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Chronic Care Management to Improve Adherence: A Comparison of Approaches in the  
Care of Diabetes

A dissertation submitted in partial fulfillment of the requirements for the degree of  
Doctor of Philosophy at Virginia Commonwealth University

by

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## TABLE OF CONTENTS

LIST OF TABLES.....	x
LIST OF FIGURES.....	xii
ABSTRACT.....	xiii
CHAPTER 1: INTRODUCTION.....	1
Introduction to the Problem.....	1
<i>Chronic Illness</i> .....	1
<i>Diabetes</i> .....	4
Chronic Illness Management.....	5
<i>Desired Outcomes</i> .....	5
<i>Adherence</i> .....	6
<i>Disease Management</i> .....	7
<i>An Alternative Practice Model</i> .....	10
Purpose of the Research.....	11
Theoretical Framework.....	11
<i>System Level</i> .....	11
<i>Ecological Theory</i> .....	12
Research Questions.....	12
Significance of the Study.....	13

Assumptions.....	14
Definition.....	15
Summary.....	15
Organization of the Study.....	16
CHAPTER 2: LITERATURE REVIEW.....	17
Purpose Statement.....	17
Introduction.....	17
The Concept of Adherence.....	18
<i>The Significance of Adherence.....</i>	19
<i>The Significance of Adherence to Diabetes Guidelines.....</i>	19
<i>Adherence to Hemoglobin A1c Monitoring.....</i>	20
<i>Adherence to Cholesterol Screening.....</i>	21
<i>Adherence to Retinopathy Screening.....</i>	22
<i>Adherence to Nephropathy Screening.....</i>	22
Improving Adherence.....	23
Theoretical Understanding of Adherence Behaviors.....	24
Approaches to Improving Adherence.....	24
<i>Individual Level Theories of Behavior Change.....</i>	24
<i>Individual Level Approaches to Improve Adherence to</i>	
<i>Diabetes Guidelines.....</i>	27
<i>Adherence Outcomes of Individual Level Approaches.....</i>	30
<i>Limitations of Individual Level Theories and Approaches.....</i>	38

<i>A System Level Theory of Behavioral Change: Social Ecology Theory.....</i>	40
<i>A System Level Approach to Improving Adherence to Diabetes Guidelines: The Chronic Care Model.....</i>	43
Ecological Theory and the Chronic Care Model.....	45
<i>Microsystem.....</i>	46
<i>Mesosystem.....</i>	48
<i>Exosystem.....</i>	49
<i>Macrosystem.....</i>	51
Improved Adherence in the Chronic Care Model Approach.....	51
Summary.....	56
CHAPTER 3: METHODOLOGY.....	59
Purpose and Introduction.....	59
Research Design.....	59
Population of Interest and Sample.....	61
Implementation of Diabetes Management Approach by Health Plans...	62
Identification of Sample.....	64
Data.....	70
Data Organization.....	71
<i>Independent Variables.....</i>	71
<i>Dependent Variables.....</i>	74
Data Analysis.....	79



Limitations.....	81
<i>Measurement Quality</i> .....	81
<i>Design Quality</i> .....	84
Summary.....	87
CHAPTER 4: RESULTS.....	90
Health Plans.....	91
Subjects.....	92
<i>Characteristics of the Study Sample</i> .....	93
<i>Characteristics of Subjects by Approach to Chronic Care</i>	
<i>Management</i> .....	93
Adherence Differences by Approach to Chronic Care Management....	95
<i>Adherence to Cholesterol Monitoring</i> .....	95
<i>Adherence to Retinopathy Monitoring</i> .....	98
<i>Adherence to A1c Monitoring</i> .....	100
<i>Adherence to Nephropathy Monitoring</i> .....	103
Multivariate Analysis.....	106
<i>Regression Results for Adherence to LDL Monitoring</i> .....	108
<i>Regression Results for Retinopathy Monitoring</i> .....	109
<i>Regression Results for Adherence to Hemoglobin A1c</i>	
<i>Monitoring</i> .....	110
<i>Regression Results for Nephropathy Monitoring</i> .....	111
Additional Analyses.....	112

Summary.....	113
CHAPTER 5: DISCUSSION AND CONCLUSIONS.....	115
Study Summary.....	115
Overview of the Problem.....	117
Discussion of the Study.....	119
Major Findings and Implications.....	122
<i>Descriptive Differences between Participants in the</i>	
<i>Two Health Plans.....</i>	122
<i>Adherence Differences between Health Plans.....</i>	123
<i>Predictors of Adherence.....</i>	126
Suggestions for Future Research.....	131
Study Limitations.....	135
Conclusions.....	138
REFERENCES.....	140
APPENDIX A.....	162
APPENDIX B.....	164
APPENDIX C.....	167
VITA.....	169

## LIST OF TABLES

Table	Page
1. Summary of Research on the Impact of Individual Level Approaches on Improving Adherence in Patients with Diabetes.....	31
2. Link between Social Ecology Theory and the Chronic Care Model.....	47
3. Summary Data for Study Hospitals / Health Plans.....	63
4. Implementation of the Chronic Care Model based on Social Ecology Levels.....	65
5. Variables with Corresponding Data Sources.....	72
6. CPT / HCPC Codes for Recommended Screenings for Diabetes Management.....	75
7. Study Variables: Independent.....	77
8. Study Variables: Dependent.....	78
9. Summary of Threats to Research Quality.....	88
10. Sample Size.....	93
11. Individual Characteristics of Total Sample.....	94
12. Characteristics of Sample Population Based on Chronic Care Program in Which They Participate.....	95
13. LDL Adherence Results by Approach - Before.....	97
14. LDL Adherence Results by Approach - After.....	97
15. Differences in LDL Adherence from Prior to Post Program by Approach.....	98

16. Retinopathy Screening Adherence by Approach - After.....	100
17. Differences in Retinopathy Screening Adherence from Prior to Post Program.....	101
18. A1c Adherence Results by Approach - Before.....	102
19. A1c Adherence Results by Approach – After.....	103
20. Differences in A1c Screening Adherence from Prior to Post Program.....	104
21. Nephropathy Screening Adherence Results by Approach - Before.....	105
22. Nephropathy Screening Adherence Results by Approach – After.....	105
23. Differences in Nephropathy Screening Adherence from Prior to Post Program.....	107
24. Logistic Regression Results for Change in LDL Adherence.....	109
25. Logistic Regression Results for Change in Retinopathy Screening Adherence.....	110
26. Logistic Regression Results for Change in Hemoglobin A1c Adherence.....	111
27. Logistic Regression Results for Change in Nephropathy Screening Adherence.....	112
28. Hypotheses and Corresponding Results.....	124

## LIST OF FIGURES

Figure	Page
1. Depiction of the Relationship between Interventions, Intermediate and End Outcomes.....	6
2. Multilevel System Depiction of Social Ecology Application.....	42
3. Elements of the Chronic Care Model.....	45
4. Conceptual Model.....	55
5. Research Design.....	60
6. Adherence Behavior: Awareness Measure.....	77

## ABSTRACT

### CHRONIC CARE MANAGEMENT TO IMPROVE ADHERENCE: A COMPARISON OF APPROACHES IN THE CARE OF DIABETES

By Mary Ellen Gervais

A dissertation submitted in partial fulfillment of the requirements for the degree of  
Doctor of Philosophy at Virginia Commonwealth University

Virginia Commonwealth University, 2010

Director: Dolores G. Clement, Dr.P.H., Professor, Department of Health Administration

Managing chronic conditions is seen as the public health challenge of the 21<sup>st</sup> century. The number of Americans with chronic conditions is expected to rise to 157 million by 2020. Diabetes prevalence and costs contribute to the growing problem. Diabetes was the seventh leading cause of death in 2006. Nationally, the cost of diabetes is expected to be \$138 billion in 2020. Diabetes leads to multiple and significant complications.

The desired outcomes of management of chronic conditions are improvement in clinical status, avoidance of complications, prevention of co-morbid conditions and avoidance of the costs associated with complications. In the 1990s, disease management programs were implemented in an attempt to effectively manage chronic conditions.

The primary approach in these programs focuses on individual-level interventions. Despite these efforts, poor outcomes exist. As a result, other approaches to diabetes management are being explored.

This study examines a system-level approach to diabetes management versus an individual level one. The system level approach is based on full implementation of the Chronic Care Model, framed in Social Ecology Theory. This retrospective, non-experimental study explores changes in adherence to select diabetes screening guidelines based on the approach to adopted by two health plans. Analyses were conducted on adherence to LDL, A1c, retinopathy and nephropathy screening 2 ½ years after program implementation. In addition, logistic regression analyses were conducted on the predictive impact of approach to chronic care management in relation to changes in adherence. Other variables known to impact health behaviors were factored into the analysis.

There were two main findings of the study. The first is that for each of the screenings, there was a statistically significant difference between participants in the two plans. Comparisons of changes in adherence by approach from before implementation to after implementation resulted in a small number of subjects in some cells which can lead to accepting the null hypothesis when it is false. The second is that approach to management was associated with changes in adherence to three of the four screenings. The logistic models, however, account for less than 23% of the variance in adherence, a moderate effect size.

## CHAPTER 1: INTRODUCTION

“The function of protecting and developing health must rank even above that of restoring it when it is impaired.” Attributed to Hippocrates by Dr. James S. Marks (Marks, 2003).

### Introduction to the Problem

#### *Chronic Illness*

Managing chronic illnesses presents a challenge for the individuals who contend with these illnesses, employers who often carry the financial burden of these illnesses, and for federal and state governments that carry the burden for those individuals insured under Medicare and Medicaid. Chronic illnesses or conditions are those health problems that persist over a long period of time and are not easily or often not at all resolvable (National Institute of Health, 2007). The prevalence of chronic illnesses has increased and is expected to continue to increase. According to a report published by the National Institute for Health Care Management “caring for individuals with chronic conditions will be the public health challenge of the 21st century” (Anderson, 2002, p. 1). According to Anderson (2002) the number of individuals with chronic conditions is expected to rise from 105 million in 2000 to 134 million by 2020. More recent data have lead to a re-adjustment of those predictions. In 2004, more than 133 million Americans were diagnosed with a chronic illness leading to a new 2020 prediction of more than 157 million affected Americans (Anderson, 2004).



Statistics from the Centers for Disease Control (CDC) on the impact of chronic conditions are staggering:

- For Americans, chronic illnesses account for seven out of ten deaths
- Chronic conditions cause limitations in activities of daily living for one of every ten Americans
- The medical care costs associated with chronic illnesses accounted for \$1.05 trillion of the nation's \$1.4 trillion medical costs which represents 75% of all medical costs. (Centers for Disease Control and Prevention, 2009; Marks, 2003)

The personal burden of chronic illnesses includes multiple stressors. Individuals with chronic conditions contend with symptoms associated with the condition, as well as associated complications. They often suffer from pain and fear that the condition may limit their ability to live a functional life. Depression is a significant co-morbidity of chronic illness. According to a report published by the Cleveland Clinic (2003) approximately a third of individuals with chronic illnesses also suffer from depressive symptoms. The personal financial burden is also high. Individuals with chronic conditions experience higher out-of-pocket costs, and a higher proportion report difficulty paying their medical bills than those without chronic conditions (Ha, 2004).

The employer's burden is realized in both the rising costs of health insurance premiums and the loss of employee productivity. Sixty-eight percent of insured individuals with chronic conditions are covered under private health insurance (Ha, 2004). The National Coalition on Health Care [ca. 2008] reported that in 2007 the cost of

insurance premiums for employers rose to 4 times the rate of inflation, a 119% rise.

Druss, Marcus, Olfson, and Pincus (2002) reported on the most expensive medical conditions in relation to lost work days on a national level. Days lost ranged from 1.1 million for congestive heart failure to 78.2 million for mood disorders such as depression. The loss of productivity is increasingly being seen as a significant factor in calculating the total cost of chronic conditions. In a report published by the American College of Occupational and Environmental Medicine (Collins et al., 2005) absenteeism and work impairment were significantly impacted by the presence of a chronic condition: absenteeism ranged from .9 to 5.9 hours in a four-week period and productivity decreased by 17.8% to 36.4%.

The federal and state government's burden is seen in the rising costs of public health insurance programs such as Medicare and Medicaid. Medicare costs are expected to continue to rise. Medicare expenditures are expected to increase from 2.7% of gross domestic product in 2005 to 11.3% in 2080 (Center for Medicare and Medicaid Services, 2007). A Kaiser Foundation report on Medicaid and the uninsured (Smith et al., 2004) found that Medicaid enrollment increased by nearly one-third since 2001 and Medicaid spending increased overall by 9.5% in 2004. In 2006, Medicaid spending rose by only 2.8%, the smallest amount in more than 10 years (Lee, 2006). This slower growth is attributed to the implementation of Medicare Part D, which covers a higher proportion of pharmacy costs (National Governors Association and National Association of State Budget Officers, 2007). However, according to the same report, Medicaid costs continue to be a high proportion of overall state spending, representing approximately 22% of state

budgets. Chronic diseases contribute significantly to these rising costs. Eighty-three percent of Medicaid dollars and almost all Medicare dollars are spent on beneficiaries with chronic illnesses (Partnership for Solutions, 2004).

### *Diabetes*

Diabetes prevalence trends and costs have contributed to the growing problem of chronic illnesses. The number of Americans diagnosed with diabetes has more than doubled since 1990 with more than 17.9 million diagnosed in 2007 and an estimated 5.7 million more who remain undiagnosed (Centers for Disease Control and Prevention, 2009). This number is expected to increase further, doubling the 2009 numbers by 2034 (American Diabetes Association, 2009). Statistics on causes of death indicate that diabetes was the seventh leading cause of death in 2006, with the risk of death for individuals with diabetes two times as high than for those without the disease (Centers for Disease Control and Prevention, 2009). Diabetes leads to a broad range of acute and long-term complications including heart disease, stroke, hypertension, blindness, amputations, and kidney and renal failure. The CDC classified diabetes as “disabling, deadly, and on the rise in 2004” (Gerberding, 2005, p. 1).

The price tag for health care of those with diabetes is significant when compared with health care costs of the general population. According to a report by the American Association of Clinical Endocrinologists (2007) the annual direct health care costs for persons with diabetes are three times those of individuals without diabetes. Projections on cost trends indicate that the \$92 billion direct cost of diabetes in 2002 is expected to rise to \$109 billion in 2010 and \$138 billion in 2020 (Centers for Disease Control and

Prevention, 2009). The annual cost to Medicare for end stage renal disease attributable to diabetes is reported to be approximately \$63,000 per recipient (Brandle et al., 2003).

Despite efforts to control costs and the implementation of programs to address the progression of diabetes, costs continue to rise.

### Chronic Illness Management

#### *Desired Outcomes*

The primary outcomes of interest to individuals with chronic illnesses and other stakeholders are improvement in clinical status, avoidance of unnecessary complications, prevention of co-morbid conditions and consequently avoidance of the costs associated with complications and co-morbidities (Kane, Priester, & Totten, 2005). Shaughnessy, Crisler, Schlenker and Arnold (1997) classified these outcomes as end-result outcomes. Programs are implemented to impact these outcomes; however, it is sometimes difficult to draw conclusions about elements of an intervention if only end-result outcomes are evaluated (Donabedian, 1985). The concept of intermediate outcomes has been introduced to bridge the gap between interventions and improvement in health, improvement in quality of life and controlled costs. Intermediate outcomes are more closely linked to the interventions and are steps towards these end-result outcomes. Intermediate outcomes include changes in behavior related to the management of a disease (Donabedian, 2003). Adherence behaviors are the intermediate outcomes of interest in this research. Adherence behaviors are influenced by program elements and, in turn, influence desired end outcomes. As attempts are made to impact the health of individuals with chronic conditions, the earliest observed outcomes associated with

chronic care management interventions are related to adherence behaviors. Figure 1 depicts the relationship between interventions, early or direct outcomes associated with the interventions, and longer term outcomes associated with the interventions.

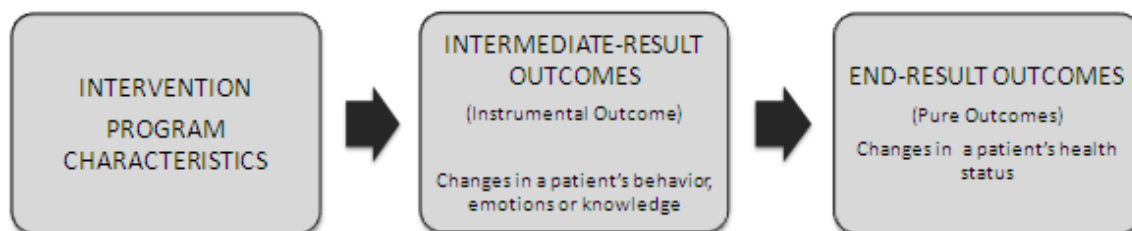


Figure 1. Depiction of the Relationship between Interventions, Intermediate and End Outcomes

### *Adherence*

The World Health Organization (WHO) highlighted the importance of focusing on adherence in their publication Adherence to Long-term Therapies (World Health Organization, 2003). While there are multiple definitions of adherence the WHO defines it as the extent to which an individual's behavior is consistent with recommendations from a health care provider. Adherence to recommendations usually signals a person's engagement in self-management. One measurement of adherent behavior involves comparison of the services received against what is recommended by evidence-based guidelines developed for management of a condition.

The WHO (2003) indicated that patient adherence is a primary determinant of positive clinical and cost outcomes. According to the WHO, adherence to treatment recommendations leads to a reduction in complications and disease progression and consequently improves quality of life. The WHO report also indicated that costs are impacted through adherence to treatment recommendations both directly and indirectly.

Improved adherence to recommended guidelines in managing chronic illnesses and associated complications results in direct cost savings when expensive health services that would have been necessary as the condition progressed are avoided. Costs are impacted indirectly by improving quality of life and sustaining vocational roles of individuals with chronic conditions, an outcome in which employers are interested.

Questions often arise as to whether adherence is patient adherence or physician adherence. This research makes the assumption that patient adherence is inextricably entwined with physician “buy in” to clinical guidelines and support of adherence. While it is acknowledged that this relation exists, it is further assumed that patients are responsible for their health. Measuring adherence then evaluates patient behavior related to evidence-based guidelines with physician support.

