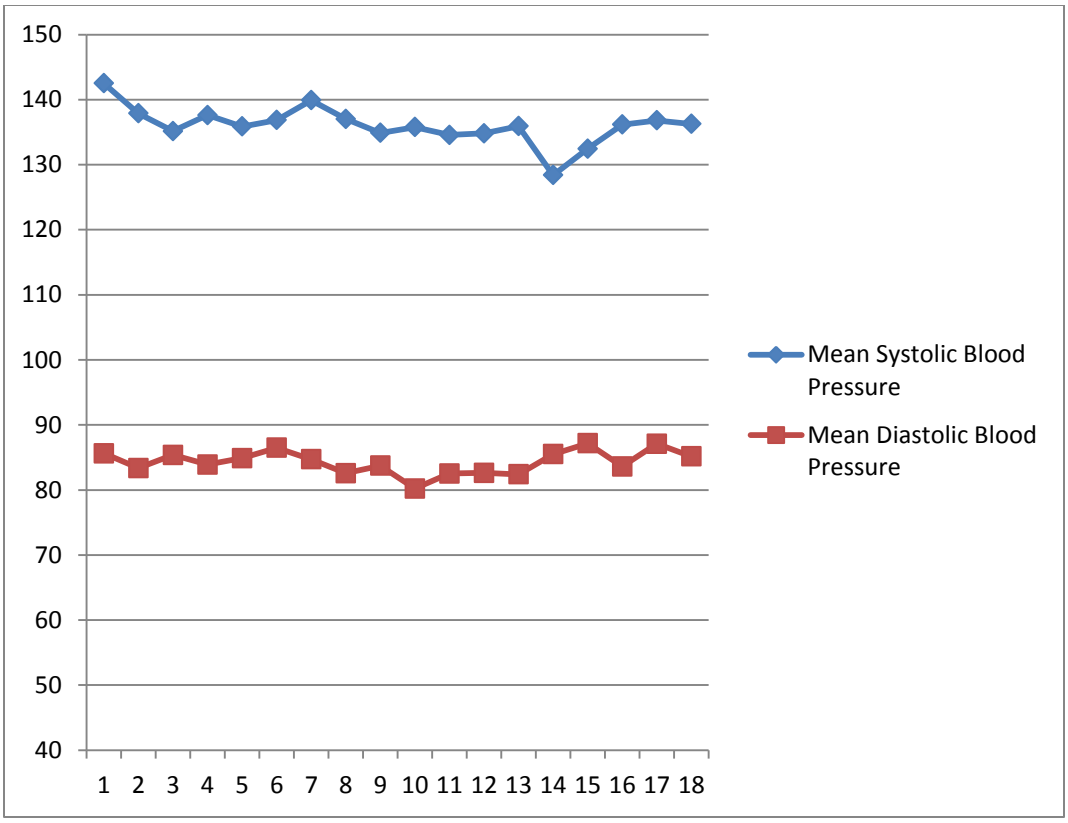


Figure 4-4 Trend of change in systolic and diastolic blood pressure values at each visit for CareNet patients without diabetes

A similar analysis as before was run to determine the number of patients that managed to attain goal anytime during the program. It was found that 155 patients or 79.1% of the patients were able to attain goal anytime during the program. This number was higher by 18.6% compared to the total number of patients that were at goal by the end of the program.

Table 4.3 Goal attainment anytime during the study period for patients without diabetes as co-morbid condition

	Frequency	Percent
Patients attaining Goal	155	79.1
Patients not attaining Goal	41	20.9
Total	196	100.0

4.3 Chi-Square Analysis

A chi-square analysis was run to determine whether goal attainment differed according to the study variables for all the study variables that were categorical in nature. If there are significant within group differences, the chi-square value would show statistical significance, as determined by the p-value of 0.05 or lower.

The chi-square analysis showed that co-morbidity level ($p<0.05$) and numbers of visits ($p<0.05$) were two variables that had statistically significant differences in goal attainment. The patients that did not have a co-morbid condition were more likely to attain goal than the patients that had a co-morbid condition. Similarly, patients who had fewer visits differed significantly from patients who had more number of visits in regard to goal attainment. The results of the chi-square analysis are presented below in Table 4.4.

Table 4.4 Chi-Square analysis to determine difference in goal attainment according to the study variables

PATIENT CHARACTERISTICS	**GOAL ATTAINMENT**		**P value**
	YES (%)	**NO (%)**	
CO-MORBIDITY	n (100%) = 269		
Present	60 (22.30)	32 (11.90)	**0.05**
Absent	95 (35.31)	82 (30.48)	
GENDER	n (100%) = 264		
Male	68 (25.75)	54 (20.45)	0.42
Female	85 (32.20)	57 (21.60)	
AGE	n (100%) = 262		
<=40	22 (8.40)	18 (6.87)	0.34
40-49	46 (17.56)	30 (11.45)	
50-59	62 (23.66)	50 (19.08)	
>=60	22 (8.40)	12 (4.58)	
RACE/ETHNICITY	n (100%) = 238		
White	46 (19.33)	27 (11.35)	0.46
African-American	66 (27.73)	53 (22.27)	
Asian	19 (7.98)	11 (4.62)	
Others	7 (2.94)	9 (3.78)	
TOBBACO USE	n (100%) = 195		

Yes	58 (29.74)	48 (13.33)	0.15
No	59 (30.26)	30 (21.33)	
NO.OF VISITS	n (100%) = 269		
1-5	58 (21.56)	67 (24.91)	**0.003**
6-10	65 (24.16)	26 (9.66)	
11-15	18 (6.70)	13 (4.83)	
>15	14 (5.20)	8 (2.97)	
BMI	n (100%) = 131		
Underweight = <18.5	1 (0.08)	1 (0.08)	0.91
Normal weight = 18.5–24.9	14 (11.02)	6 (4.72)	
Overweight = 25–29.9	18 (14.17)	12 (8.66)	
Obese= ≥ 30	49 (37.80)	30 (22.05)	
PHARMACOTHERAPY	n (100%) = 269		
None	65 (24.16)	58 (21.56)	0.28
Monotherapy	35 (13.02)	19 (7.06)	
Multiple Medications	55 (20.45)	37 (13.75)	

Statistically significant p-values are presented in bold.

4.4 Regression Anlaysis

A logistic regression was carried out to determine the factors that influence goal attainment among the CareNet population. Logistic regression

calculated the odds of the primary outcome of interest (goal attainment). An enter method was used for entering variables and all variables were entered together into the model. The variable "Baseline BMI" was not used for the final estimation as Wald scores were highly non-significant and therefore, the variable was not found to contribute to improving the fit of the model. The results of the logistic regression are presented here as Odds Ratio (OR) with a 95% Confidence Interval (CI). Odds ratio are interpreted as the likelihood of a variable category to have an event (goal attainment here), when compared to the reference category. The results of the regression output are presented below in Table 4.5

Table 4.5 Binomial logistic regression to predict goal attainment

Variable	Reference Category	Odds Ratio	95% Confidence Interval		Sig.
Co-Morbidity					
Absent	Present	1.894	.878	4.086	0.104
Gender					
Females	Males	1.572	.789	3.131	0.198
Tobacco					
Users	Non-Users	0.592	0.296	1.185	0.592
Age					
40-49	<40	1.143	0.396	3.303	0.805
50-59		0.821	0.300	2.249	0.701
>60		1.397	0.375	5.196	0.618
Race/Ethnicity					
African-American	Whites	0.705	0.316	1.573	0.393
Asian		0.621	0.200	1.932	0.410
Others		0.341	0.077	1.506	0.156
Pharmacotherapy					
Monotherapy	None	1.248	0.457	3.407	0.665
Multiple Therapy		1.548	0.702	3.415	0.279
Number of Visits					