### *Disease Management*

Increasing awareness of the impact of chronic illnesses on individuals, families, and society precipitated a search for solutions by the health care industry. In the late 1980s and early 1990s the concept of evidence-based medicine developed as an approach to provide consistent, research-driven, standardized management of illness, particularly chronic illness (Evidence-Medicine Working Group, 1992). In the 1990s, the American Diabetes Association developed national evidence-based guidelines for the management of diabetes. These guidelines provide the foundation for effective diabetes management.

At the same time evidence-based guidelines were introduced, the concept of disease management arose as a mechanism to manage chronic conditions (Todd & Nash, 1997). Disease management is an attempt to mitigate the effects of chronic conditions.

Disease management programs focus on prevention of disease progression and complications by utilizing evidence-based guidelines and by empowering individuals to effectively manage their disease (Disease Management Association of America, 2007).

Full service disease management includes six major components:

1. Population identification processes through which individuals with a condition are identified and in some cases risk stratified;
2. The use of evidence-based practice guidelines to guide the recommended services;
3. Collaborative practice models which include physicians and other providers who support the guidelines;
4. Patient education in self-management;
5. Measurement of the success of the intervention that include process and outcome measures; and
6. Routine reporting and feedback.

Since the introduction of disease management, programs have been adopted by private insurance companies and managed care organizations as an approach to address chronic illnesses. The main focus of these disease management programs was on educating patients on evidence-based guidelines and facilitating self-management. In 2003 and 2004, almost 60% of large employers offered disease management programs (Glabman, 2005). Medicare has implemented disease management programs and is exploring the impact of a disease management approach on the health of Medicare recipients. Two major initiatives established by the Centers for Medicare and Medicaid

Services (CMS) have occurred over the past nine years. In 2000, the Benefits Improvement and Protection Act (BIPA) mandated a demonstration program designed to evaluate the impact of a disease management approach on improving the health of randomly selected individuals with congestive heart failure, diabetes and coronary heart disease (Center for Medicare and Medicaid Services, 2003). The three year demonstration project was implemented in early 2004. In 2003, the Medicare Modernization Act authorized another initiative, initially called the Chronic Care Improvement Program and changed to Medicare Health Support, to establish eight pilot programs for disease management (Center for Medicare and Medicaid Services, 2010).

In October 2008, the second report of the outcomes from this program was published. Five of the eight organizations originally selected to participate terminated their involvement by the time of the report. The program produced limited effect on behavioral change, savings, satisfaction, care experience, and functional status. One finding was that the number and type of contacts was not significant enough to effect change (McCall, Cromwell, Urato & Rabiner, 2008).

Despite the proliferation of disease management programs, reports indicate that receipt of health care services within guideline parameters remains low, placing individuals with chronic conditions at risk for the development of complications associated with a worsening condition. According to McGlynn, Asch, Keesey, Hicks, and DeCristofaro (2003), only 54.9% of services determined to be quality indicators for chronic care were received within established guidelines. In 2004, the Congressional Budget Office (CBO) commissioned an analysis of research on the impact of disease



management programs on cost. The analysis concluded “there is insufficient evidence to conclude that disease management programs can generally reduce overall health spending” (Congressional Budget Office, 2004, p. 1). The report stated that even in instances where there were savings, these resulted from interventions provided in controlled settings. The authors questioned the applicability to larger populations. Conflicting reports also surround the effectiveness of disease management programs in improving clinical status. The Employee Benefit Research Institute (Christensen, 2002) reported on disease management research related to who implemented programs, reasons for implementing programs and the reported impact of the programs on health and costs. The report concluded that there is “no conclusive evidence that DM programs, in general, improve health or reduce costs in the long term” (p. 4).

#### *An Alternate Practice Model*

Given the complexities of managing chronic illnesses, a multi-dimensional approach has been proposed and a practice model has been developed. The Chronic Care Model (Wagner, Austin, & Vonkorff, 1996) acknowledges the importance of the self-management support component of disease management programs but proposes that a system level approach must be added to improve chronic care. Self-management support, one of the six elements of the model, is combined with organizational factors including a health system designed around chronic rather than acute care; a partnership with the community for support and education; clinical information systems that help to identify patients and provide feedback regarding outcomes; the availability of community support; and leadership in the community or organization that supports these changes.

## Purpose of the Research

The struggle to identify effective strategies for managing chronic conditions and the current short-comings of established programs in impacting adherence to evidence-based guidelines point to the need for additional research. What other strategies can impact adherence behaviors? Are approaches that involve broader health system interventions necessary before adherence levels change significantly and disease progression is slowed or stopped?

The purpose of this research is to explore the relationship between adherence to diabetes guidelines and approaches to diabetes management adopted by two employer-sponsored self-insured health plans. The approaches include a traditional disease management one in which individual level interventions were used and one in which a system level approach containing all the components of the Chronic Care Model (CCM) was used.

## Theoretical Framework

### *System Level*

Most theories and conceptual models that help to explain the factors impacting adherence behaviors focus on interpersonal or individual level factors. These theories, further discussed in Chapter 2, explain adherence as a result of increasing an individual's perception of risk and the level of skills needed to address the risks. Education is the major focus of programs using these theoretical approaches. However, according to the World Health Organization (2003), system changes are required to improve adherence levels. One of the system changes addressed by the WHO is the need to move away from

an approach to health care that is episodic and related to acute episodes of need to one that focuses on health and wellness along a continuum.

### *Ecological Theory*

Social ecology theory (SET) acknowledges that health behaviors are influenced by multiple factors at many different levels in an individual's environment. The factors range from characteristics of the individual, social relationships, characteristics of the community and institutions and the presence or absence of policies supporting healthy behaviors. The theory posits that an individual's health both influences the environment in which they function and is influenced by that environment in a reciprocal way.

Spheres of influence impact the well-being of an individual. The spheres include those individuals and systems with which the patient directly interacts; linkages between those individuals and settings; individuals and settings with which the patient does not directly interact but which have influence over the patient; and finally the policies, culture and context in which the other spheres function. According to SET, since each of the spheres influences a person's health and behaviors, when programs are designed to address the health of populations these spheres of influence should be considered. Such programs involve more than patient education. They are designed to include efforts to change organizational behavior, the physical environment and social milieu. (National Cancer Institute, 2005).

### *Research Questions*

The purpose of this research is to explore the relationship between adherence to diabetes guidelines and approaches to diabetes management adopted by two employer-

sponsored self-insured health plans. The approaches include a traditional disease management one in which individual level interventions were used and one in which a system level approach containing all the components of the CCM was used. The research examines the influence of the system level factors in relation to individual level factors known to influence health-related behaviors. The following questions are addressed:

In relation to individuals with diabetes:

1. Is there a difference in adherence behaviors between individuals in a health plan that implemented a system level program and those in a health plan that implemented an individual level program only?
2. Can adherence to selected evidence-based guidelines be predicted by age, gender, co-morbid conditions, number of hospitalizations, evidence of a consistent medical provider, and approach to diabetes management (system-level versus individual-level only)?

### Significance of the Study

The major historical initiative to impact outcomes for chronic illnesses has been disease management. Evidence of the impact of disease management programs on adherence behaviors is conflicting and inconclusive. Questions remain regarding the features of a disease management program that have the greatest impact on adherence. Wagner (1997) stated that “Following the failure of health care reform, we are experiencing unprecedented, unevaluated tinkering with basic care models and values” (p. 702). He called for research to assess the effectiveness of different approaches to providing care for the chronically ill. This research is designed to advance what is

known about the management of chronic illnesses by examining the impact of a system level approach on adherence to diabetes guidelines and comparing them to the traditional approach adopted in most disease management programs.

### Assumptions

For the purpose of this research, there is no distinction between adherence and compliance. In the literature both terms indicate the receipt of services according to clinical recommendations in the patient's treatment plan. The main distinction between the two terms is that adherence implies patient agreement with the treatment plan. Since it is difficult to obtain information on patient agreement where the terms compliance and adherence are used they are treated as synonyms.

There are three different types of diabetes: type 1, type 2 and gestational. Type 1 diabetes results from the inability of the body to produce insulin. Type 2 diabetes results primarily from the body's difficulty in using the insulin that is produced with a secondary deficit in production and release of insulin. This study excludes gestational diabetes since this type is generally self-limited and disease management programs for individuals with gestational diabetes focus on all the clinical needs of pregnant women at risk. The majority of individuals diagnosed with diabetes suffer from type 2 (Center for Disease Control and Prevention, 2005). While the pharmaceutical approaches to the different types of diabetes may be different, the American Diabetes Association (ADA) guidelines for the four areas of interest of this study are the same for type 1 and type 2 diabetes.

### Definition

Adherence is a complex concept but the definition presented by the WHO is one that is often referenced in literature (Bissonnette, 2008; Bosworth, Oddone & Weinberger, 2006; Pathman, Konrad, Freed, Freeman & Koch, 1996). Adherence behaviors are those behaviors that indicate engagement in following clinical guidelines for frequency and type of care. Adherence in diabetes management includes: obtaining lab work at recommended frequencies and obtaining screening services for disease progression, such as retinopathy and nephropathy.

### Summary

Federal and state governments and private insurers are struggling with managing the complications associated with chronic illness and the rapidly rising costs associated with them. Disease management is one approach that has gained increasing popularity over the past decade. However, two issues with the current approach have been identified in the literature. First, results from previous studies are inconclusive on the impact of disease management programs and low adherence to guidelines is still being reported. Secondly, it has been proposed that system wide interventions may need to occur in order to support chronic illness management.

This research explores the difference in adherence behaviors between individuals enrolled in a health plan that provides traditional disease management and those enrolled in a system-level program. It is hoped that this research will help to identify strategies to ameliorate the burden of chronic disease.

### Organization of the Study

The remainder of this study is organized into four additional chapters, references and appendices. Chapter 2 presents theoretical foundations for understanding behavioral change. It also presents the literature that addresses the current body of knowledge on the impact of adherence behaviors in the management of chronic diseases and methods taken to improve adherence. Chapter 3 delineates the research design and methodology. It defines the sample for the study, the characteristics of the study groups and the data collection instruments to be used. Chapter 4 contains the results of the analysis. Chapter 5 provides a summary, discussion of the findings and recommendations resulting from the study. Chapter 5 is followed by a bibliography and appendices.

## CHAPTER 2: LITERATURE REVIEW

### Purpose Statement

The purpose of this research is to explore the relationship between adherence to diabetes management guidelines and diabetes management programs implemented by two health plans. The subjects are individuals with diabetes who are covered under one health plan that has implemented a system level program to address chronic illness care and individuals covered under one health plan that has not implemented a system level program but rather a traditional individual level program. The study determines whether there is a significant difference in adherence between the two groups two and a half years after the implementation of the chronic care programs. In addition, the study explores whether the type of approach to diabetes management is predictive of improvement in diabetes-related adherence behaviors.

### Introduction

This literature review provides a brief overview of the significance of adherence in relation to improving health outcomes for individuals with chronic illnesses particularly diabetes. A brief overview of theories of behavioral change is presented. The review continues with an exploration into what is currently known about approaches to managing diabetes and improving adherence to diabetes management guidelines. Individual level approaches are examined as well as recent developments in models for



chronic care management that propose a system-level approach to improving chronic condition management. The chapter concludes with a presentation of recent research in system-level approaches.

### The Concept of Adherence

Adherence is a complex concept. In the literature there are multiple definitions reflecting different levels of patient involvement in the decision to engage in health-related behavior (Bosworth, Oddone & Weinberger, 2006; Hearnshaw & Lindenmeyer, 2005; Helvi Kyngas Kyngae, 2000). Terms that are used to signify adherence are compliance, self-care, self-management, concordance, acceptance and obedience (Bissonnette, 2008; Evangelista, 2008). Adherence involves the adoption of behaviors that are consistent with recommendations for appropriate health management.

Multiple factors impact adherence behaviors such as health perceptions; individual characteristics such as coping styles; social circumstances such as supportive resources; knowledge; past success in improving health behaviors; the quality of the patient-provider relationship; treatment; and, disease characteristics (Sherbourne, Hays, Ordway, DiMatteo and Kravitz, 1992; World Health Organization, 2003). Different models of adherence are presented in the literature. One model presents three steps towards adopting adherence behaviors. In order to adopt the required behavior the patient begins with awareness of the behavior and an understanding of the importance of adopting the behavior. The patient then moves towards agreement to engage in the behavior and initially engages in the behavior. Finally, the patient proceeds to consistently demonstrate sustained adherence (Pathman, Konrad, Freed, Freeman & Koch,

1996). The medication adherence model presents two concepts associated with adherence behavior. The first is purposeful action, the extent to which an individual engages in a select behavior. The next is patterned behaviors, which is the extent to which an individual adopts a habit of engaging in the health-related behavior (Johnson, 2002). The precaution / adoption process model posits that the process involved in adhering to health-related behaviors involves four general steps (Bosworth, Oddone & Weinberger, 2006). The individual becomes aware of the need to perform the behavior; forms the intention to adopt the behavior; acts (or decides not to act); and maintains the behavior.

### *The Significance of Adherence*

Adherence is the key link between recommended therapies and positive clinical outcomes (Kravitz and Melnikow, 2004). The WHO recognized the significance of adherence in impacting overall health and commissioned a publication on the topic (World Health Organization, 2003). The publication called for a focus on adherence, indicating that measurement of adherence helps in identifying and refining effective interventions.

### *The Significance of Adherence to Diabetes Guidelines*

In relation to diabetes, the WHO indicated that adherence behaviors such as self-monitoring of blood glucose and receipt of the necessary screenings have been linked to a lower incidence of complications and a slowing of disease progression among diabetics (World Health Organization, 2003). Sloan, Bethel, Lee, Brown, and Feinglos (2004) examined the impact of adherence to screening guidelines on hospitalizations in

Medicare patients with diabetes. The authors concluded that there was a significant association between high rates of adherence and lower rates of hospitalizations for complications of diabetes. McGlynn, Asch, Keesey, Hicks, and DeCristofaro (2003) reported on quality in relation to diabetes care; identified gaps in adherence to basic diabetes care; and emphasized the need to develop strategies to reduce these gaps that threatened the health of the American public.

#### *Adherence to Hemoglobin A1c Monitoring*

Hemoglobin A1c (HbA1c) is a measure of a patient's glucose level over the two to three months prior to the test. The American Diabetes Association recommendation for frequency of monitoring HbA1c is every six months for all individuals whose diabetes is well controlled and every quarter for those individuals whose diabetes is not well-controlled and whose glucose levels are not within target range (American Diabetes Association, n.d.).

Monitoring glucose levels as recommended is seen as important because controlled glucose prevents or delays the onset of complications associated with diabetes (American Diabetes Association, n.d.). There are correlations between elevated A1c and cardiovascular diseases such as silent myocardial ischemia (DeLuca, Saulle, Aronow, Ravipati, & Weiss, 2005); coronary artery disease (Ravipati, Ahn, Sujata, Saulle, & Weiss, 2006); and peripheral artery disease (Selvin, Wattanakit, Steffes, Coresh, & Sharrett, 2006). In addition, elevated glucose levels are associated with microvascular changes that lead to complications such as diabetic retinopathy and kidney disease (Blonde, 2007; The Diabetes Control and Complications Trial Research Group, 1993).

According to the National Diabetes Information Clearinghouse (2005), every one point drop in A1c level corresponds with a 40% decrease in the risk for complications associated with microvascular changes. The significance of these linkages between glucose levels and diabetes complications highlights the importance of frequent monitoring of patients' A1c. National adherence levels for individuals who have had at least two A1c tests per year have ranged from 64.3 to 68.8% from 2000 to 2005, the most recent data available (Centers for Disease Control, 2007).

#### *Adherence to Cholesterol Screening*

Cholesterol levels out of the acceptable range in patients with diabetes have been shown to be significantly correlated to atherosclerotic changes and predictive of cardiac events associated with atherosclerotic changes (American Heart Association, 2007; Drexel, et al., 2005). Heart disease presents a significant risk to individuals with diabetes. In fact, 65% of deaths in patients with diabetes are associated with heart disease and stroke (American Diabetes Association, 2007). For patients with diabetes, lowering LDL cholesterol can reduce the risk of heart attack by 42% (American Heart Association, 2007). Standards for diabetic care include the use of lifestyle changes and lipid lowering medications in patients with diabetes and coronary heart disease. These treatments are thought to be effective in lowering the risk of mortality, recurrent myocardial infarction, and stroke. Diabetic standards of care recommend at least yearly monitoring of lipid levels in order to detect dyslipidemia early, treat early and prevent the development of diabetes complications (American Diabetes Association, 2007). No

national trend information is available for rates of cholesterol monitoring in individuals with diabetes.

#### *Adherence to Retinopathy Screening*

Diabetes is the leading cause of new cases of blindness in adults and leads to 12,000 to 24,000 new cases of blindness every year (American Diabetes Association, 2007). Diabetes retinopathy, a condition caused by blood vessel damage caused by diabetes, progresses from non-proliferative to proliferative, leading to blindness. This progression can occur without the patient's awareness (The American Diabetes Association, nd). There are treatments available to prevent or delay the onset of diabetic retinopathy, thereby preventing loss of vision (The American Diabetes Association). Early detection leads to early intervention and can lead to the prevention of blindness and visual impairment. Screening for diabetic retinopathy by an ophthalmologist or an optometrist is recommended yearly for individuals with diabetes type 2 when first diagnosed and three to five years after diagnosis for patients with diabetes type 1 (The American Diabetes Association, 2007). National rates of adherence to annual retinopathy screening have ranged from 56.8% in 1996 to 66.5% in 2001. There has been a decline in adherence since 2001. In 2005, the latest results available, the national adherence rate was 60.6% (Centers for Disease Control, 2007).