6-10	1-5	3.705	1.670	8.218	**0.001**
11-15		1.098	0.367	3.281	0.867
>15		2.032	0.630	6.552	0.235

c-statistic: 0.661

Table 4.6 Goodness of Fit test for the model: Hosmer and Lemeshow test

Chi-square	df	Sig.
6.276	8	.616

df= Degree of Freedom

The inferential goodness-of-fit was determined through the Hosmer and Lemeshow test and was found to yield a $\chi^2(8)$ of 6.276 and was not significant (p=0.616). A non-significant result of the test shows that the model was fit to the data well.[38]

The odds of attaining goal differed based on individual variables in the model. All individual variables were found to be non-significant predictors except the variable category "6-10 visits to the physician". Patients without any co-morbidity present along with hypertension were almost two times likely to attain their blood pressure goals (OR=1.895, CI=0.878-4.086).

Females compared to males were found to have higher odds of attaining goal (OR=1.572, CI=0.789-3.131). Participants that reported tobacco use were found to have lower likelihood of attaining goal when compared to their counterparts who did not consume tobacco (OR=0.592, CI=0.296-1.185). Age wise

distribution showed an uneven pattern of odds of attaining blood pressure goals. When compared to patients aged less than 40 years, patients between the ages of 40-49 (OR=1.143, CI=0.396-3.303) and those aged 60 and over (OR=1.397, CI=0.375-5.196) were found to have higher odds of reaching goal. Whereas those patients that were between 50-59 years of age were found to have lower odds (OR=0.821, CI=0.300-2.249). Goal attainment likelihood was found to vary in study participants based on the race/ethnicity groups that they belonged. African-American (OR=0.705, CI=0.316-1.573), Asians (OR=0.621, CI=0.200-1.932) and others (OR=0.341, CI=0.077-1.506), were all found to have lower odds of attaining goal when compared to the Whites. For the type of pharmacotherapy, the likelihood of attaining goal was found to increase as the number of hypertensive medications they were on increased. Those on monotherapy (OR=1.248, CI=0.457-3.407) and multiple therapy (OR=1.548, CI=0.702-3.415) were more likely to reach goal when compared to those patients who were not taking any medication for controlling their hypertension. Based on the number of visits to the physicians, those who visited 6-10 times during the course of their enrollment were almost 4 times more likely to reach goal (OR=3.705, CI=1.670-8.218) when compared to those who came in just 1-5 times. Those who came in 11-15 times had nearly comparable odds of reaching goal (OR=1.098, CI=0.367-3.281), while those who had greater than 15 visits were more than two times likely to attain goal (OR=2.032, CI=0.630-6.552).

The overall assessment of the predicted probabilities was determined by the c-statistic which was found to be 0.661 i.e. the model was found to correctly predict the outcomes in 66.1% of the cases.

4.5 Summary

The overall goal attainment in the CareNet population was found to be 42.39% in the patients with diabetes as co-morbidity and 60.45% among the members without diabetes as co-morbidity. It was also found that a higher percentage of patients were able to attain goal but regressed back to above goal values by the time their last readings were taken. Among the study variables, co-morbidity and number of visits were found to have a statistically significant effect on the chance of attaining goal in the study population. Goal attainment was lower among the patients who had co-morbidity and among those who had a lower number of visits. The goal attainment frequency was highest among the patients with 6-10 visits to the provider.

The results of the regression model revealed notable trends in the study population. Among all the predictor variables, only the 6-10 visits strata of the number of visits variable was found to be a statistically significant predictor of the goal attainment.

Chapter 5

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, implications of the findings, study limitations, future research and conclusion.

5.1 Goal attainment among CareNet patients and effect of co-morbidity and number of visits

The goal attainment among CareNet members in this study was found to be 60.45% among hypertensive patients and 42.39% among the diabetic hypertensive. The overall goal attainment among CareNet population therefore stood at 51.42%. These figures are slightly higher than the desired objective of 50% that has been set by Healthy People 2010 for the entire US population.[8] Studies done using nationally representative samples have also looked at the magnitude of goal attainment in the hypertensive population. One such study found that goal attainment stood at 34% during 1999-2000, while the most recent

NHANES statistic puts the control rate as 50%.[39,40]The goal attainment in real-world settings have been reported to range from 51.6%-60.5% in hypertensive patients.[41]While figures from the previously mentioned studies are nationally representative of the hypertensive population, in a study done by Eisert et al., the authors specifically looked at how well the patients in an urban safety net operated by Denver Health reached control.[42] Using the data for over 1,500 hypertensive patients, they found that 51.6% of the patients had their blood pressure under control. These figures were once again comparable to the ones seen in our population.The Healthcare Effectiveness Data and Information Set (HEDIS) is a quality assessment tool to measure the plan performance in terms of care and service and is widely used among health plans in America.[43] A comparison of the performance of CareNet patients when compared to commercial, Medicare and Medicaid plans are presented below in Fig. 5-1. As shown, the goal attainment figure in the study population was higher than everyone but the commercial plan members.

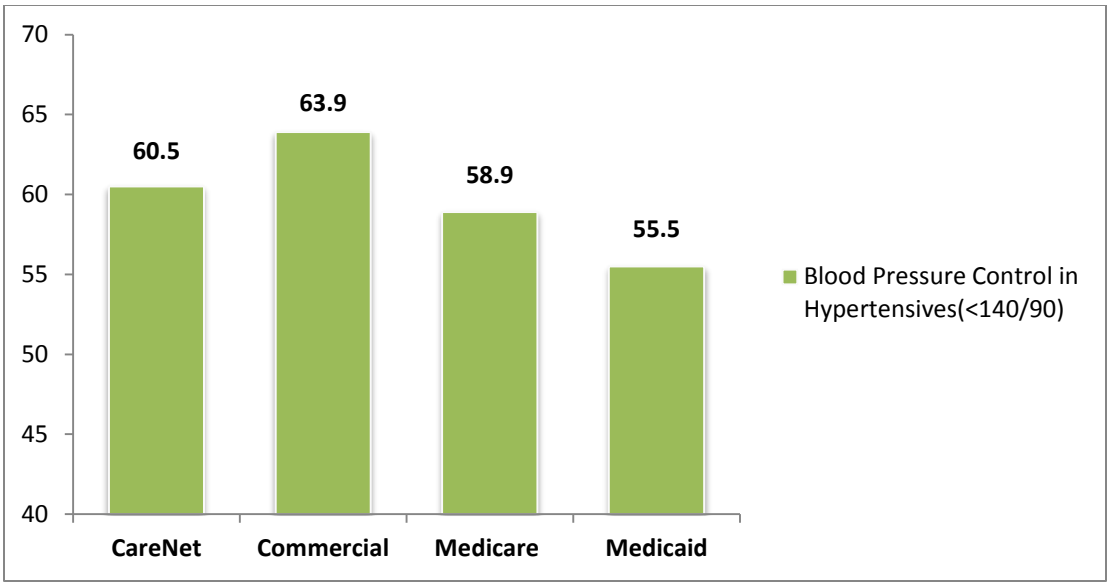


Figure 5-1 Comparison of goal attainment of hypertensive CareNet patients with Commercial, Medicare and Medicaid plans

While the patients that had only hypertension seemed to meet this figure, the patients with co-morbidity had a measure of difficulty in attaining goal. The goal attainment figures were found to be lower in magnitude than their counterparts who didn't have a co-morbid condition. The lower goal attainment seen among diabetic hypertensive patients was also on par with some of the statistics seen in the literature, when dealing with similar populations. Bell et al. reviewed the performance of 14 programs for low-income populations who suffered from or were at-risk for diabetes mellitus. This program in North Carolina was a part of Project IDEAL (Improving Diabetes Education, Access to care and Living). They found that blood pressure control was achieved by only 43.6% of the study population at the end of the three year study period.[44] Similar results were obtained in a multi-site quality improvement initiative for enrollees

of New York state Medicaid program aged 18-64 with diabetes. The percentage of patients of this initiative who had the most recent blood pressure reading of 130/80 mmHg was found to be 44.81%.[45] When the goal attainment results in our study were compared with the performance of the different health plans, it was seen that higher proportion of hypertensive CareNet members who had diabetes as their co-morbid condition reached control figures. The comparison is presented in Fig.5-2 below.