#### *Adherence to Nephropathy Screening*

The prevalence of chronic kidney disease continues to rise, with a reported 40% increase since the 1988 to 1994 data was collected (The United States Renal Data System, 2007). Diabetes is the most common cause of chronic kidney disease and

subsequent kidney failure. It occurs in 20 – 40% of patients with diabetes (The American Diabetes Association, 2007, p. S19). Almost 45% of all newly diagnosed cases of kidney failure are attributed to diabetes (National Kidney and Urologic Disease Information Clearinghouse, 2008). Untreated chronic kidney disease results in kidney failure and ESRD, leading to dialysis, transplantation or death. Significant complications are associated with dialysis and transplantation and individuals with diabetes are at a higher risk for these complications. The combination of diabetes and end-stage renal disease (ESRD) leads to higher rate of cardiac decompensation, sepsis and pulmonary disease than with other diseases. These serious complications lead to a higher death rate for patients with diabetes (Friedman, 2007). If detected early, treatments can be initiated that slow the rate of kidney disease and the progression to ESRD. Annual screening for the presence of microalbuminuria is recommended for individuals with type 1 diabetes five years after diagnosis and for individuals with type 2 diabetes at the time of diagnosis. No national trend information is available for rates of nephropathy monitoring in individuals with diabetes.

### Improving Adherence

Adherence outcomes in relation to programs implemented to address the needs of individuals with chronic conditions have received mixed reviews in the literature over the past several years. Some reviews reported a slight improvement in adherence to diabetes management guidelines (Agency for Health Care Research and Quality [AHRQ], 2006; National Committee for Quality Assurance, 2007). At the same time CDC statistics showed a slight decrease in adherence to some of the guidelines and an increase in co-

morbid conditions such as renal and cardiac disease (Centers for Disease Control, 2007). Even those reports that showed an improvement in adherence acknowledged that improvements were slight and additional efforts are needed to aggressively attack the problem of poor adherence to guidelines for the management of chronic conditions (The Agency for Health Care Research and Quality [AHRQ], 2006).

### Theoretical Understanding of Adherence Behaviors

Research in the management of chronic disease in relation to adherence behaviors has rarely been presented within the context of a theoretical perspective. Understanding the relationship between theories and models of behavior change and adherence behaviors may lead to a greater understanding of what works to improve adherence behaviors in individuals with chronic conditions. According to Patterson (2001), “Theories can guide the search to understand why people do or do not follow medical advice, help identify what information is needed to design an effective intervention strategy, and provide insight into how to design a successful educational program” (p. 27). Most approaches to improving adherence have focused on individual level factors and most theories of behavior change focus primarily on individual behavior change processes, not system level factors (Grizzell, 2003).

### Approaches to Improving Adherence

#### *Individual Level Theories of Behavior Change*

Theories and conceptual models that help in the understanding of individual level factors associated with behavior change include the Health Belief Model, the Transtheoretical Theory, the Theory of Planned Behavior, and a model called the

Information-Motivation-Behavioral Skills Model (IMB). It is important to understand these theories since individual level factors are among the factors that influence behavior change.

The Health Belief Model (HBM) focuses on several precursors to taking action to improve one's health. According to Glanz, Lewis, and Rimer (1997), the HBM has its root in expectancy theory. A basic tenet of the theory is that an individual desires to be healthy and to avoid illness. Belief that a specific action will prevent an illness leads the individual to adopt a particular behavior. The HBM focuses on ways in which one's belief can be changed. Through its focus on how beliefs can be changed, the HBM provides an understanding of how preventive behaviors can be stimulated by specific motivational factors. It posits that individuals perceive their susceptibility or risk in relation to their health and the seriousness of not taking preventive action. Modifying factors within the HBM point to internal and external factors that impact each individual's perception of risk. Cues to action are additional modifying factors that increase the perception of risk and the likelihood of adopting the desired behavior. In addition to the perceived susceptibility and the perceived risk in the Health Belief Model, the individual also needs to perceive a benefit to taking the action. Perceived barriers also must be identified and addressed in order for the action to be taken. Because the model deals with individual perception the HBM focuses primarily on knowledge and education as the main cues to action. Programs informed by this model of behavior change are designed to increase the individuals' perception in all these areas. An individual will be



educated regarding the risk, the susceptibility and the benefits in order to move them to action. Skills to address the barriers are developed.

One of the most widely cited theories for behavioral change is the Transtheoretical Theory. This theory, posed by Prochaska and DiClemente (1983), presents the concept of a staged process of behavioral change. The stages represent a continuum and address readiness to change a behavior that is contributing to poor health. There are five stages of change: pre-contemplation; contemplation; preparation; action; and maintenance. This readiness to change theory is used in many health promotion programs. Programs framed in this theory focus on evaluating the individual's readiness and based on that readiness the individual is educated in the skills necessary to succeed in each stage and move along to the next one. Self-management skills are taught in the action and maintenance stage.

Glanz, Lewis, and Rimer (1997) indicated that the Theory of Planned Behavior posits that behavior change is immediately preceded by an intention to change. This intention is modified by: 1) belief about the likely consequences of adopting the behavior or not adopting it (behavioral beliefs); 2) belief about societal or other person's expectations in relation to adopting the behavior (normative beliefs); and, 3) perceived control over the behavior (control beliefs) (Ajzen, 2002). The combination of these beliefs impacts the individual's intention to perform the behavior, which then impacts the performance of the behavior. In general, a behavior is more likely to be performed when beliefs are strong about the consequences of performing the behavior, about others' expectations, and about the individual's perception of ability. Programs framed and

informed by this theory focus on increasing an individual's beliefs about the consequences of performing or not performing the behavior. Support is coordinated for the individual in the performance of the behavior and expectations of the health professional are conveyed regarding the health-related behavior. Self-management skills education and support are also components of such programs.

DiClemente, Crosby, and Kegler (2002) presented another theory in health promotion, the Information-Motivation-Behavioral Skills Model (IMB). Although the IMB has been primarily used in HIV prevention, it has been presented as a model for other health behaviors as well. Three basic skill sets are proposed as determinants of adopting and performing preventive behaviors. Informational skills are enhanced by providing information related to the condition and associated with the desired behaviors. Motivational skills are enhanced by conveying information on risk level and personal susceptibility and also by improving perception of available social support. Behavioral skills are enhanced by addressing the individual's ability and perceived ability to perform the sequence of behaviors required. Programs framed by this model disseminate educational materials that are designed to provide facts that are easy to translate into action.

#### *Individual Level Approaches to Improve Adherence to Diabetes Guidelines*

Much of the literature in the 1990's and early 2000's related to the management of chronic conditions focused on disease management programs. Programs for the management of chronic conditions in the current nomenclature of disease management came to the surface in the late 1980's at the Mayo Clinic. More attention was drawn to

disease management as a formalized program in the early 1990's, when the Mayo Clinic and the John Deere Health Plan joined to build a clinic and establish programs designed to address the needs of individuals with chronic conditions (Todd & Nash, 1997). In the 1990's pharmaceutical companies were instrumental in providing disease management services; disease management organizations were developing; and there was wide adoption of the concepts of disease management by the payers of health care (Matheson, Wilkins, & Psacharopoulos, 2006). According to the literature describing the elements of disease management, some common characteristics are: self-management education and empowerment; the use of evidence-based guidelines to educate and to measure outcomes; feedback to providers on the patient's progress related to evidence-based guidelines; and, engagement with physicians in the management of chronic conditions (Congressional Budget Office, 2004; Disease Management Association of America, 2007).

Disease management programs reported in the literature are rarely presented from a theoretical perspective. Most of these programs approach chronic illness management from an individual factor level. The most frequently reported approaches to the management of diabetes are self-management education and support. Self-management education and support incorporate many of the individual-level components of behavioral change theories. Self-management education is designed to increase a patient's knowledge of the specifics of the disease, possible complications, consequences of poor management (providing a cue to action), and the components and rewards of effective management. Self management support is designed to reinforce appropriate behavior.

Self management education for the majority of disease management programs involves the mailing of educational material and reminders regarding guidelines (Espinet, Osmick, Ahmed, & Villagra, 2005; Gold & Kongstvedt, 2003; Shojania et al., 2006; Steffens, 2000; Guadagnino, 2005). In addition to mailing educational materials some programs offer support by providing monitoring devices such as blood glucose devices that are uploaded to a central database for clinicians to review (Kim, Yoo & Shim, 2005; Hensley, Jones, Williams, Willsher, & Cain, 2005; Villagra & Ahmed, 2004). On-site diabetes education classes and group support are included in some disease management approaches (Clancy, Huang, Okonofua, Yeager, & Magruder, 2007; Nolte, Elsworth, Sinclair, & Osborne, 2007; Peters & Davidson, 1998; Stern, 2005). Web-based educational programs have been developed and adopted as another approach to improving overall management of diabetes (Lorig, Ritter, Laurent, & Plant, 2006; McMahon et al., 2005; Meigs et al., 2003). Often more intense interventions are implemented to provide support based on a patient's level of risk for complications. Individuals at higher risk are offered more intense interventions such as on-site and/or telephonic interactions by nurses who provide education, reinforce education, provide feedback on progress and coordinate needed resources (Domurat, 1999; Espinet, Osmick, Ahmed, & Villagra, 2005; Fireman, Bartlett, & Selby, 2004; Guadagnino, 2005; Halderman, Read, & Hart, 2001; Steffens, 2000; Thomson Healthcare Company, 2005).

Involvement of the treating physician is also seen as an essential component of any program designed to address the needs of individuals with chronic conditions (Disease Management Association of America, 2008). Rothman & Wagner (2003) point

to the role of the primary care provider in the care of individuals with diabetes, indicating that the patient looks to a person who has the ability to coordinate across disciplines and who can provide more holistic care. The primary care provider meets these characteristics. The strength of the patient–provider relationship is also cited as an important factor for the realization of positive outcomes in the management of chronic illnesses (Ciechanowski, et al., 2004; Maddigan, Majumdar & Johnson, 2005).

#### *Adherence Outcomes of Individual Level Approaches*

The varying results reported by programs focusing on individual level disease management interventions have caused a number of experts to question the effectiveness of this approach. Outcomes reported on these programs include cost, clinical, and adherence factors. Since adherence is the focus of this research, literature on individual level approaches and their impact on adherence is presented. Table 1 provides a summary of the literature and details of the research follows.

Traditional large scale diabetes disease management programs involve phone calls to patients; educational materials sent to patients and families; phone calls to remind patients of appointments or when preventive tests are due; mailings to physicians regarding evidence-based guidelines; and feedback to physicians on how their patients are performing against these guidelines. In 1998, the John Deere Company implemented a large scale study of the disease management program implemented in the early 1990s. There were approximately 20,000 John Deere Health Plan participants with diabetes, the study evaluated half of these participants (N=10,000) who were enrolled in the diabetes management program. Results of the program were published in 2000

Table 1. Summary of Research on the Impact of Individual Level Approaches on Improving Adherence in Patients with Diabetes

<b>Program Intervention</b>	<b>Reference</b>	<b>Theory</b>	<b>N</b>	<b>Outcomes</b>
Phone calls and educational mailings; reminders; and feedback to physicians	Steffens, 2000	No theoretical foundation presented	10,000	After one year, screening rates for HbA1c, lipid levels and nephropathy risk were reportedly significantly improved. No statistical significance was reported.
Telephonic and mailed interactions as well as some face-to-face contact designed to increase knowledge and self-management skills.  Tested participation primarily	Espinet, Osmick, Ahmed, & Villagra, 2005	No theoretical foundation presented	7,000	HgbA1c testing, lipid testing, retinopathy exams and nephropathy screening - Statistically significant improvement in adherence scores over those who partially participated and those who did not participate ( $p < 0.001$ ).
A computer tracking system that was used to facilitate team care of patients with diabetes. The intervention group was the patients with highest risk.	Domurat, 1999	No theoretical foundation presented	10,000	Significantly better adherence to HgbA1c, lipid tests and nephropathy screening ( $p < .001$ ). The risk level of the participant could have impacted the improvement in adherence rather than the intervention.

Table 1, continued

<b>Program Intervention</b>	<b>Reference</b>	<b>Theory</b>	<b>N</b>	<b>Outcomes</b>
Comparison of 3 approaches: regular clinic visits, an additional one-time education class, the addition of a telephonic case manager	Howe, et al., (2005)	Transtheoretical theory	75	Adherence in the education and case management group was significantly better compared to the standard care group ( $p = .0006$ ). No information on the exact areas of adherence.
On-site diabetes education classes and group support were provided monthly for one year	Clancy, Huang, Okonofua, Yeager, & Magruder, 2007	No theoretical foundation presented	186	Adherence to HbA1c, Lipid screening, retinopathy screening and nephropathy screening were measured. Retinopathy screening was the only statistically significant result.
A pharmacist intervention in which subjects met with a pharmacist who established a care plan. Follow up meetings occurred weekly.	Odegard, Goo, Hummel, Williams, & Gray, 2005	No theoretical foundation presented	77	No improvement in the intervention group and instead the control group consistently reported statistically significant improvement in adherence

Table 1, continued

<b>Program Intervention</b>	<b>Reference</b>	<b>Theory</b>	<b>N</b>	<b>Outcomes</b>
Studied the influence of attachment style on self-care for patients with diabetes	Ciechanowski, et al. (2004)	Attachment theory	4,095	Greater patient-provider collaboration was significantly associated with adherence to diet ( $p < .001$ ) and exercise ( $p < .001$ ).
Studied the effect of patient perception of their relationship with their provider on adherence	Maddigan, Majumdar & Johnson (2005)	No theoretical foundation presented	372	Positive perceptions of the patient-provider relationship were significantly associated with adherence to diet ( $p < .05$ ) and exercise ( $p < .05$ ).

(Steffens, 2000). Some program participants received an educational approach designed to raise their awareness of their diabetes and to encourage them to engage in self-management. Individuals who had certain levels of risk, such as those who were newly diagnosed; those who had recently been hospitalized for diabetes complications; or those who had significant co-morbid conditions, were provided with more intense interventions and support by a case manager. After one year, screening rates for HbA1c, lipid levels and nephropathy risk were reportedly significantly improved although no statistical significance was reported. The report did not present results for each of the two types of interventions so it is difficult to draw conclusions on whether the mailing of



reminders and newsletters had as much of an impact as the more intense one-on-one support for the higher risk population.

A study of over 7,000 participants in a national diabetes program was conducted to determine the impact of program participation on adherence to the recommended screenings (Espinet, Osmick, Ahmed & Villagra, 2005). The program was implemented in 20 health plans associated with one managed care organization. The main goal of the program was to measure the subjects' adherence outcomes based on participation in the program. The measures included adherence to HbA1c, lipid testing, nephropathy screening, and retinopathy screening. Adherence to these screenings for three groups was compared. The three groups were those who were engaged in the program for different lengths of time or chose not to engage. The groups were labeled as groups with full participation, partial participation and no participation. Interventions were individual level. Patients were contacted by phone and by mail to provide education on diabetes and tools for self-management. Physicians were provided with feedback on their patient's adherence. Adherence to HgbA1c testing, lipid testing, retinopathy exams and nephropathy screening was measured through a retrospective review of a 12 month study period. Those patients who fully participated in the program showed statistically significant improvement in adherence scores over those who partially participated and those who did not participate ( $p < 0.001$ ). Adherence rates were reportedly better for partial participants than for non-participants although the results were not statistically significant ( $p = 0.108$ ). This research was designed to study the impact of program participation on adherence since one of the limitations of disease management programs

is participation. Low participation in disease management programs has been reported with only a 7% continuing participation rate after 12 months (Lynch, 2006). The investigators concluded that program participation was an important factor in improving adherence to recommended screenings.

A few other research reports show varying degrees of improvement in adherence to recommended screenings. A study of the impact of a diabetes care program implemented by Kaiser Permanente compared adherence rates for individuals enrolled in the program ( $n = 2617$ ) versus those who received usual care from their primary care physicians ( $n = 5993$ ). Individuals involved in the program are those who are at the highest level of risk, defined by the author as those who had multiple hospitalizations, complications or co-morbidities; newly diagnosed with diabetes; and poor understanding of self-care. The intervention group received support from a team of clinical staff including endocrinologists, nurse practitioners, physician assistants, and pharmacists. Individuals in the program visited with a single clinician; had group visits and classes, and received telephone follow-up providing education and support. The intervention group showed significantly better adherence to HgbA1c, lipid tests and nephropathy screening ( $p < .001$ ) (Domurat, 1999). However, awareness of risk could have had a significant influence on improved adherence rather than the intervention.

A comparison of three approaches to managing diabetes was reported by Howe, et al., (2005). The three approaches were standard care (four times a year clinic visits); standard care plus a one-time education class; and standard care with a one-time education class with telephone case management added. Results in relation to clinical

improvement, knowledge and adherence were reported. After six months no statistically significant difference in the HgbA1c results or the level of knowledge between the three groups was found. An adherence score was obtained using a clinician checklist that evaluated diabetes adherence behaviors in relation to problem-solving skills and safety involving self-management. Adherence in the education and case management group was significantly better compared to the standard care group ( $p = .0006$ ). There is no specific information on the exact areas of adherence. The authors report, however, that content validity was established.

A two-group comparison study was conducted at an Adult Primary Care Center serving minority patients (Clancy, Huang, Okonofua, Yeager, & Magruder, 2007). The two groups were a standard of care group whose members received regularly scheduled care delivered by academic internal medicine physicians, residents and nurse practitioners and those selected into the intervention group who received group visits. The group visits occurred monthly for a year and provided education on diabetes and opportunities for support and socialization. The patients were those with poorly controlled diabetes defined as having a HgbA1C greater than 8%. While the authors indicated that patients who attended group visits were more likely to have adhered to the recommended screening for diabetes there was only one statistically significant result (HgbA1C  $p = .1193$ , Cholesterol  $p = .0815$ , Microalbumin  $p = .5119$ , and eye exams  $p = .0171$ ). The research spanned a time period of 12 months.

A study of a pharmacist intervention provided at eight primary care clinics was conducted (Odegard, Goo, Hummel, Williams, & Gray, 2005). The goal of the study

was to determine whether patients with diabetes who received focused education by pharmacists had better adherence scores than those individuals who received usual care. Usual care was defined as continuation of care by the patients' primary care providers. The pharmacists in the intervention group worked with the patients to develop an individual plan of care and provided the patients with education on diabetes and feedback on their progress. The program lasted for six months and self-reported adherence behaviors were measured at six and twelve months. There was no improvement in the intervention group and instead the control group consistently reported statistically significant improvement in adherence throughout the 12 months ( $p = 0.003$ ).

Two studies reported on the link between the patient-provider relationship and adherence outcomes related primarily to exercise and diet. While these studies do not address adherence behaviors that are of interest to this research, they are included here because they present results that indicate the patient-provider relationship may be a significant variable associated with improved adherence behavior. Ciechanowski, et al., (2004) studied the influence of attachment style on self-care for patients with diabetes (4095 subjects). The primary variable of interest was attachment style. The authors measured the patient-provider relationship by determining the patient's perception of the degree to which the provider collaborated with them. Greater patient-provider collaboration was significantly associated with adherence to diet ( $p < .001$ ) and exercise ( $p < .001$ ). Maddigan, Majumdar & Johnson (2005) measured the patient-provider relationship using two indicators from the Diabetes Lifestyle Form. The indicators measured patient perception of their relationship with their provider. As with the

Ciechanowski, et al. (2004) study positive perceptions of the patient-provider relationship were significantly associated with adherence to diet ( $p < .05$ ) and exercise ( $p < .05$ ).

While there were no studies that report on the impact of age and gender on adherence to the diabetic screenings, there are studies that report on adherence to other health-related behaviors for diabetes and the correlation between those and age and gender. The results are conflicting, however. In relation to other adherence measures such as medication administration and diet for glucose control, gender was associated with improved adherence in some of the literature (Hertz, Unger, & Lustik, 2005; Korbel, Wiebe, Berg, & Palmer, 2007; McCullum, Hansen, Lu, & Sullivan, 2005) and was not associated with adherence in others (Hartz, et al., 2006; Toljamo & Hentinen, 2001). Where there was a difference in adherence associated with gender, females were less likely to adhere. In relation to age, there are also varying results associated with adherence. Hartz, et al. found that age was inversely associated with adherence to glucose monitoring, medication administration and following a recommended diet. However, Hertz, Unger, & Lustik, found that younger individuals were more likely to discontinue medications for diabetes.

#### *Limitations of Individual Level Theories and Approaches*

DiClemente, Crosby & Kegler (2002) noted that individual level theories such as those delineated earlier in this chapter (the Health Belief Model, the Transtheoretical Theory, the Theory of Planned Behavior and the Information-Motivation-Behavioral Skills Model) have been dominant in health promotion efforts. The reason for this dominance is that individual-level theories:

1. Correctly place the individual as the key decision maker in relation to their health.
2. Assume that people value health and are therefore motivated to improve health and prevent illness.
3. Assume that beliefs and attitudes drive individuals towards the health-related behavior.

Although the importance of placing health care decisions in the hands of the patients is acknowledged, researchers have questioned whether individual-level approaches would lead to significant and sustained changes in health-related behaviors (DiClemente et al., 2002).

Meta-analyses of diabetes disease management research have identified problems with the quality of the studies (Knight et al., 2005; Norris, Engelgau, & Narayan, 2001; Vermeire et al., 2005). Unclear descriptions of interventions make it difficult to draw conclusions about what factors may impact adherence (Knight et al., 2005). Improved clinical and adherence outcomes are modest (Knight et al.) or conflicting (Knight et al., 2005; Norris, Engelgau, & Narayan, 2001; Norris et al., 2002; Vermeire et al., 2005). After reviewing research on adherence outcomes of individual level interventions, Vermeire et al (2005) concluded that, despite the reported efforts to improve adherence in patients with diabetes, no significant improvement nor harm was documented (Vermeire et al., 2005).

Chronic illness management interventions have primarily focused on impacting individual level factors. The failure of these programs to demonstrate positive clinical

and adherence outcomes has led to explorations into other approaches. In an attempt to discover what will work most effectively in the management of chronic illnesses Wagner (1997) called for other focused health services research. The author emphasized that patients with chronic illnesses are at risk particularly because some of the programs that have been implemented to address chronic illnesses disrupt already established relationships with health care professionals. The author also points out that patients with chronic illnesses will benefit greatly if deficiencies in the established approaches are corrected.

*A System Level Theory of Behavioral Change: Social Ecological Theory*

Ecological approaches to behavioral change assign as great an importance to the creation of supportive environments and on the reorientation of the health system as on the development of personal skills. These theoretical approaches have been evolving over time from public health and psychological traditions (Glanz, Lewis, & Rimer, 1997). A social ecological approach gives significant weight to the individual's environment including the social, institutional and cultural aspects of that environment (Jamner & Stokols, 2000). Jamner & Stokols presented the core assumptions within Social Ecological Theory as applied to health:

1. The health of an individual is influenced by many factors in the physical environment (i.e. geography and technology) and in the social environment (i.e. as economics and culture).
2. Health is influenced by personal factors, including genetics, psychology and behavior patterns.

3. The environment is multidimensional and complex.
4. Because of these multidimensional factors, interventions need to involve individual, interpersonal and social strategies.

The authors noted that “...simple appeals to individuals may not be effective since they constitute only one influence on the choice to be made...” (p. 41-42).

Social ecological theory provides insight into the multidimensional factors that impact behaviors and it is useful in guiding the development of programs whose goal it is to improve health-related behaviors. It focuses on the multiple levels of influence and the interdependence between those levels as well as the individual level influences (Grzywacz, 2000; McLaren & Hawe, 2005). As shown in Figure 2, ecological models place the individual at the center with concentric or nested circles around the individual representing different levels of environmental influences. The circles widen as they extend away from the center and represent the microsystem which is the individual's most immediate context; the mesosystem represents the linkages between the different settings in which an individual directly interacts; the exosystem represents linkages between systems that impact the individual, but with which the individual does not directly interact; and the macrosystem is the overall context in which the micro -, meso – and exo-systems function (Bronfenbrenner, 1979; Fisher et al., 2005; Grzywacz, 2000; McLaren & Hawe, 2005).

Social ecology theory has formed the basis of research on programs designed to impact changes in health-related behaviors. A social ecology perspective was used in a



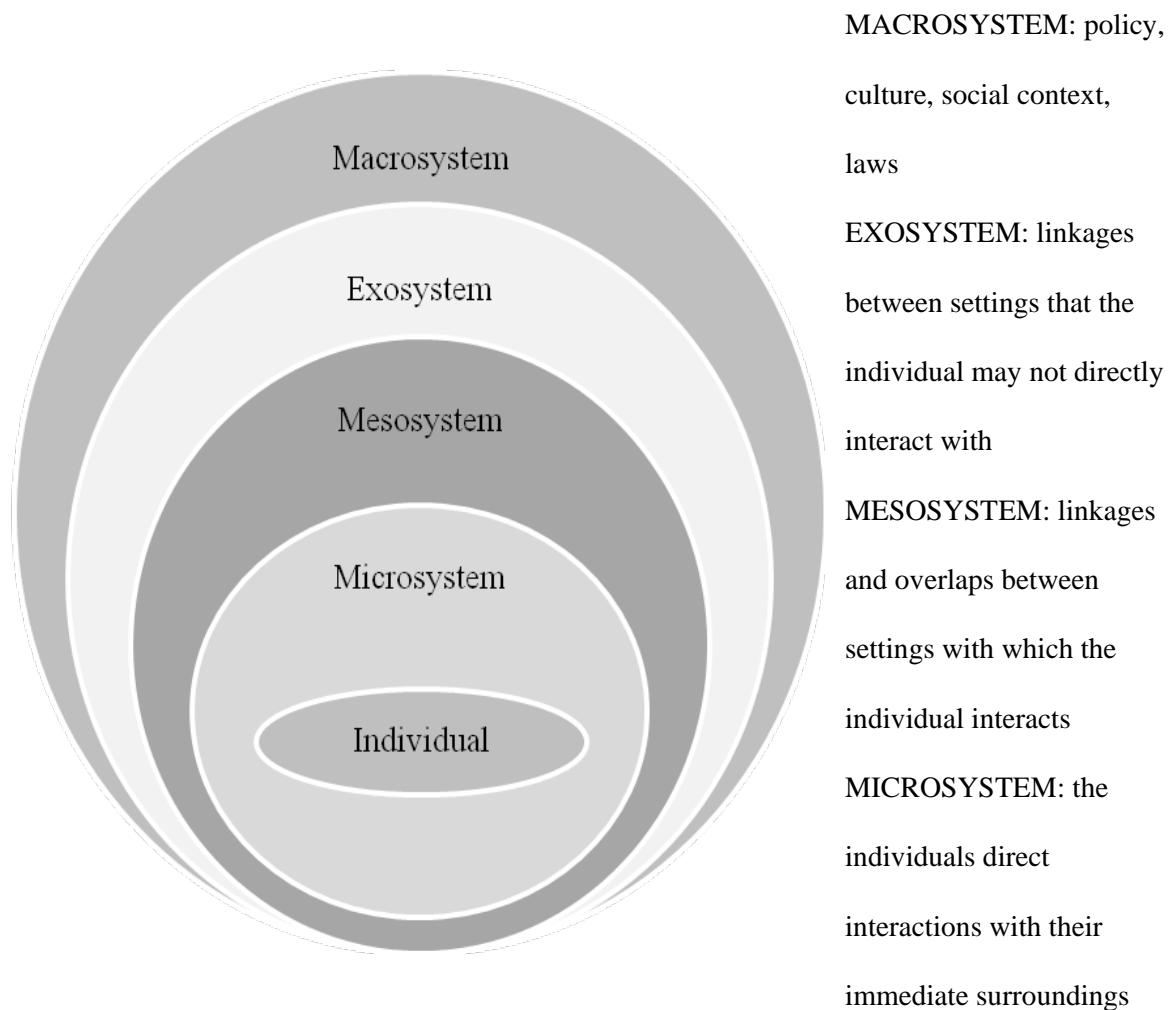


Figure 2. Multilevel System Depiction of Social Ecology Application

program that was designed to develop guidelines for best practices in smoking cessation (Hopkins, Husten, Fielding, Rosenquist & Westphal, 2001; Patrick, Intille & Zabinski, 2005). Multifaceted approaches have been seen as being successful in impacting smoking cessation and sustaining healthy behaviors over time. Individual level assessment, education and assistance in the development of strategies to quit were seen as effective

(microsystem). Health system interventions which involved a combination of provider education and provider reminders were also seen as effective in supporting cessation. These represent external systems set up to remind the providers of the efforts being made to support smoking cessation (exosystem) and supported interactions between the smoker and the provider (mesosystem). Policy changes that are implemented, such as raising the unit price of cigarettes and limiting the sites where tobacco is allowed, are also seen as effective interventions (macrosystem). No studies were found using this type of a social ecology theory that report on programs designed to improve adherence to diabetes guidelines that have been implemented to the extent reported in this study.

A social ecology perspective can also be seen as the theoretical foundation for the Chronic Care Model (CCM), the first formal system-level practice model reported in the literature designed to address the needs of individuals with chronic conditions. The CCM acknowledges the importance of individual approaches to managing chronic illness such as self-management support but posits that effective management of chronic illnesses must include system level support and interventions (Wagner, Austin, & Vonkorff, 1996). The components of the CCM parallel the micro-, exo-, meso-, and macro-system levels of social ecology.

*A System Level Approach to Improving Adherence to Diabetes Guidelines:*

*The Chronic Care Model*

The components of the CCM are designed to address the multifaceted approaches to behavioral changes that are addressed within social ecology theory. The CCM approaches the management of chronic conditions from an ecological perspective by

integrating system and organizational level factors in addition to individual level ones.

An amalgamation of the best available information on effective management of chronic illnesses, the CCM addresses systems and the interrelations between different ecological levels of influence on health. Wagner, Austin, and Vonkorff (1996) reviewed available literature to help define factors related to effective management of chronic illness. The Chronic Care Model (CCM) was developed based on the identified elements. As shown in Figure 3, six elements were identified by Wagner, Austin and Vonkorff: a health care delivery system that is organized around support for chronic care management; links to community resources and partnerships between care systems and the local community; self-management support; delivery system re-design; advanced clinical information systems that provide feedback on performance; and, decision support for the providers of care (Wagner et al., 2001). The CCM practice model is designed to impact patient outcomes through productive interactions between an informed, engaged patient and a highly qualified practice team (Bonami, Wagner, Glasgow, & Von Korff, 2002).

Some of the components of the model can be used to support individual-level interactions. For example, advanced clinical information systems are used to trigger individuals to the program. They are also used to provide feedback to the providers and the chronic care management staff as they work directly with the individuals to improve their knowledge and their adherence. The significance of the model, however, is the system-wide interventions and support that reflect an organizational approach to address the problems of managing chronic illness. The following sections will more closely relate the CCM to Social Ecology Theory.

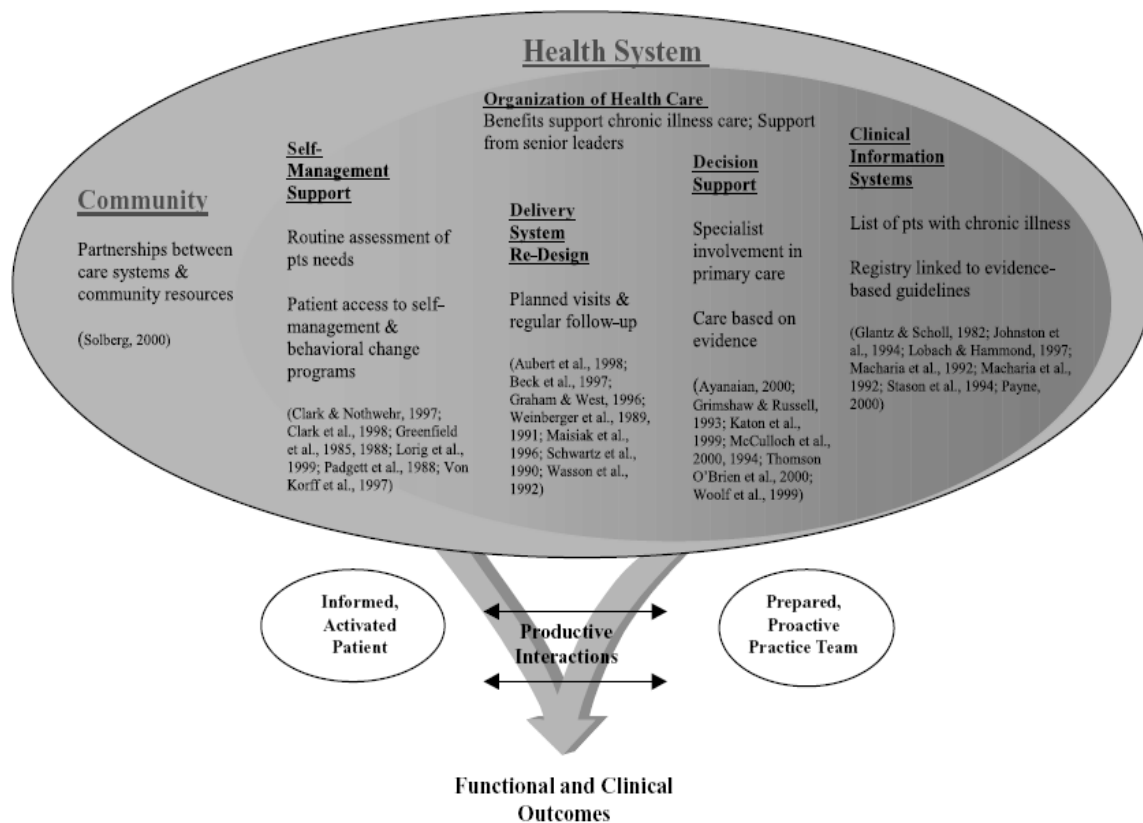


Figure 3. Elements of the Chronic Care Model

Wagner E. H. Chronic disease management: What will it take to improve care for chronic illness? *Effective Clinical Practice* 1998; 1: 2-4 (Used with permission from the American College of Physicians).

### Ecological Theory and the Chronic Care Model

The CCM can be understood in the context of social ecology theory. The CCM acknowledges the need to use individual-level approaches, but proposes that widespread system-level intervention is the best way to have an impact on the behavior of individuals with chronic conditions. Components of the CCM practice model address changes at

every level of the ecosystem delineated in the social ecology theoretical model. Table 2 summarizes how the CCM links to Social Ecology Theory. This study tests social ecology theory in relation to impacting adherence to select guidelines in individuals with diabetes through the use of the CCM practice model.

### *Microsystem*

The microsystem is the individual's most immediate context and includes activities, roles and interpersonal relationships. This level involves relationships and interactions with family, friends, social support systems, work environment, and health professionals involved in the individuals life. The microsystem encompasses the person's immediate contacts with whom face-to-face interactions occur; the situations and settings in which the interactions occur; and the direct or indirect influence these contacts and situations have on the individual (McLaren & Hawe, 2005). The CCM components related to microsystem influences on health behaviors are self-management support and linkages to community resources.

Self-management support uses individual level interventions to improve self-management and adherence to practice guidelines. Behavioral principles are applied in order to provide individuals with the knowledge and skills necessary to reach the desired outcomes (VonKorff, Gruman, Schaefer, Curry, & Wagner, 1997; Wagner et al., 2001). Effective self-management support involves providing education on the chronic condition and facilitating the individual's ability to identify issues, identify resources and skills needed to address the issues identified, and to access the essential skills and resources (Epping-Jordan, Pruitt, Bengoa & Wagner, 2004). Often case management personnel are

Table 2. Link between Social Ecology Theory and the Chronic Care Model

<b>Social Ecology Theory Level</b>	<b>Chronic Care Model Components</b>
MicroSystem	Self-management Support – provided in the context of patient-provider relationship and by nurses educating the patient on their condition and self-management skills
Interpersonal relationships	Presence of community resources that interface with the patient
MesoSystem	Advanced clinical information system which is used to link the patient, the treating provider and the nurse providing self-management support
Linkages between the different settings in which an individual directly interacts	Non-physician support (nurses) who act as the link between the patient and the other members of the care system and community resources
Exosystem	Organization of health care away from acute care and towards chronic care management, including strategies throughout the organization focused on chronic care.
The larger social system in which the individual resides but with which the individual may not directly interact	Health system redesign which provides financial and policy support for the additional time required in the management of patients with chronic conditions
	Decision support which involves local physicians and other providers in the development and support of clinical guidelines

employed to help provide this support with the goal of empowering individuals and facilitating effective interactions between the individual patient and the treating providers.