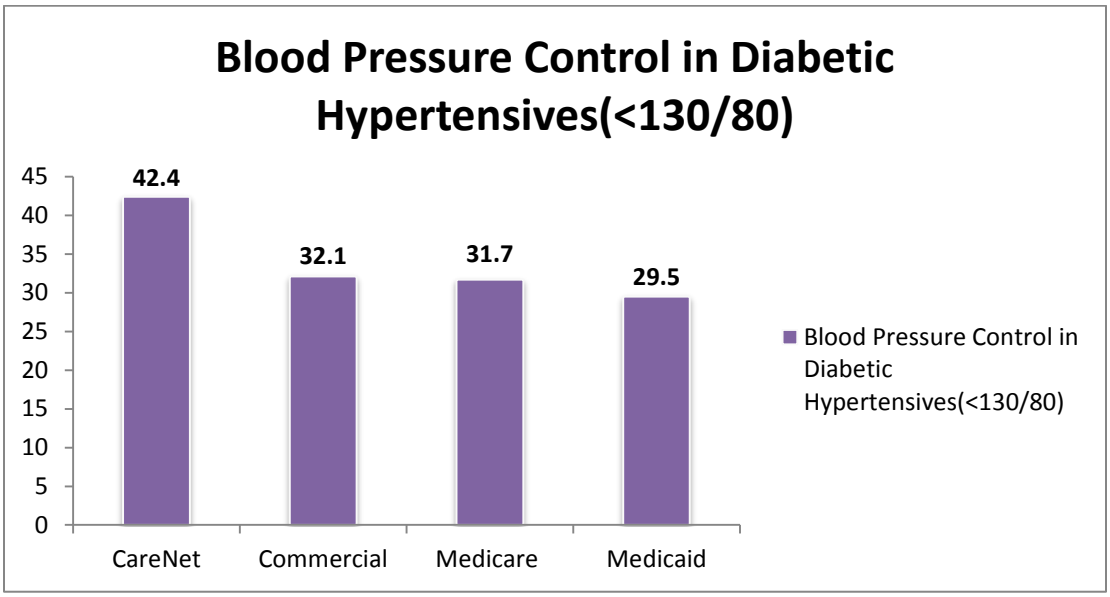


Figure 5-2 Comparison of Goal Attainment of diabetic hypertensive CareNet patients with Commercial, Medicare and Medicaid plans

Logistic regression results for the present study also showed that patients who had a co-morbid condition were less likely to attain the recommended blood pressure goals. This is despite the fact that optimal blood pressure control in patients with diabetes has been an oft suggested recommendation.[46,47]

A large scale study done in Europe called the UK prospective diabetes study (UKPDS) has even quantified the effect of lowering the blood pressure on the diabetic patients. They estimated that on average, every 10mmHg reduction in blood pressure lowers the risk of adverse end points by 12% and also decreases diabetes related mortality by 15%.[48] The difficulty that patients with co-morbid conditions have in reaching control figures may be due to several reasons. When faced with co-morbid conditions such as diabetes, it has been seen that physicians tend to give treatment of blood pressure control a low priority.[49] As a result, an increase in the number of antihypertensive medications to counter the rising blood pressure, also known as treatment intensification, by the provider might not take place and has been found to be an issue in the presence of comorbid conditions.[50,51] The problem becomes even more pronounced with the low-income population because they often tend to forego treatment in face of limited money that they have for spending on healthcare.[52] This lack of resources is maybe related to poor medication adherence in presence of co-morbid conditions but the actual effect is debatable. Some researchers have said that having a co-morbid condition is actually beneficial and specifically in hypertension might help improve the medication adherence and in other cases might help the patient receive an improved quality of care.[53,54] Other studies point towards a decrease in adherence in the hypertensive population when the number of medications they are taking goes up or if the patient comes from a low-income population.[55,56] While further research is needed to explore the

reasons, improving blood pressure control among the CareNet population is warranted.

It was also seen in our population that patients were not very regular with their visits to the physician. Ahuluwalia et al. studied low-income rural women who were afflicted with chronic conditions that increased the risk of cardiovascular abnormalities such as hypertension and hyperlipidemia. In this population, they found that hypertensive patients that had regular physician visits and care were less likely to have uncontrolled hypertension when compared to patients without regular physician care.[57] The lack of regular physician care has been a known issue among uninsured patients with chronic conditions. Blanchard et al. found this issue to cause a significant difference in success rate for scheduling appointments for hypothetical patients who differed by their insurance status. While hypothetical insured patients were able to gain appointments 70% of the time, the hypothetical uninsured patients had a success rate of a mere 13%.[58] This can explain the lack of regular care among the general population but for a safety net population, attempts should be made to improve the regularity of their physician office visits. Visiting a physician not only helps in proper management of the disease but also in suitably titrating medications in accordance to the observed changes in blood pressure, all of which may help in increasing the proportion of patients that attain goal.[6]

Another result observed in the present study that highlights the importance of having more visits to the physician was the ability of the patients

to attain control during their period of enrollment. While goal attainment in our population using the final recorded clinical value was found to be on par with the national population, the analysis to determine how many patients were actually able to reach goal anytime during the enrollment of the program revealed interesting trends. It was found that both in patients with co-morbidity and patients without co-morbidity; the percentage of patients that reached goal at some point during the study period was higher by over 15% when compared to those that were at goal at the final reading. This indicates that the patients reached goal at some time during the program but then failed to remain within the recommended control values. A potential reason for this could be poor medication adherence seen particularly among the uninsured and low-income population. Gai et al. used the Medical Expenditure Panel Survey (MEPS), a nationally representative household survey of the US population aged 18-65. They found that the individuals that had any form of insurance gap or those that remained continuously uninsured for the study duration had the lowest odds of continuing their medication.[59] Burnier also determined that poor adherence is a major issue in the hypertensive population, particularly because of the asymptomatic nature of the disease.[60]

The presence of a regular source of care as seen in safety net programs like CareNet has been shown to be helpful in improving the utilization of care. Broyles et al. using the Behavioral Risk Factor Survey (BRFSS) survey done among Oklahoma residents found that those respondents who reported the

presence of a usual source of care utilized early detection services such as blood pressure measurement and cholesterol screening more frequently than those who were without a usual source of care.[61] A similar trend of shifting from urgent care to usual source of primary care was seen among Charlottesville free clinic users. It was seen for patients who had chronic illness and were less than 65 years of age had a trend of increasing use of primary care during the first five years of initiation of the clinic.[62] This behavior of utilizing healthcare services more on obtaining a usual source of care behavior is in concordance with Anderson's behavioral model to describe utilization of services. The model states availability of physician and access to services as one of the enabling factors for patients to utilize primary care services.[63] Regular enrollment and continuing of services will therefore be more likely to aid in improvement of health of chronically ill patients.

5.2 Effect of Age, Gender, Tobacco Use, Race/ethnicity and Pharmacotherapy Use on goal attainment in CareNet patients

In the present study, when looking at gender, goal attainment was found to be more likely in females when compared to males. The national health statistics as seen in the national health interview surveys, have been reporting a trend of higher percentage of females visiting a physician during a year when compared to males.[64,65] The greater number of visits makes them more likely to get their blood pressure checked and this was actually observed in a study by

Vaidya et al. using national population estimates derived from MEPS.[66] A lower likelihood for goal attainment was also seen among people who consumed tobacco. While the effect of tobacco has been shown to be detrimental for a hypertensive patient, its use has been linked to a lower likelihood of using preventive care services such as blood pressure checks.[34,61] Age was not found to predict goal attainment in the present study and all the categories had almost similar odds with the older population having slightly better odds of goal attainment. The slightly higher odds of older people might be explained by the lowering of blood pressure that happens due to natural causes such as lowered cardiac output, which makes them more likely to attain blood pressure goals.[67,68] Siegel et al. in their study using a hypertensive population from Veteran Affairs even found that increased age increased the likelihood for better adherence in the population.[55]