The presence and availability of patient-oriented community support and resources is another micro-system level component of the CCM. The resources available and accessed by patients provide opportunities for direct interaction with professionals and peers who help to sustain positive health-related behaviors. Access to, and use of,

community resources such as exercise programs, hospital chronic disease programs and local support groups, has been shown to be an effective element of chronic illness management (Rothman & Wagner, 2003; Bodenheimer, 2003).

### *Mesosystem*

The mesosystem represents the linkages between the different settings in which an individual directly interacts. The interconnectedness of the settings and structures in which the individual functions is seen as just as important as the individual's interpersonal relationships in the support of an individual's health (McLaren & Hawe, 2005). The CCM focuses on the link between the patient and the health system; the patient and the available community resources; and the patient and the physicians involved in their care. There are two components of the CCM that facilitate the linkage between the microsystem settings or structures: advanced clinical information systems and the services of non-physician professionals.

The information systems are used to link the payer, the different providers involved with the individual, and the providers of self-management support. These advanced clinical information systems use administrative data from claims as well as data from electronic health records to identify individuals with the condition and to risk stratify individuals so that comprehensive approaches to address their needs can be applied. In addition to the use of clinical information systems to identify patients and their needs these systems provide feedback to the treating physician on adherence behaviors (Bodenheimer, 2003; Rothman & Wagner, 2003; Rundall et al., 2002; VonKorff, Gruman, Schaefer, Curry, & Wagner, 1997; Wipf & Langner, 2006).

Non-physician professionals are also used as linkages between settings and thus a meso-system level of influence on a patient's health. These professionals, often case managers, bring skills in relation to providing direct self-management support but also coordination between the different settings with which the individual directly interacts. They are also available to the treating physician to support the treatment plan.

### *Exosystem*

The exosystem is the level of influence that represents the larger social system in which the individual resides but with which the individual may not directly interact. The systems and settings in this level interact with systems and settings in the individual's microsystem. Despite the fact that the individual does not directly interact with the settings in the exosystem, decisions are made in this system that directly impact the individual (Bronfenbrenner, 1979; Grzywacz, 2000; McLaren & Hawe, 2005). The components of the CCM associated with the exosystem level are the organization of health care away from acute care management toward chronic care management; health system re-design; and decision support. These supports provide a contextual framework for behavioral change and improved chronic care management at a exosystem level.

The CCM views the support for chronic care management within the organization as an important addition to the individual level approaches to improving care of chronic illnesses. The CCM posits that to effectively address health, health care organizations must be organized to support new approaches to chronic care. The model suggests that policies must be established that facilitate new approaches to care. As mentioned in the discussion on the mesosystem level, relationships between providers and payers need to



be enhanced so that both support chronic care. Support from senior leadership within the health system can provide support for this relationship. Policies and payment structures can be enhanced to provide for the additional time required by providers to effectively manage chronic illnesses (Health Resources and Services Administration, 2006).

Beyond organizational support is the redesign of the health delivery system to effectively enhance chronic illness care. One example of this redesign and leadership support is change in the payment structure to physicians that provide reimbursement for the longer patient visits that are often required for individuals with chronic illnesses. Other health system redesigns involve the development of incentives to providers for quality chronic care management and the establishment of systems that facilitate coordination of care across organizations and settings (Bonami, Wagner, Glasgow, & Von Korff, 2002; Institute for Alternative Futures, 2006; Seaton, 2006).

Another exosystem level of influence in this model is decision support. This involves the engagement of clinical practitioners in establishing, selecting, or reviewing disease specific clinical guidelines. It also involves making available to practitioners the clinical guidelines established or adopted by the organization (Epping-Jordan, Pruitt, Bengoa & Wagner, 2004). Processes and financial support are needed that facilitate continuing education of providers in the advances and changes in chronic care management. When clinical practitioners obtain continuing education on updated or newly developed clinical guidelines they become or remain current in evidence-based approaches to the management of chronic conditions (Rothman & Wagner, 2003; VonKorff, Gruman, Schaefer, Curry, & Wagner, 1997; Wagner et al., 2001a).

### *Macrosystem*

The macrosystem is the overall context in which the other ecosystem levels exist. Under the influence of the macrosystem, the individual interacts with levels of the ecosystem and interactions between other ecosystem levels occur. McLaren & Hawe (2005, p. 11) define the macrosystem as "... the overall patterns of ideology and organisation that characterize a given society or social group, and may thus be used to describe the culture or social context of various societal groups ...". It is within the context of the macrosystem that changes are made. The CCM approaches chronic care management from an organization level and does not necessarily address the larger community milieu that is represented by the macrosystem level. Fisher, Brownson, O'Toole, Anwuri & Shetty (2007) have proposed an expansion of the CCM to include the wider community and systems that impact the health of individuals in the daily management of chronic conditions as well as the creation of policies that support chronic care. The World Health Organization and the McColl Institute for Healthcare Innovations have joined to expand the CCM to the Innovative Care for Chronic Conditions framework. Policy and wider community interventions are integrated into the framework to provide a more comprehensive milieu for chronic care management (Epping-Jordan, Pruitt, Bengoa & Wagner, 2004).

### Improved Adherence in the Chronic Care Model Approach

Reports on programs implemented using the CCM practice model are beginning to emerge in the literature. In 2006, Bodenheimer, Wagner, and Grumbach conducted a review of the research to date on the extent to which the chronic care model improved the

management of diabetes. Thirty-nine studies were reviewed. The authors examined which of the six components of the CCM were implemented. Four or less of the components were implemented (self management support, decision support, delivery system design and clinical information systems). The two that were not reported are the organizational changes and the integration of community resources. Based on the reviews they concluded that interventions based on the components of the CCM model were associated with some improvement in adherence behaviors. Thirty-two of the 39 studies reviewed reported improvement in at least one adherence measure or one clinical measure. At the same time the authors questioned the methodological quality of many of the studies and deduced that study interventions varied enough to make generalization difficult.

Limited research has been conducted on the impact of the elements of the CCM on adherence for patients with diabetes. Solberg et al. (2006) and Hroschikoski et al. (2006) reported on the results of implementing a program that incorporates the elements of the CCM into 17 primary care clinics. The authors reported on the implementation of the CCM from a quantitative and qualitative perspective. All six elements were in place at baseline and a 24% overall improvement was reported at the end of the study period. Changes in how the clinics implemented each of the six components were also measured. Delivery system design and self-management support improved the least and the improvement was not significant ( $p = .11$  and  $.10$  respectively). No significant correlations between the CCM interventions and adherence behaviors were noted. A review of two of the other research studies on implementing the CCM revealed that very

limited implementation of the components of the model occurred (Piatt et al., 2006; Siminerio, Piatt, & Zgibor, 2005). Only one other program, implemented by the University of Pittsburgh and delineated below, reported on the overall support for wide-spread policy and system level interventions.

One program established by the University of Pittsburgh reported on the implementation of the CCM in an integrated delivery system serving over 15,000 patients (Siminerio, Zgibor & Solano, Jr., 2004; Siminerio, et al., 2006). The program implemented all 6 elements of the CCM and focused on outcomes associated with improvement in self-management. The program was implemented in 2000 and results were evaluated in 2003. Provider practices were measured at baseline and at year three. The authors concluded that physician practices improved their patients A1C results from baseline. No statistical significance was reported, however. In addition to the reported improvement in A1C results by physician practice, adherence to an annual nephropathy screening was at 74% for the more than 4,000 patients who were tracked. This was the only adherence result reported. There was no comparison made either to pre-implementation results or to a referent group and no statistical significance was reported.

Both social ecology theory and the CCM point to the importance of overall system level interventions in impacting health-related behaviors. Much of the research on the impact of the CCM takes the components of the CCM and tests only the impact of those components rather than the implementation of all components of the model. For example in the research review conducted by Bodenheimer, Wagner, and Grumbach (2006) none of the 39 studies reported on the component of the CCM that represents the

overall organization of a health care system that supports chronic care management. This approach ignores system level support for the management of chronic conditions. Little is known of the impact of full implementation of the CCM on adherence to diabetes guidelines. No studies to date have been conducted that compare adherence for individuals in programs that have implemented the full components of the CCM to those in groups that have not.

This study views the CCM in the context of social ecology theory. It is designed to test social ecology theory and the practice model for four areas of adherence to diabetes guidelines: HbA1c monitoring; lipid monitoring; nephropathy screening; and retinopathy screening. Adherence to these guidelines are compared between patients whose health plan approached the management of diabetes by implementing only an individual level program and patients whose health plan has implemented a system-level program. Figure 4 shows the relationship between the constructs of interest and the variables being studied.

The hypotheses associated with these analyses are as follows:

H1. There is no difference in adherence to lipid monitoring of individuals in a health plan that implemented a micro-, meso-, and exosystem approach to chronic care management compared to individuals in a health plan that implemented a microsystem approach alone.

H2. There is no difference in adherence to retinopathy monitoring of individuals in a health plan that implemented a micro-, meso-, and exosystem approach to chronic

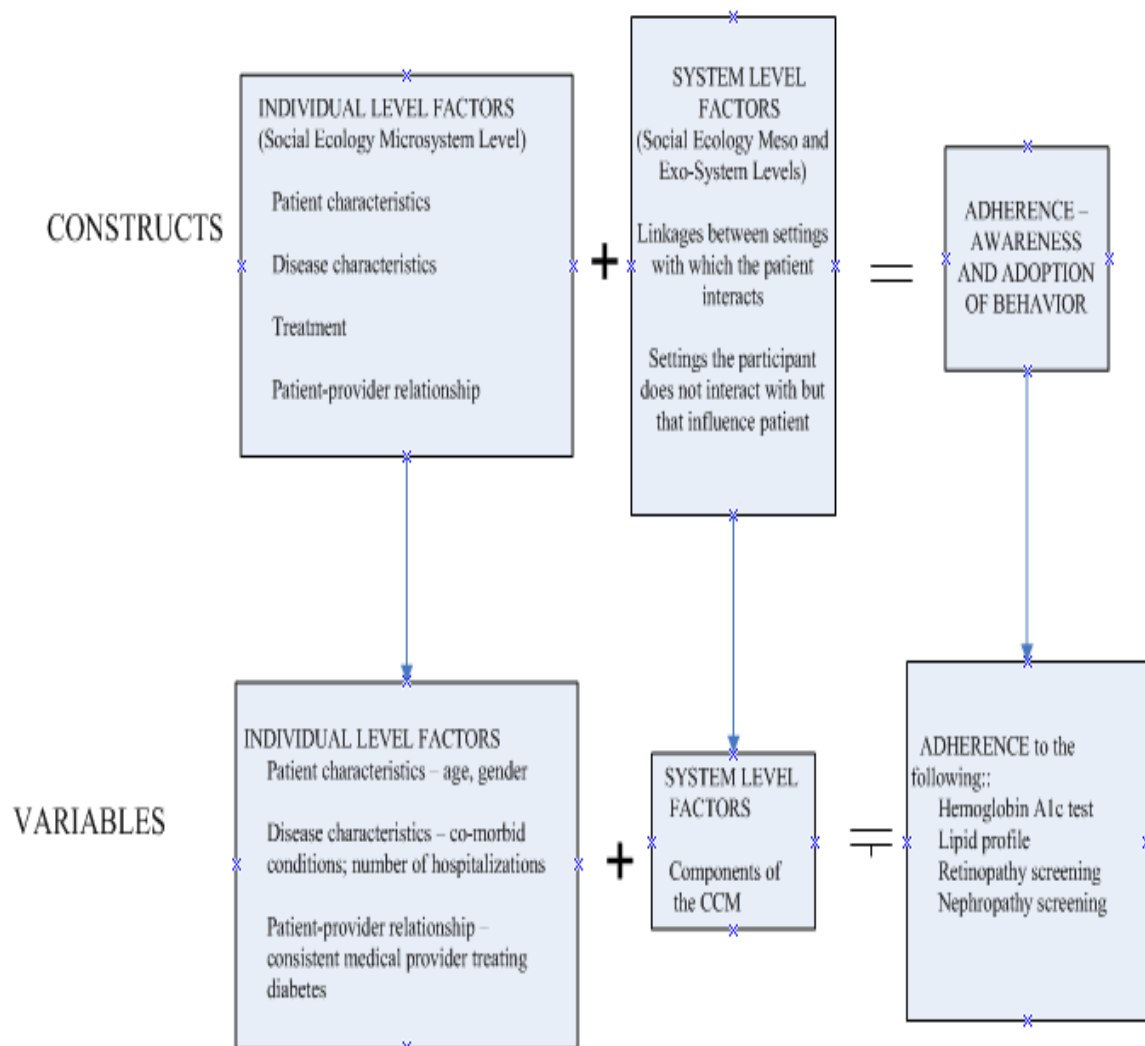


Figure 4. Conceptual Model

care management compared to individuals in a health plan that implemented a microsystem approach alone.

H3: There is no difference in adherence to HbA1c monitoring of individuals in a health plan that implemented a micro-, meso-, and exosystem approach to chronic care management compared to individuals in a health plan that implemented a microsystem approach alone.

H4. There is no difference in adherence to nephropathy monitoring of individuals in a health plan that implemented a micro-, meso-, and exosystem approach to chronic care management compared to individuals in a health plan that implemented a microsystem approach alone.

The research also examines the influence of the diabetes management approach, as well as individual level factors known to influence health-related behaviors, on improvement in adherence from pre program implementation to post program implementation. The hypotheses associated with these analyses are as follows:

H5: Approach to diabetes management is associated with a change in lipid monitoring adherence from pre-program implementation to post program implementation.

H6: Approach to diabetes management is associated with a change in retinopathy monitoring adherence from pre-program implementation to post program implementation.

H7: Approach to diabetes management is associated with a change in HbA1c adherence from pre-program implementation to post program implementation.

H8: Approach to diabetes management is associated with a change in nephropathy monitoring adherence from pre-program implementation to post program implementation.

### Summary

The management of patients with diabetes presents challenges that the health care industry continues to face. Adherence is reportedly an important step towards improved clinical status and can be closely linked to interventions. Because of the mediating role adherence plays, mediating between interventions and improved health, it is a variable that is important to focus on (Bodenheimer, Lorig, Holman & Grumbach, 2002;

Donabedian, 1985; Jamner & Stokols, 2000; Kravitz & Melnikow, 2004; Patterson, 2001; & World Health Organization, 2003, p. 23).

Since the formalization of disease management programs almost 20 years ago, attention has been on programs designed to impact the health of individuals with diabetes. Many of these programs have been based on individual-level approaches and framed in individual-level theory, placing the focus on raising patients' awareness of their disease, educating patients on the risks associated with poor disease management, increasing patient's understanding of evidence-based guidelines, and enhancing patients' self-management skills. Results of programs focusing on these individual-level interventions have been varied, leading to the development of other approaches to managing diabetes and other chronic conditions.

Since the late 1990s increasing focus has been on system-level approaches which can be framed within a social ecology theory of behavior change. Social ecology acknowledges the importance of the individual in behavior change thus integrating individual-level theories and approaches in the totality of a sociological approach. Social ecology theory, however, points out that behavior change is multifaceted and interventions that impact behavior therefore must be multi-faceted. As the health care industry has worked towards improvement in the management of diabetes a systems-level practice model has emerged.

The Chronic Care Model incorporates interventions at the ecosystem levels of influence posited in the social ecology theory. Research in relation to application of this practice model is in its infancy. The complexity of diabetes and the persistent gaps in



care despite efforts at the individual level have lead to the application of system-level models to improve management of diabetes. Chapter 3 presents the methodology used in this research to study the impact of these different approaches on adherence to diabetes screening guidelines.

## CHAPTER 3: METHODOLOGY

### Purpose and Introduction

This research explores the relationship between adherence to diabetes guidelines and approaches to diabetes management adopted by two employer-sponsored self-insured health plans. It tests the effectiveness of applying social ecology theory, specifically the CCM practice model, to efforts to improve adherence to diabetes guidelines. The study is designed to determine whether there is a significant difference in select adherence behaviors between a health plan in which only individual level approaches have been implemented to address diabetes and a health plan in which system-level approaches as well as individual-level ones have been implemented. In addition, the study examines the contribution of the approach to management of diabetes in relation to individual-level factors that are known to impact adherence. This chapter describes the research design, the variables of interest, the population being studied, the source of the data and the data analysis that is conducted.

### Research Design

This study is a retrospective, descriptive, non-experimental study of a phenomenon that has occurred naturally as health plans have implemented programs to improve adherence behaviors and corresponding health outcomes for individuals who are covered under their plans. The covered individuals are employees and dependents of

two hospitals located in Maryland, each having a unique health plan. One of the health plans implemented a traditional chronic care program with an individual-level approach and one implemented a system-level effort to impact the health of their covered individuals with diabetes. The study involves a comparison of adherence to select guidelines for diabetes care in these two groups of patients for a two and a half year period post program implementation. In addition it examines the relationship between the different approaches to diabetes management and change in adherence from two and a half years pre-program implementation to two and a half years post program implementation. Figure 5 represents the design of this analysis with  $O_1$  representing multiple measures of compliance prior to the implementation of the diabetes programs, depending on the variable being assessed, and  $O_2$  representing multiple measures of compliance post implementation of the programs. The comparison of the two approaches is assessed by evaluating differences between  $O_2$  for participants in the two health plans. Change in adherence behaviors are assessed by evaluating  $O_2$  minus  $O_1$  for each individual in each of the two health plans.

$O_1$	X	$O_2$
<hr/>		
$O_1$	$X_1$	$O_2$
Adherence in the 2 <sup>1/2</sup> years prior to program implementation		Adherence in the 2 <sup>1/2</sup> years post program implementation

Figure 5. Research Design

Data analysis is performed in three phases. First, descriptive statistics are generated for the entire sample. Second, a comparison between individuals in the health plan that implemented an individual-level approach to chronic condition management and individuals in the health plan that implemented a system-level approach are conducted. The comparison is designed to identify commonalities and differences between the groups on age, gender, number of hospitalizations since the program was implemented, number of co-morbid conditions, the presence of a consistent provider treating diabetes, and adherence to the guidelines for HbA1c, lipid, retinopathy and nephropathy monitoring. T-tests are performed to compare the groups on age, the number of hospitalizations, the number of co-morbid conditions and the number of physicians treating diabetes. Chi-square analyses are conducted on gender and the categories of adherence. The third phase of the study identifies the impact of the approach to diabetes management on changes in adherence from pre- to post-program implementation in relation to individual level factors through a logistic regression model. In this phase of the analysis,  $\text{change in adherence}_{it} = f(x)$  (age, gender, co-morbid conditions, the presence of a consistent medical provider and approach to chronic care management) where “it” equals individual change in adherence behavior over time. This analysis is conducted for each of the areas of adherence.