African-American and Asians were both found to have lower likelihood of attaining goal when compared to the Whites. There is widespread literature showing that there are differential blood pressure outcomes for African-Americans when compared to whites.[29,69,70]Downie et al. carried out a study in North Carolina using a racially diverse and low-income Medicaid using population to identify goal attainment and potential reasons for any disparities. They found that African-Americans had much lower likelihood of attaining goal and found that disparities still existed even in presence of similar access to care, and socio-economic factors.[71] The presence of racial disparities even when

controlling for the above characteristics have been seen in other studies as well, and were also seen to exist in the present study.[72,73] Research has also been done to try and explain reasons for racial disparities existing in similar populations. Kressin et al. administered a questionnaire to users of a north-eastern urban safety-net hospital to explore factors that may influence blood pressure control. They found African-Americans were less adherent to their blood pressure medication, felt that they were discriminated against while receiving care, and had higher level of concern about the medications that they were receiving.[74] Controlling for these factors was found to eliminate differences in goal attainment. Goal attainment has also been found to be easier to achieve in the presence of strict therapy protocols. In the African American Study of Kidney Disease and Hypertension (AASK), African-American patients whose blood pressure was above goal were randomized to an aggressive multi-dose antihypertensive protocol or a single daily-dose dosing. Blood pressure goal was attained by almost 80% of the former group and 40% in the latter.[75] The study highlights the need for initiation and maintenance of therapy to achieve desired goals, especially among groups that are less likely to attain goal.

The lack of aggressive therapy was another concern among the CareNet population. Being on either monotherapy or multiple therapies increased the odds of goal attainment among the population with higher odds observed for multiple therapy population. But initiation of therapy of therapy was found to be an issue among the study population. The inability to initiate treatment when the

treatment goals are not met has been referred to as clinical inertia or therapy inertia.[76] Studies in the literature have found clinical inertia to be one of the primary reasons for inadequate BP control in the hypertensive population.[77,78] Viera et al did a study among North Carolina Medicaid recipients, who were aged 21 and above and had hypertension, to determine the association between the BP values and intensification in therapy. They found that in the cases where the BP values were above goal, initiation or intensification in therapy occurred in only 46% of cases.[79] The current study also had similar numbers with therapy not being initiated in almost 39% of the patients whose blood pressure were not at guideline recommended values. There have been several explanations given for the lack of intensification among hypertension patients. Kerr et al. and Basile have pointed out that therapy intensification is often an issue especially in the presence of co-morbidities such as diabetes.[80,81] The difficulty in goal attainment was noticeable among the CareNet population that had existing co-morbid conditions and may be potentially explained by the lack of treatment intensification. Other reasons for clinical inertia have included inadequate consultation time with the provider, lack of training among physicians, absence of adequate infrastructural support, and use of "wait until next visit" approaches to delay initiation.[81-83] While adherence has been a known issue with the low-income population, recent research has shown that intensifying therapy even in presence of suboptimal adherence may have beneficial effects on the clinical outcome of the patients.[84]

5.3 Implications of the Findings

The objectives of the study were to determine how the CareNet hypertensive population is adhering to national guidelines and to characterize the guideline adherent/non-adherent population. While the adherence to national guidelines was found to be on par or even better than those seen on national level, further analysis revealed trends in utilization that can be used to improve the performance of CareNet members.

The clinical outcome was affected mostly by the presence of co-morbidity and total number of visits to the physician. CareNet should therefore pay special attention to its members who suffer from more than one chronic condition. Physicians should be encouraged to handle all chronic conditions with an equal intensity. Models such as the 'Chronic Care Model' have been used to direct the changes needed in the health care system to improve the care for patients with chronic conditions.[85] The model encourages paying attention to treatment guidelines, and promoting the patient's role as self-manager and regular interaction with the caregiver. Regular visits to the physician were found specifically lacking in the study population. The CareNet members should therefore be advised and encouraged to visit the physician on a periodic basis, even though they might not be experiencing any symptoms. The health care provider should pay special attention in passing this message along to patients who have attained goal, as maintaining blood pressure was an issue.