#### Population of Interest and Sample

The target population is individuals with diabetes. The accessible sample is individuals covered under the health plans associated with the two self-insured hospital employers in this study. The sample used to represent the population of interest is a

convenience sample. All individuals covered under the health plans who meet select criteria are included in the study. The criteria used to identify those eligible for the study are: they must have diabetes, as identified from the predictive modeling tool used by the Third Part Administrator (TPA); they must have been enrolled in the diabetes program; they must be 18 years or older throughout the study years; they must have been covered under the health plan for two and a half years prior to enrollment in the chronic care program and two and a half years after enrollment; and, the health plan must be the primary source of insurance. The units of analysis for the study are individuals in self-insured health plans. Health plans are interested in improving the health of the covered individuals and mitigating their health-related costs. Self-insured employers assume financial risk for the health benefits of their employees and dependents instead of paying an insurance carrier for coverage. Individuals covered under self-insurance programs represent about 55% of all individuals under private insurance (Employee Benefit Research Institute, 2008). Table 3 provides some information on the hospital employers whose health plans are the subject of this study including information on the health plans' overall health care cost burden. This is represented in the per-employee-per-month (PEPM) cost. The PEPM is an average of the medical and pharmaceutical claims submitted over the past year per employee as of April 2008.

#### Implementation of Diabetes Management Approach by Health Plans

Both health plans implemented two components of the CCM: self-management support and clinical information systems. These components are associated with individual level approaches. For both of the plans self-management support is provided

Table 3. Summary Data for Study Hospitals / Health Plans

<b>HOSPITAL</b>	<b># Employees Covered</b>	<b># Total Covered Lives</b>	<b>PEPM Average cost</b>
A (Individual level)	1989	3998	\$531
B (System level)	2259	5046	\$558

through nurses identifying the needs of each individual triggered for the program and contacting them for education on the disease and support in the development of self-management skills. The same level and type of self-management support was provided for both health plans. Although the self-management support was provided by different nurses, the nurses follow a standard process using specific guidelines for each of the areas of adherence of interest to this study. Samples of these guidelines are found in Appendix A.

The same clinical information system was used by both health plans. The clinical information system was used to identify individuals with diabetes who were then enrolled in the self-management program. It was used to organize the claims information in a way that provided a picture of the needs of the individual. The claims for both plans were used to measure adherence to diabetes practice standards. This information was accessible to the nurses who worked with the patients to support self-management. In addition, the plan that implemented the system-level approach used the clinical information system to provide feedback to the treating physicians. A sample of this participant level claims information is found in Appendix B.

The other four components of the CCM were implemented by the health plan that provided system-level support for diabetes management. The details of how these components were implemented are presented in Table 4.

#### Identification of Sample

Participants in the diabetes programs were identified by each plan through the use of a predictive modeling tool that has been assessed by the Society of Actuaries for predictive accuracy. Their assessment of the tool concluded that it is 86.4% accurate in its ability to predict those individuals who will have claims associated with a condition in the upcoming 12 months (Winkelman, Mehmud & Wachenheim, 2007). The tool, Episode Risk Grouper (ERGs), developed by Ingenix, uses episodes of care (Episode Treatment Groups or ETGs) and demographic variables to provide an analysis of a population, as well as the identification of individuals with particular illnesses and level of risk. ETGs were developed as an illness classification system with a methodology similar to Diagnosis Related Groups (DRGs), one of the most widely used illness classification systems. The major limitation of DRGs is that they apply only to inpatient episodes. ETGs, however, utilize information from all encounters with health care providers obtained from claim or encounter form information from inpatient and ambulatory settings (including pharmacy).

The tool builds “episodes” from this claim and encounter information, collecting all relevant utilization information and grouping it under one of 574 groups that have been determined to be statistically stable by the researchers at Ingenix (2006). The information used by the tool for grouping clinical events includes diagnosis codes (ICD9);

Table 4. Implementation of the Chronic Care Model Based on Social Ecology Levels

<b>Level</b>	<b>CCM</b>	<b>Plan A implementation</b>	<b>Plan B Implementation</b>
MicroSystem	Self-management Support	Provided by nurses who are instructed to use the same guidelines for educating patients on their condition, the impact of poor management and self-management skills	Provided by nurses who are instructed to use the same guidelines for educating patients on their condition, the impact of poor management and self-management skills
MicroSystem	Linkages to / partnerships with community resources	Not applicable	Organized relationship with Diabetes education program; behavioral health services; home health services.  Once diabetes education is complete patient is "handed back" to the nurse who continues self-management support. If additional education is needed the patient is re-referred to the diabetes education program for a refresher.
MesoSystem	Advanced clinical information system	Not applicable for providing linkages across the settings directly involved with the patients.  Used only to identify patients who have diabetes; risk stratifies patients and organizes claims information.	Used to identify patients who have diabetes; risk stratifies patients and organizes claims information for the nurses providing self-management support.  Used to provide feedback to the treating physicians - mailed to the physicians and /or physicians access on line.  Community physicians, diabetes education center, medical director and nurses providing self-management support access the same clinical information system and current information



Table 4, continued

<b>Level</b>	<b>CCM</b>	<b>Plan A implementation</b>	<b>Plan B Implementation</b>
MesoSystem	Advanced clinical information system	<p>Not applicable for providing linkages across the settings directly involved with the patients.</p> <p>Used only to identify patients who have diabetes; risk stratifies patients and organizes claims information.</p>	<p>Used to identify patients who have diabetes; risk stratifies patients and organizes claims information for the nurses providing self-management support.</p> <p>Used to provide feedback to the treating physicians - mailed to the physicians and /or physicians access on line.</p> <p>Community physicians, diabetes education center, medical director and nurses providing self-management support access the same clinical information system and current information</p>
MesoSystem	Self-management support linking the patient with the resources / services - services of non-physician professionals	<p>Not applicable for providing linkages across the settings directly involved with the patients.</p> <p>Nurses provide only individual support as patients' needs are identified</p>	<p>Nursing staff; team of physicians; medical director; diabetes education, behavioral health and home health professionals; executive team; meet to develop plans for individuals and outreach to community physicians</p> <p>Community physicians are notified of the program and the availability of nursing professionals to support the treatment plan.</p> <p>Weekly meetings by interdisciplinary team (care coordination team) to assure that patients have easy access to community resources.</p>

Table 4, continued

<b>Level</b>	<b>CCM</b>	<b>Plan A implementation</b>	<b>Plan B Implementation</b>
Exosystem	Organization of health care away from acute care and towards chronic care management	Not applicable	Support throughout the organization. Strategic engagement in improving chronic care. Initiative adopted by hospital executives; health plan administrator and key community physicians. Improving chronic care illness care and coordinating between the hospital and the community physicians is set as an organizational initiative.
Exosystem	Health system redesign	Not applicable	Involves community physicians in design of feedback report. Engages with community physicians in developing plans to allow additional visit time for individuals with chronic care as well as time to review the feedback from the clinical information system
Exosystem	Decisions support	Not applicable	Hospital and community physicians collaborate to review and adopt clinical guidelines used to support patients with diabetes. Endocrinology, podiatry and ophthalmology specialists accessed to lead the review of clinical guidelines. Care coordination team meets with community physicians to educate them on the guidelines and the use of the clinical information system.

procedure codes (CPT and HCPC); pharmacy information (NDC); the specialty of the providers (if known); and the place of service. As these data come into the claims system the ETG grouper evaluates the information with respect to each other and in relation to criteria tables. The claims data are grouped with a specific ETG and continue to be grouped as long as the illness is being treated. The ETGs then become the building blocks of the ERGs (Symmetry, 2006). Both of the plans use the ERG tool routinely to identify individuals for chronic care programs.

For the diabetes programs implemented by the plans, individuals who were predicted to have diabetes-related claims in the next 12 months were chosen for enrollment. This same tool was used to identify subjects for this study. Initially there were a total of 468 individuals identified as having diabetes in the plan providing the individual-level approach only (plan A). There were 483 individuals identified as having diabetes in the plan providing not only an individual-level approach but also a system-level approach (plan B). These individuals had been identified by each plan for enrollment in the diabetes management programs. Individuals were removed from this list for this study based on the following criteria: There was no indication of enrollment in the diabetes program or enrollment in the program occurred before the age of 18. In addition, claims data had to be available two and a half years pre-enrollment in the program and two and a half years post-enrollment in the program. Once the individuals not meeting all criteria were removed the total number of study subjects in plan A (individual) was 150 individuals and plan B (system) 174 individuals.

Sample size for testing the hypotheses was assessed. A power analysis was conducted using general guidelines. Three pieces of information are needed to determine the sample size: a significance criterion, a power and an effect size. A significance criterion of .05 and a power of .80 were selected. These are conventional standards for the research in this phase of the study (Polit & Hungler, 1999). Since there is no previous research providing information on effect size, estimates of expected effect size were made. The effect size provides an indication of the strength of the effect of the independent variable on the dependent variable. Sample sizes using the following effect sizes are: a.) 0.30 requires a sample of 174; b.) 0.40 requires a sample of 98; and c.) 0.50 requires a sample size of 63. The sample size used in this study is adequate for the different effect sizes that represent a moderate effect (Polit & Hungler; p 492). Although the sample size is adequate, the sample is a convenience one. Therefore, caution is taken in interpreting the results.

Neither racial nor socioeconomic information are available as demographic data are obtained from files obtained when the employee enrolls in the health plan. Racial and socioeconomic questions are not routinely captured in this administrative data. All individuals in this study are either employed or a dependent of an employee and all individuals have private health insurance only. No participants with Medicare, Medicaid or other insurance were included in the study because the receipt of services through Medicare, Medicaid or other insurance would not be captured in the administrative data.

## Data

For this study the data for both the independent and dependent variables are secondary data, obtained from enrollment and claims files. These are categorized as administrative data. Administrative data are described as data that are collected for purposes other than those specified for research. The purpose for the data collection is usually for reimbursement or billing. They may be obtained from a variety of sources often from federal and state governments and private health insurers. Data are aggregated by diagnosis codes and procedure codes (Iezzoni, 1997a; Iezzoni, 1997b). Administrative data have limitations but can be useful in initially assessing a topic of interest. The usefulness of administrative data in research has been acknowledged by the Advisory Panel on Research Uses of Administrative Data of the Northwestern University / University of Chicago Joint Center for Poverty Research (Hotz, Goerge, Balzekas & Margolin, 1998). The usefulness of administrative data has also been recognized by the Agency for Healthcare Research and Quality (AHRQ). The problems associated with inaccurate data can be minimized through a process of analysis of the quality and validation of the information (Billings, 2007). Despite the drawbacks associated with administrative data, Iezzoni (2002) stressed the benefits of using administrative databases particularly for measurements of payment, costs and patterns of service utilization.

Enrollment data are gathered by each of the self-insured plans at the time of enrollment in the plan and are maintained over time. Enrollment data provide information on gender and age. They also provide information on date of enrollment in the plan and termination from the plan. This information was used to identify subjects for

the study and to describe the subjects enrolled in the diabetes programs. Claims data are gathered only when claims are made and are used in this analysis to determine adherence to diabetes guidelines; the involvement of a consistent treating physician; the number of hospitalizations; and the number of co-morbid conditions. Claims information for each of these plans is used for payment, but it is also used to predict risk and to develop a clinical profile that is encounter-based. In this analysis it is used to measure adherence to evidence-based guidelines. Adherence to guidelines is a measure of interest to the plans since improvement in adherence is seen as an indication of program success and is linked to positive clinical status. Procedure codes from the administrative data are used to measure adherence to the recommended guidelines for management of diabetes. Table 5 provides a summary of the data sources used for this study.

### Data Organization

#### *Independent Variables*

The primary independent variable for testing of the four hypotheses is the approach to diabetes management used by the health plans that are the subject of this study. Each plan implemented their chronic care management program and enrolled participants in the program over a period of 10 to 12 months. Adherence results are examined for each participant based on their date of enrollment. An initial assessment of the difference in adherence between patients receiving the different approaches is conducted using adherence data for two and a half years after the implementation of the chronic care program. This analysis helps to answer the research question: Is there a

Table 5. Variables with Corresponding Data Sources

<b>Variables and Source of Data</b>	
<b>Independent Variables</b>	
<b>Variable</b>	<b>Source</b>
Approach to chronic care management	Plan description – System versus Individual
Age	Administrative data – enrollment
Gender	Administrative data – enrollment
Co-morbid chronic conditions	Administrative data – claims
Hospitalizations post implementation	Administrative data – claims
Consistent clinical provider	Administrative data – claims
<b>Dependent Variables</b>	
Adherence to diabetes care: HgbA1c, lipid, nephropathy and retinopathy screening	Administrative data – claims

difference in adherence behaviors of individuals in a health plan that implemented a system level program and those in a health plan that implemented an individual level program only? The system-level program is the one in which all components of the CCM were implemented to provide support for chronic illness care. The implementation of these components is an indication of a full system level approach to the management of chronic illnesses. The individual-level group is the one in which only an individual level approach was implemented with no system level approach.

Other variables of interest are included into the regression analysis. These variables are age, gender and the following. The significance of these factors in relation to management of chronic conditions was discussed in detail in Chapter 2 and the factors are summarized here:

- Co-morbid chronic conditions. Co-morbid conditions may impact the patient's perception of risk thus impacting behavior change. According to individual level theories, individual perceptions of risk are often associated with changes in health-related behaviors. The Health Belief Model (Glanz, Lewis & Rimer, 1997), the Transtheoretical Theory (Prochaska & DiClemente, 1983) and the Theory of Planned Behavior (Ajzen, 2002; Glanz, Lewis & Rimer, 1997) all indicate that an increased awareness of the consequences of inaction may lead to behavior change.
- Hospitalizations post implementation of the program. As with the presence of co-morbid conditions, hospitalizations may impact the patient's sense of urgency to change health-related behavior. Since diabetes impacts many body systems, the hospitalizations are not limited to hospitalizations for a diabetes diagnosis.
- Evidence of a consistent clinical provider in the management of diabetes. Research indicates that a well established relationship with a treating physician can impact the adoption of healthy behaviors (Ciechanowski, et al., 2004; Maddigan, Majumdar & Johnson, 2005; Rothman & Wagner, 2003). The number of physicians is a proxy for patient-physician relationship, with the assumption that the more physicians treating diabetes, the less likely the relationship between patient and physician is consistent and productive.

The addition of these variables in the logistic regression model are used to answer the research question: Can adherence to selected evidence-based guidelines be predicted by age, gender, co-morbid conditions, number of hospitalizations, evidence of a consistent



medical provider, and approach to diabetes management (system-level or, using SET categories, micro-meso-exo level versus individual-level only or micro level only)?

### *Dependent Variable*

The dependent variable in this study is adherence to four diabetes management guidelines, specifically adherence to the recommended frequency for the following: hemoglobin A1c monitoring (two times per year), cholesterol monitoring (yearly), retinopathy screening (yearly) and nephropathy screening (yearly). CPT and HCPC codes are used to identify receipt of these services. Table 6 shows the codes that are used and the corresponding categories of adherence for each of the variables of interest. Receipt of a service with one of these codes counts as adherence for this analysis.

Adherence is a multidimensional concept and is reportedly challenging to measure. There are also no accepted guidelines for measuring adherence (World Health Organization, 2003 & Mihalko, et al., 2004). Recommendations for frequency of these services are yearly (lipid levels, retinopathy and nephropathy screenings) or at least twice a year (HgbA1c). Changes in adherence are measured by determining the pattern of adherence prior to enrollment in the program in comparison with post enrollment. The results are categorized as follows. If frequency of receipt of the service increased post implementation the result is designated as improvement in adherence. If there is no change in receipt of the service post implementation and gaps in recommended frequency exist or frequency of receipt of the service decreased post implementation the results are

Table 6: CPT / HCPC Codes for Recommended Screenings for Diabetes Management

Exams - CPT / HCPCs					
Retinopathy Screening – CPT / HCPCs					
2022 F	Dilated retinal exam w/ interpretation	67208	Dilated Eye Exam	92230	Ophthamological visit
3072 F	Eye exam – low risk for retinopathy	67210	Dilated Eye Exam	92235	Ophthalmological visit
67101	Dilated Eye Exam	67218	Dilated Eye Exam	92240	Ophthalmological visit
67105	Dilated Eye Exam	67227	Dilated Eye Exam	92250	Ophthalmological visit
67107	Dilated Eye Exam	67228	Dilated Eye Exam	92287	Ophthalmological visit
67108	Dilated Eye Exam	92002 – 92014	Ophthalmolog ical visit	99172	Ophthalmological visit
67110	Dilated Eye Exam	92015	Ophthalmolog ical visit	99173	Ophthalmological visit
Exams - CPT / HCPCs					
67112	Dilated Eye Exam	92018 – 92019	Ophthalmolog ical visit	S0620	Ophthalmological visit
67141	Dilated Eye Exam	92225	Ophthalmolog ical visit	S0621	Ophthalmological visit
67145	Dilated Eye Exam	92226	Ophthalmolog ical visit	S0625	Ophthalmological visit
Hemoglobin A1c – CPT					
83036	Glycosolated Hemoglobin (A1C)		83037	Glycosolated Hemoglobin by a device approved for home use	
Lipid – CPT / HCPCs					
80061	Lipid Panel	83704	Lipid Testing	83718	Lipoprotein
83700	Lipid Testing	83715	Lipoprotein	83721	Lipoprotein
83701	Lipid Testing	83716	Lipoprotein	84478	Triglycerides
				3011 F	Lipid Panel results documented and reviewed

Table 6, continued

Nephropathy – CPT / HCPCs					
82042	Albumin – urine or other sources	82044	Microalbumin, Semi-quant	3060 F	Positive Microalbumin test result documented and reviewed
82043	Microalbumin, Quantitative	3062F	Positive macroalbumin test result documented and reviewed	3061 F	Positive Microalbumin test result documented and reviewed

designated as no improvement in adherence. If there is no change in receipt of the services and no gaps in recommended care exists pre and post program implementation the result was removed from the analysis. Since the required frequency for the diabetes screenings is every six months (HgbA1c) and yearly (lipid, nephropathy and retinopathy screening) and since the data available covers only two and a half years post implementation the limited time frame makes it difficult to link the approach with sustained changes in adherence. However, initial changes in the behaviors of interest for this study are seen as steps towards adherence. They represent awareness of the behavior and initial engagement in the behavior. Maintenance of the behavior is not measured at this time because of the short range of time for the study. The concept of adherence for the purposes of this analysis is depicted in Figure 6, where the nurses who provide self-management support raise the participants' awareness of the required behavior and the performance of the behavior by the patient is measured through claims.

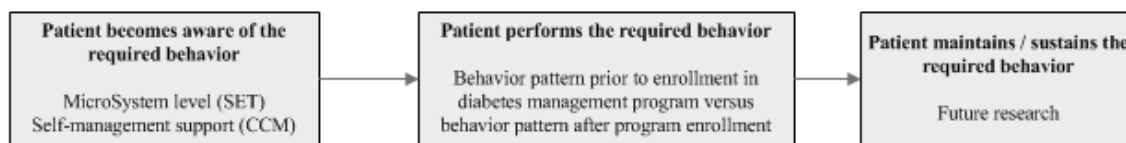


Figure 6. Adherence Behavior: Awareness Measure

The variables of interest represent both individual-level and system-level factors that influence adherence. Table 7 presents all independent variables in this analysis. It also provides information on the type or level of each variable and a summary of how each variable is measured.

Table 7: Study Variables: Independent

<b>VARIABLES</b>		
<b>Independent Variables</b>		
<b>Variable</b>	<b>Measure</b>	<b>Type / Level</b>
Approach to chronic care management	0=Individual    1=System	Nominal
Age	Years	Continuous
Gender	M / F	Nominal / Dichotomous
Co-morbid chronic conditions	Number of conditions	Continuous
Hospitalizations post implementation	Number of hospitalizations	Continuous
Consistent clinical provider	Number of providers managing diabetes	Nominal

Table 8 presents information on the dependent variables for both phases of the study. Information on the level of the variable is also presented. In addition, the table presents specific information on how change in adherence is determined.

Table 8. Study Variables: Dependent

Dependent Variables		
Variable	Measure	Type / Level
<p>Adherence to diabetes care post-program implementation: HgbA1c, lipid, nephropathy and retinopathy screening</p> <p>For comparison of the subjects receiving the different approaches</p>	Yes / No	Nominal
<p>Changes in adherence to diabetes care: HgbA1c, lipid, nephropathy and retinopathy screening</p> <p>For regression analysis</p>	<p>Change in adherence behaviors is represented in the research model as <math>O_2 - O_1</math> for each individual with <math>O_2</math> representing adherence behavior patterns two and a half years after implementation of the program and <math>O_1</math> representing adherence behavior patterns two and a half years prior to program implementation.</p> <p>Results:</p> <p>No change in adherence behaviors if gaps in required screenings are present or adherence behaviors in relation to guideline frequency for screenings is less two and a half years post as compared to two and a half years prior to program implementation – assigned 0</p> <p>Adherence behaviors in relation to guideline frequency for screenings is more two and a half years post as compared to two and a half years prior to program implementation – assigned 1</p>	Nominal

## Data Analysis

Raw claims data in a de-identified form are supplied by the TPA to the researcher. Permission has been obtained from both of the plans for access to their de-identified administrative and claims data for the purpose of this analysis. The TPA has approved the use of the data for this research and a HIPPA disclosure has been signed. According to the VCU Office of Research Compliance and Education, this research is not considered human investigation and therefore does not require IRB review. The following criteria have been met that qualifies the research for IRB review exemption: the coded, private information was not collected specifically for the research being conducted and the researcher can not readily ascertain the identity of the individuals to whom the information pertains. An attestation signed by the representative from the TPA, the dissertation chairperson and the student investigator confirms agreement to these criteria.

This study involves a retrospective analysis of the administrative data from claims and enrollment. Enrollment and claims data provide information used in the descriptive statistics. Information on age, gender, date of enrollment in the plan and date coverage is terminated (if applicable) is available in the enrollment data. Claims data include the number of hospitalizations, other chronic conditions and the presence of a consistent clinical provider. Individuals are designated as receiving micro-level approach only and micro-, meso-, exo-level approach. T-tests for independent samples are conducted for age, number of hospitalizations, number of co-morbid chronic conditions and number of physicians treating diabetes. Chi-square tests are conducted for gender and adherence to

each of the four guidelines of interest. The comparison between the two approaches on adherence post-program implementation helps to answer the research question: Is there a difference in adherence behaviors of individuals in a health plan that implemented a system level program and those in a health plan that implemented an individual level program only?

Descriptive statistics are completed on the entire sample and comparisons are completed on patients receiving the different approaches to diabetes management. Once this is complete the impact of the approach on adherence changes from pre-program implementation to post program implementation is assessed through logistic regression. Logistic regression analysis is used to predict a dichotomous categorical variable from multiple predictive variables (Leech, Barrett, & Morgan, 2005). Variables that are being assessed for their predictive relationship to change in adherence are entered into the model. The odds ratio ( $\text{Exp } \beta$ ) for each independent variable is assessed to determine the predictive relationship between the dependent variables and changes in adherence. The correlation coefficient ( $R^2$ ) is assessed to determine the strength of the model, with all variables, in relation to change in adherence. These analyses help to answer the research question: Can adherence to selected evidence-based guidelines be predicted by age, gender, co-morbid conditions, number of hospitalizations, evidence of a consistent medical provider, and approach to diabetes management (system-level versus individual-level only)? The analysis for each dependent variable is performed in the same way (HgbA1c; lipid levels, nephropathy and retinopathy screening). Results are presented in the next chapter.

## Limitations

### *Measurement Quality*

Measurement quality involves the validity and reliability of the variables chosen and the tools used to determine the results. In relation to measurement validity, face, construct and criterion-related validity are considered. These address how the variables are operationalized. The dependent variables selected for this study have face and construct validity since they represent the construct of adherence to diabetes guidelines. Some of the major complications of diabetes are blindness, kidney disease and heart disease. To control the progression towards these complications the American Diabetes Association (ADA) and the Centers for Disease Control (CDC) recommend control of both glucose and lipid levels. Proper control is monitored through the regular testing of HgbA1c and lipids. To help control the progression towards kidney disease and blindness both the ADA and the CDC recommend regular screening for nephropathy and retinopathy through tests for Microalbumin and eye exams (American Diabetes Association, n.d.; Centers for Disease Control, 2007).

Measurement reliability relates to the consistency of the measurement. Test / re-test and Cronbach's Alpha are used to test the reliability of measures. A test / re-test is conducted and a test for correlation of results is completed. Since these are administrative data collected for other reasons than for research test / re-test is not possible in this study. Cronbach's Alpha test for internal consistency takes the set of measures and splits them in different ways to test the correlation between them and the sum of related items. The data used in this study provide information on dates selected tests were received. From



this date information, conclusions regarding changes in adherence are being made. The conclusions are nominal. Therefore a Cronbach's alpha analysis is not a possible test for reliability.

However, measurement quality is assessed through an analysis of the strengths and weaknesses of the administrative data. Some of the strengths are that this data provide utilization information across all service providers and the utilization patterns can be linked to the individuals covered by the specific plans of interest to this study. There are several approaches that can be taken to obtain utilization information. One method is chart review. This would involve obtaining access to charts for identified individuals and obtaining agreement from all participants and their service providers. It is also costly to perform. The second method is self-report from patients regarding the services they have received. Again, individuals would have to be identified and surveyed and patient recall is not always exact. The third method is the use of administrative data.

The accuracy of administrative data has been compared to the accuracy of self-report in relation to the ability to identify risks and measure performance against standard guidelines (Fan, Maciejewski, Liu, McDowell & Fihn, 2006; Thompson, et al., 2001; Vojta, et al., 2001). In Fan, et al. (2006), administrative data was reported to be at least as accurate as self-reported data and at times substantially more accurate. Thompson et al. (2001) concluded that administrative data provide more accurate information particularly when the information desired is related to utilization patterns and procedure codes.

The accuracy of administrative data has also been compared to a review of medical records. Diamond, Rask & Kohler (2001) conducted a study that assessed outpatient performance indicators through administrative data and review of medical records. The report indicated that administrative data identified more patients who received select screenings. One of the outpatient services that were evaluated was specific to the receipt of retinopathy screening for patients with diabetes. The authors concluded that administrative data captured a greater proportion of patients who received retinopathy screenings (44% versus 27%,  $p < 0.001$ ). They pointed out that the lack of standardization of medical record documentation can lead to limitations in identifying the receipt of services.

The limitations of administrative data have also been reported in the literature, particularly in relation to the ability of the data to reflect clinical quality and the accuracy of the coding (Iezzoni, 1997). The main weakness of this administrative data is that there are no tests of its reliability, although the quality of the data is checked through the process performed by the Third party Administrator (TPA). Evidence of the quality report card generated by the TPA is included in Appendix C. The report card is generated through the quality process performed when claims and enrollment data are received. Once collected by the plan, the data are imported into one central database maintained by a common TPA, used by both of the represented health plans. The TPA provides the plan with a data layout that identifies the fields that are necessary for a complete file. Once the data are imported, a report card is generated and reviewed by the plan. Errors are addressed until they are resolved. Quality assurance reviews are

performed to assure that the data are complete and accurate. Once the process is completed, an automated process is performed that updates the files on a monthly basis. Report cards are generated on a monthly basis, as well and reviewed by the TPA and the health plan.

### *Design Quality*

Threats to research design quality fall into several categories. External validity refers to the ability of the research to be generalizable. Generalizability is related to the ability to say that the research was designed in such a way that the results can be applicable to other situations and other populations. The sample may not be representative of the entire diabetic population. The individuals being studied in this research are covered under self-insured health plans. While a high percentage of privately insured individuals are covered under self-insured plans, 27% of all individuals are covered under government insurance and 15.8% of individual are uninsured (DeNavas-Walt, Proctor & Smith, 2007). Because they are not represented in the study results are not generalizable to these coverage types. The employers are both hospital systems. The employees, their dependents and the providers are located in a single state. These factors also limit the generalizability of the study.

Internal validity of research design refers to the ability of the research to support the claim that the intervention is linked to the outcome. History is one specific threat that falls into this category. History threats can occur when external factors impact the results rather than the intervention itself. This research examines changes in adherence to diabetic screenings and monitoring over a two and a half year period. Other factors may

have played a role in the results. Increased awareness of the importance of diabetes management may have occurred, such as local media reports of healthy behaviors related to diabetes. Maturation is another threat to the internal validity of the research. Maturation is the effect of time on the changes being studied. For this research, the patients have naturally matured over the five years of the study. The program itself may have matured and changed over the period of time as well. Assurances have been made, however, that no substantive changes in the program occurred during the two and a half years after the programs were implemented through interviews with leaders in each of the health plans. However, as physicians have become more aware of the initiatives to improve diabetes management their involvement in making the initiative a success may have impacted the overall program.

Selection of subjects refers to a bias that may occur as a result of selection of the subjects. Selection of the subjects was completed on a convenience basis and included patients who had continuous coverage with the plans for at least four years. There may be a quality in the individuals that remain with stable employment and stable insurance coverage that influences the intermediate outcome of adherence. While these threats are acknowledged as possible in this research, the statistical control employed in the comparative analysis help mitigate some of the risks associated with these threats. Caution must be used in interpretation and discussion of the results.

Statistical conclusion validity is related to biases that may occur as a result of an improper use of statistics including a low reliability of measures and reliability of treatment implementation. The low reliability of measures may be seen in the selection of

the screenings. The screenings that were selected for this study are required annually (lipid, nephropathy and retinopathy screening) or every six months (A1c). Adherence measurements for the study span a two and a half year period prior to implementation of the chronic care program and two and a half years after implementation. The short time span of the study may represent a threat to conclusion validity. Statistical conclusion validity can be strengthened through a research design with adequate power (at least .80) which this research has attempted to address. However, an issue with sample size has been identified that may lead to a type 2 error and an overestimation of the odds ratio. The issue is related to sample size. Although overall sample size is adequate, the sample size for three of the logistic regression analyses is lower than desired.

Multiple factors impact adherence behaviors, including health perceptions; individual characteristics such as coping styles; social circumstances such as supportive resources; knowledge; motivation and past success in improving health behaviors; the quality of the patient-provider relationship; ease of access to providers and services; treatment; and, disease characteristics (Sherbourne, Hays, Ordway, DiMatteo and Kravitz, 1992; World Health Organization, 2003). Controlling for all of these factors was not possible as measures were not available in the administrative data. However, some of these factors are considered in this research. The research factors included in this research are: individual characteristics such as age and gender; the patient-provider relationship as measured by the patient consistently receiving services from one provider; and disease characteristics as measured by the presence of co-morbid conditions and frequency of hospital admissions.

A threat to reliability of treatment implementation may be evident in the fact that different nurses interact with the patients to provide self-management support. The different personalities may impact the outcome as opposed to the system-level approach implemented. The tools and processes used by the plans, however, may help to mitigate this threat. The nurses who educate the patients on the guidelines undergo the same training. They also use the same tool that contains the diabetic guidelines and instructions on how to help the participant improve adherence behaviors.

Threats to construct validity occur when there are not clear operational definitions. Adherence is a complex term. For this study adherence is defined as the extent to which a person's behavior is consistent with recommendations from health providers. Using claims data for analysis of screening and monitoring completed standardizes the measurement for all participants. Sustained changes in adherence are not measured by this research since there are only two and a half years of data post implementation of the program. However, initial changes in behavior are seen as evidence of awareness and beginning adoption of the behavior, the steps towards sustained adherence (Johnson, 2002; Pathman, Konrad, Freed, Freeman & Koch, 1996). The changes in adherence behavior are consistent with recommendations in national guidelines and are the focus of this analysis. Table 9 provides a brief summary of the threats to research quality identified in this study.

### Summary

This chapter presents the methodology used in this research. This retrospective, non-experimental study examines changes in adherence to diabetes guidelines based on

Table 9. Summary of Threats to Research Quality

<b>THREAT / LIMITATION</b>	
<b>Design Quality</b>	<b>Description</b>
Generalizability	Study group is fully insured and employed by a self-insured employer. Results may not be generalizable to other coverage types and the uninsured.
History	Study period covers a five year span of time. Other factors may have occurred over that span of time that influence the results.
Maturation	Both the patients and the programs may have matured over the five year period in such a way as to influence to results.
Selection of Subjects	A convenience sample and the inclusion criteria may lead to a non-representative sample. The sample consists of patients who had continuous coverage with the employer for five years. There may be characteristics of these employees that influence adherence.
Statistical Conclusion Validity	Possible low reliability of measures due to the frequency of monitoring required in relation to the time span of the study
<b>Measurement Quality</b>	<b>Description</b>
Reliability of Treatment Implementation	Different nurses delivered the information to the patients regarding the required screenings. A script, however, was used by all the nurses for both plans.
Construct Validity	Adherence is a complex and multifaceted construct making it difficult to control for all factors that contribute to adherence
Construct Validity	How variables are operationalized - Variables selected are accepted as measurements of adherence to diabetes guidelines
Reliability	Administrative data - no tests of reliability are possible. TPA process for assuring accuracy and quality of the data will be reported

health plan implementation of a system-level approach. Administrative data are used to assess adherence to HgbA1c, lipid monitoring, retinopathy screening and nephropathy monitoring. Descriptive analyses are conducted. Comparison of adherence between

patients covered by plans that had implemented an individual-level approach only versus the one in plans in which a systems-level approach has been implemented is conducted. Finally, for all individuals in this study an analysis of factors that are most predictive of improvement in adherence is conducted



## CHAPTER 4: RESULTS

This research explores the relationship between adherence to diabetes guidelines and approaches to diabetes management adopted by two employer-sponsored self-insured health plans. Framed in social ecology theory, this study explores the effectiveness of using the CCM practice model on efforts to improve adherence to diabetes guidelines. The study is designed to determine whether there is a significant difference in select diabetes adherence behaviors between a health plan in which only individual level approaches have been implemented (micro only) and a health plan in which system-level approaches, as well as individual-level ones, have been implemented to improve the health of individuals with diabetes (micro- meso - exo). In addition, the study examines the contribution of the approach to management of diabetes in relation to individual-level factors that are known to impact adherence.

This chapter presents the results of this study. It begins with descriptive information about all the subjects in the study and the differences between the two populations enrolled in programs providing chronic care through the different approaches. An analysis of the differences between the two groups on adherence after implementing the diabetes programs is also presented. The chapter then focuses on the results of the regression analysis, analyzing adherence while controlling for individual factors that affect it.

## Health Plans

The focus of this study is the approach to diabetes management adopted by two health plans. The approach is framed in social ecology theory. Both health plans are self-insured hospitals. Both implemented an individual level approach, micro-system in social ecology theory, in which the same information system was used to identify patients with diabetes. In addition to patient identification, the information system used claims and enrollment data to provide a clinical picture of the needs of each participant. This information was used by the nurses who provided self-management support. Both systems employed nurses who outreached to the identified patients and educated them on the management of diabetes. The same patient management system and guidelines were used by the nurses who outreached to the patients from both health plans. One health plan's program implemented these individual-level interventions only. The second health plan implemented system level changes in addition to the individual level approach. This health plan began their efforts to improve diabetes management by establishing organizational support for the initiative. The initiative was adopted by top executives of the organization. The health plan engaged with community organizations to establish a support system for participants in the program. The plan also engaged with community physicians, eliciting their help in supporting the guidelines and processes. The information system used by the nurses was also used by the community physicians to provide feedback on the patient's progress. A care coordination team, made up of members from multiple disciplines, met on a regular basis to provide ongoing support for the chronic care program. These features of the program enhanced the micro level

approach implemented by both health plans by adding meso- and exo-system level support.