As racial disparities were seen in goal attainment, extra attention may also be given to African-American patients, who often require a more aggressive therapy. Referring tobacco users to tobacco cessation programs should also be carried out and might help improve clinical outcomes. Clinical inertia and lack of initiation of therapy was another major issue for the CareNet members. CareNet should encourage its physicians to start an intensive therapy even if suspecting below par adherence, as it can still improve outcomes among patients. Besides these, a uniform documentation method across all CareNet providers can help in a better tracking of the patients' when they utilize different care sites.

5.4 Study Limitations

The present study had limitations that may have potentially reduced the precision of the results. The manner of organization of data at every health system led to varying manners of data collection and a potential increase in chance of errors while documenting data. To try and minimize these errors, the researcher verified his data entry with another investigator who was involved in the collection of data. Any differences that were observed were verified for accuracy and suitably corrected in the database that was maintained. Also, the time period for which the data was available varied from one site to another. For e.g. medical records beyond 2005 were not available for the study population at Promedica. These issues might have influenced some of the variables such as number of visits in the regression analysis. Duration between each visit or the

date of visit would have been a good resource to find out the duration between visits but Health Insurance Portability and Accountability Act of 1996 (HIPPA) regulations forbade their collection by the researcher.

5.5 Future Research

Future research in this population can explore the causes for infrequent visits to the provider especially when a known barrier of access to care is absent for these patients. The costs of health care for these patients after they join the program can also be tracked to determine how their utilization of care changes and any costs that they are being saved after they have joined the program. Research using a control group, such as non-CareNet members at the particular site, can answer questions regarding differences in care and outcomes. As many of the effects seen in this study could have been potentially explained by medication adherence issues, future research can explore medication adherence in the population.

5.6 Conclusion

The study was able to determine the goal attainment rates in CareNet members with hypertension. The goal attainment for HTN patients were found to be comparable or sometimes even better than figures seen at national level. The study was also able to determine the variables that influenced goal attainment. Co-morbidity and number of physician visits were found to have a significant effect on the ability of the study subjects to attain goal by the end of

the study period. The results can help CareNet to pay special attention to members with co-morbidity; also the organization can encourage all its members to visit their physician on a more regular basis. The organization can also use the results of this study to further improve their services and improve the clinical outcomes of their members. Future research can explore potential reasons for non-optimal utilization of services.

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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 exact order. In addition, the last page in this appendix contains the standard data collection form.

THE UNIVERSITY OF
TOLEDO
1872

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

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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
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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

ST. VINCENT
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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: 3/30/2010	IRB Number: (Assigned by RO&E)	
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: Mercy	Email: Becky_Honingford@mhsnr.org	
Department, Section, Unit: Mercy Physician Enterprise	Phone: (419) 251-2376	Pager: 419-539-0495
Address: Mercy St. Vincent Family Care Center 2213 Franklin Ave, Toledo, Oh 43608	Fax: 419-251-2393	
Contact Person: (If not the Principal Investigator) Dr. Monica Holiday-Goodman		
Institution/Organization: The University of Toledo	Email: MHolida@utnet.utoledo.edu	
Department, Section, Unit: College of Pharmacy, Pharmacy Practice.	Phone: 419-530-1968	Pager:
Address: 2801 Bancroft Toledo, Ohio 43606	Fax:	

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-SVMMC sites/sources.

Possible Sources – this is not an exhaustive list:
Billing records,
Lab, pathology, and/or radiology samples/results,
Physician/clinic records,
Questionnaires/Interviews,
Hospital/medical records (in and out patient),
Mental Health records,
PHI previously collected for research purposes,
MRI scans, X-rays, etc,
...

SVMMC 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)

PROMEDICA
HEALTH SYSTEM
Institutional Review Board (IRB)

IRB#: 1000,

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			
Printed Name: Sue Ohler			Date: 1-20-10
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(I)] 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?*

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 outcomes will be collected from the patient chart reviews.

2. **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.

_____ _____ _____ 1-20-2010
Signature of Researcher / Principal Investigator **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.