### Subjects

The subjects, whose adherence to diabetes guidelines are analyzed in this research, are individuals with diabetes who are members of the two health plans. A total of 951 individuals were identified through the claims data of the two plans as having claims associated with diabetes. Of the individuals identified (n=951), patients were initially excluded from the study (n=531) for the following reasons: other insurance as primary thus limiting access to claims to be used for the analysis; not enrolled in the plan for a long enough period of time for the analysis to be accurate (two and one-half years prior to and post program implementation); and under the age of 18 at the time of the initial measurement. Once this sample was selected, further review of the data was conducted and missing fields were identified. According to Polit & Hungler (1999) there are five ways of dealing with missing or incorrect variables: deletion of the cases where data are missing; deletion of the variables; substituting the mean value; estimating the missing value; and, deleting cases selectively and pairwise. All of these were considered. However, where missing fields were identified, the subjects were removed from the study since the variables that were missing or incorrect were essential to the research. To include subjects without the information would impact the results in a way inconsistent with the research design. In addition, the sample size was large enough and the number of cases removed was small enough to maintain statistical power relative to the overall number of subjects. Based on these criteria, an additional 96 subjects were removed,

leaving a total sample size of 324, as seen in Table 10. This is the number of subjects for the first part of the analysis and used to answer the first research questions: Is there a difference in adherence behaviors of individuals in a health plan that implemented a system level program and those in a health plan that implemented an individual level program only?

Table 10. Sample Size

APPROACH	COVERED LIVES	TOTAL W/ DIABETES	INITIAL EXCLUSION	ADDITIONAL EXCLUSION	TOTAL IN STUDY	% OF DIABETICS IN STUDY
A - Individual	3998	468	278	40	150	32%
B - System	5046	483	253	56	174	36%
TOTAL	9044	951	531	96	324	34%

### *Characteristics of the Study Sample*

Table 11 displays demographic and clinical characteristics of the independent variables being studied. The study sample includes 194 women and 130 men. The mean age of the study sample is 52.1 years with the range being 20 to 64 years old. The average number of hospitalizations per subject since start of the diabetes programs is 0.43, with the range being zero to six. The subjects have an average of 2.35 co-morbid chronic conditions and a range of zero to six conditions. The number of physicians treating each subject for diabetes average 3.34 with the range at one to nine.

### *Characteristics of Subjects by Approach to Chronic Care Management*

Both health plans whose participants are the subject of this study provided different approaches to the management of their covered individuals with diabetes.

Table 11. Individual Characteristics of Total Sample

Characteristic	Value	Range
Gender		
Female	194 60%	
Male	130 40%	
Age (Average)	52.1	20-64
Hospitalizations since start of program (Average)	0.43	0-6
Co-morbid Conditions (Average)	2.35	0-6
Physicians treating diabetes (Average)	3.34	1-9

Framed in social ecology theory, one plan implemented a program from a micro-level approach while the other plan implemented a micro-, meso, and exo-level approach, incorporating support throughout the organization. The descriptive information on the independent variables by approach is presented in Table 12.

There is no statistically significant difference between the two groups on age, the number of physicians treating the subjects for diabetes, and gender. A statistically significant difference is noted on the number of hospitalizations since enrollment in the diabetes program. Subjects in the plan that implemented the individual level approach had more hospital admissions (mean=0.56) than subjects in the plan that implemented the system level approach (mean=0.31). There is also a statistically significant difference between the two plans on the number of co-morbid conditions with which subjects were diagnosed. Conditions included were heart failure, coronary artery disease, hypertension,

Table 12. Characteristics of Sample Population Based on Chronic Care Program in Which They Participate

	<b>MICRO -MESO-EXO-SYSTEM APPROACH (System) N=174</b>			<b>MICRO APPROACH ONLY (Individual) N=150</b>				
	<b>M / %</b>	<b>SD</b>	<b>Range</b>	<b>M / %</b>	<b>SD</b>	<b>Range</b>	<b>Mean Diff</b>	<b>p value</b>
Age	52.35	9.56	20-64	51.81	8.54	29-64	0.537	.413
Hospitalizations since enrollment in program	0.31	0.65	0-3	0.56	1.1	0-6	-0.250	.000
Co-morbid conditions	2.55	1.23	0-6	2.11	0.87	0-4	0.433	.000
Physicians treating diabetes	3.42	2.11	1-9	3.25	1.98	1-8	0.173	.288
Gender:								
Female	98 56%			96 64%				.160
Male	76 44%			54 36%				

hyperlipidemia, chronic renal failure, asthma / chronic obstructive pulmonary disease, and depression. On average, subjects in the system level plan had a higher number of co-morbid conditions (mean=2.55) than subjects in the individual level plan (mean=2.11).

#### Adherence Differences by Approach to Chronic Care Management

One question being addressed by this research is: In relation to individuals with diabetes is there a difference in adherence behaviors between individuals in a health plan that implemented a system level program and those in a health plan that implemented an individual level program only? Results of the chi-square analyses are presented below.

#### *Adherence to Cholesterol Monitoring*

Recommendations for the management of diabetes include at least annual monitoring of the LDL in order to detect changes early in the disease progression

(American Diabetes Association, 2007). The two health plans being studied in this research incorporated goals for improving adherence to cholesterol monitoring. Is there a difference post program implementation between the two plans in relation to LDL monitoring adherence? This research was conducted to test the null hypothesis that there is no significant difference in adherence to lipid monitoring of individuals in a health plan that implemented a micro-, meso-, and exosystem (system) approach to chronic care management compared to individuals in a health plan that implemented a microsystem approach alone (individual).

Since there was a significant difference in adherence to LDL monitoring between the two plans after implementation of the different approaches, further analysis was conducted to determine if there was a significant difference between the two health plans prior to implementation of the program. Table 13 presents results of the comparison between the two health plans on LDL monitoring adherence prior to the start of the program.

Table 13. LDL Adherence Results by Approach - Before

<b>Adherence Result</b>		<b>TOTAL</b>	<b>MICRO -MESO-EXO-SYSTEM APPROACH (system)</b>	<b>MICRO APPROACH ONLY (Individual)</b>
Yes	N	107	80	27
	%	33.0%	46.0%	18.0%
No	N	217	94	123
	%	67.0%	54.00%	82.0%

\*p=.000

The results in Table 13 indicate that prior to implementation of the program there was a statistically significant difference in adherence between the two groups with the micro-meso-exo system level approach showing a higher percentage of subjects who were adherent. The subjects in the micro-, meso- and exo-system level plan had a 46% adherence level as compared to the 18% adherence level associated with the micro level only approach.

Table 14 presents the results after the program was implemented. The results in Table 14 indicate a statistically significant difference in adherence to LDL monitoring between the two plans after implementation of the different approaches. The system level approach is associated with 70.1% adherence to LDL monitoring compared to a 37.3 % adherence associated with the individual level approach.

Table 14. LDL Adherence Results by Approach - After

<b>Adherence Result</b>		<b>TOTAL</b>	<b>MICRO -MESO-EXO-SYSTEM APPROACH (system)</b>	<b>MICRO APPROACH ONLY (Individual)</b>
Yes	N	178	122	56
	%	54.9%	70.1%	37.3%
No	N	146	52	94
	%	45.1%	29.90%	62.7%

\*p=.000

To determine whether there was a significant difference in adherence before and after program implementation, chi square analyses were conducted by each approach on the level of adherence before as compared to the level of adherence after. Table 15 presents the results of these analyses. For both approaches there was a statistically



Table 15. Differences in LDL Adherence from Prior to Post Program by Approach

	Adherence Prior to		TOTAL	Adherence Post No	Adherence Post Yes
Adherence to LDL Guidelines - Micro Level Approach (Individual)	No	N	123	89	34
		%		72.4%	27.6%
	Yes	N	27	5	22
		%		18.5%	81.5%
	*p=.000 $\chi^2= 27.431$				
Adherence to LDL Guidelines - Micro- Meso-Exo System Level Approach (System)	No	N	94	45	49
		%		47.9%	52.1%
	Yes	N	80	7	73
		%		8.8%	91.3%
	*p=.000 $\chi^2= 31.568$				

significant difference in adherence before program implementation as compared to adherence after program implementation. For the micro level approach, of the 123 subjects who were non-adherent prior to program implementation, 72.4% remained non-adherent after program implementation and 27.6% moved from non-adherence to adherence. Of the 27 subjects who were adherent prior, 81.5% remained adherent and 18.5% moved from adherent into non-adherent. For the micro-meso-exo system approach, of the 94 subjects who were non-adherent prior to the implementation of the program, more than half moved from non-adherence to adherence (52.1%) and 47.9% remained non-adherent. Of the subjects who were adherent prior, 8.8% moved into non-adherence while 91.3% remained adherent.

#### *Adherence to Retinopathy Monitoring*

Each of the two health plans have integrated retinopathy screening adherence into their programs for the management of participants with diabetes. Annual retinopathy

screening is the recommended frequency, according to the American Diabetes Association (American Diabetes Association, 2007). This research asks the question: Is there a difference in post program implementation between the two plans in relation to adherence to retinopathy screening? The hypothesis associated with this question is: there is no significant difference in adherence to retinopathy screening of individuals in a health plan that implemented a micro-, meso-, and exo-level (system) approach to chronic care management compared to individuals in a health plan that implemented a micro-level (individual) approach alone. Based on what was learned in the analysis of LDL adherence analyses of before adherence for the two health plans was conducted as well as analyses for post program implementation adherence. There was no statistically significant difference in adherence to retinopathy screening for the two plans prior to program implementation ( $p=.379$ ). Adherence levels for the micro-, meso-, and exo-level approach was 13.8% and for the micro level only was 17.3%.

There was, however, a statistically significant difference between the two plans in retinopathy screening adherence after program implementation ( $p=.022$ ). Results for adherence levels after program implementation are presented in Table 16. Although adherence is low for both plans, as with LDL adherence, the plan that implemented the micro-, meso-, and exosystem approach showed a higher level of compliance (30.5%) than the plan that implemented the micro level approach only (19.3%).

There were statistically significant differences in adherence before program implementation and after implementation for the two plans. For the subjects in the plan that implemented the micro level only approach, 124 were non- adherent prior to program

Table 16. Retinopathy Screening Adherence by Approach - After

<b>Adherence Result</b>		<b>TOTAL</b>	<b>MICRO -MESO-EXO-SYSTEM APPROACH (system)</b>	<b>MICRO APPROACH ONLY (Individual)</b>
Yes	N	82	53	29
	%	25.3%	30.5%	19.3%
No	N	242	121	121
	%	74.7%	69.50%	80.7%

\*p=.022

implementation. Of these, 95.2% remained non-adherent and 4.8% moved from non-adherence into adherence. Of the 26 subjects that were adherent prior to program implementation, 88.5% remained adherent after program implementation. For the subjects in the plan that implemented the micro, meso and exo system level approach to chronic care management, 150 subjects were non-adherent prior to program implementation. Of these, 76% remained non-adherent and 24% moved from adherence to non-adherence. Of the 24 subjects who were adherent prior to program implementation, 70.8% remained adherent while 29.2% moved from adherence to non-adherence. One cell, representing the number of participants receiving the micro-level only approach who moved from adherence to non-adherence, had less than five participants in the cell. Small cell sizes can lead to accepting the null hypothesis when it is false. These results are presented in Table 17.

#### *Adherence to A1c Monitoring*

Hemoglobin A1c monitoring is recommended at least every six months for individuals with diabetes (American Diabetes Association, 2007). Both health plans

Table 17. Differences in Retinopathy Screening Adherence from Prior to Post Program

	<b>Adherence Prior to</b>		<b>TOTAL</b>	<b>Adherence Post No</b>	<b>Adherence Post Yes</b>
Adherence to Retinopathy Guidelines - Micro Level Approach (Individual)	No	N	124	118	6
		%		95.2%	4.8%
	Yes	N	26	3	23
		%		11.5%	88.5%
*p=.000 $X^2=96.372$					
Adherence to Retinopathy Guidelines - Micro-Meso-Exo System Level Approach (System)	No	N	150	114	36
		%		76.0%	24.0%
	Yes	N	24	7	17
		%		29.2%	70.8%
*p=.000 $X^2=21.424$					

adopted this frequency goal into their programs and helped to support their participants to improve their adherence levels in relation to monitoring A1c. This research is designed to answer whether there is a difference in this monitoring post program implementation between the two plans. The following hypothesis was tested: there is no significant difference in adherence to hemoglobin A1c monitoring of individuals in a health plan that implemented a micro-, meso-, and exosystem approach to chronic care management compared to individuals in a health plan that implemented a microsystem approach alone.

Table 18 presents the results of the chi square analysis comparing adherence prior to program implementation by each approach. There was a statistically significant difference in adherence between the two plans prior to implementing their diabetes

Table 18. A1c Adherence Results by Approach - Before

<b>Adherence Result</b>		<b>TOTAL</b>	<b>MICRO -MESO-EXO-SYSTEM APPROACH (system)</b>	<b>MICRO APPROACH ONLY (Individual)</b>
Yes	N	70	47	23
	%	21.6%	27.0%	15.3%
No	N	254	127	127
	%	78.4%	73.0%	84.7%

\*p=.011

program (p=.011). Not only did the plan that implemented the system-level approach have a higher level of adherence post program implementation than the plan with the individual level approach, it also had a higher level of adherence prior to program implementation (27.0%) than the plan with the individual-level approach (15.3%).

As with LDL and retinopathy monitoring, there is a statistically significant difference between the two plans in relation to adherence to A1c monitoring during the two and a half years after program implementation (p=.000). There was a 60.3% adherent rate for the plan that implemented the system-level approach, as compared to 16.6% adherence for the plan that implemented the individual-level approach. Based on these results the null hypothesis for hemoglobin A1c monitoring adherence is rejected. Results are presented in Table 19.

Comparison by approach to chronic care management shows a statistically significant difference in both plans from before program implementation to after program implementation. For the plan that implemented the micro-level approach only, there

Table 19. A1c Adherence Results by Approach – After

<b>Adherence Result</b>		<b>TOTAL</b>	<b>MICRO -MESO-EXO-SYSTEM APPROACH (system)</b>	<b>MICRO APPROACH ONLY (Individual)</b>
Yes	N	130	105	25
	%	40.1%	60.3%	16.7%
No	N	194	69	125
	%	59.9%	39.7%	83.3%

\*p=.000

were 127 subjects who were non-adherent to A1c monitoring. Of the 127, 90.6% remained non-adherent and only 9.4% became adherent. Of the 23 subjects who were adherent, 56.5% remained adherent but 43.5% became non-adherent. Of the 127 non-adherent subjects receiving the systems-level approach, 52.0% remained non-adherent and 48.0% moved from non-adherence to adherence. Of the 47 subjects that were adherent, 93.6% remained adherent and 6.4% became non-adherent. The 6.4% represents only three subjects in that cell, a problem that can lead to accepting the null hypothesis when it is false. Table 20 summarizes these results.

#### *Adherence to Nephropathy Monitoring*

Nephropathy screening is recommended on an annual basis to detect changes in kidney function that can be caused by poorly managed diabetes (American Diabetes Association, 2007). Both plans made adherence to nephropathy screening one of their program goals. This research is designed to answer the question: Is there a difference post program implementation between the two plans in relation to nephropathy screening adherence? The hypothesis being tested is: there is no significant difference in adherence

Table 20. Differences in A1c Screening Adherence from Prior to Post Program

	<b>Adherence Prior to</b>		<b>TOTAL</b>	<b>Adherence Post No</b>	<b>Adherence Post Yes</b>
Adherence to A1c Guidelines - Micro Level Approach (Individual)	No	N	127	115	12
		%		90.6%	9.4%
	Yes	N	23	10	13
		%		43.5%	56.5%
*p=.000 X <sup>2</sup> =31.068*					
Adherence to A1c Guidelines - Micro-Meso-Exo System Level Approach (System)	No	N	127	66	61
		%		52.0%	48.0%
	Yes	N	47	3	44
		%		6.4%	93.6%
*p=.000 X <sup>2</sup> =29.790					

to nephropathy screening monitoring of individuals in a health plan that implemented a micro-, meso-, and exosystem approach to chronic care management compared to individuals in a health plan that implemented a microsystem approach alone. The results of the comparison between the two plans on nephropathy screening adherence prior to program implementation are presented in Table 21 and show a statistically significant difference ( $p=.001$ ) in adherence prior to program implementation. There is a high rate of non-adherence for both groups with the micro-level only at a 98% non-adherence rate and the micro-, meso-, and exo-level approach with an 88.5% non-adherence rate. While there are few subjects in one cell, SPSS results indicate that no cells have an expected frequency of less than five.

Table 21. Nephropathy Screening Adherence Results by Approach - Before

<b>Adherence Result</b>		<b>TOTAL</b>	<b>MICRO -MESO-EXO-SYSTEM APPROACH (system)</b>	<b>MICRO APPROACH ONLY (Individual)</b>
Yes	N	23	20	3
	%	7.1%	11.5%	2.0%
No	N	301	154	147
	%	92.9%	88.5%	98.0%

\*p=.001

Results for the analyses on nephropathy screening after program implementation are presented in Table 22. The adherence rates are still low. Results show that the plan with the micro-level only approach demonstrates a 93.3% non-adherence and the one with the micro-, meso- and exo-level approach demonstrates a 64.4% non-adherence rate.

In comparing the before program adherence rate to the after program adherence rate by the two different approaches there is a statistically significant difference in rates of adherence for the micro-, meso-, and exo-level approach (p=.000) and a non-significant difference for the micro-level approach (p=.061). For the system-level

Table 22. Nephropathy Screening Adherence Results by Approach – After

<b>Adherence Result</b>		<b>TOTAL</b>	<b>MICRO -MESO-EXO-SYSTEM APPROACH (system)</b>	<b>MICRO APPROACH ONLY (Individual)</b>
Yes	N	72	62	10
	%	22.2%	35.6%	6.7%
No	N	252	112	140
	%	77.8%	64.4%	93.3%

\*p=.000



approach, of the 154 non-adherent subjects 29.2% moved from non-adherence to adherence and of the 20 subjects that were adherent 85% remained adherent. There are four cells, representing movement from non-adherence to adherence for the micro-level approach, that have less than five subjects. Table 23 summarizes these results.

### Multivariate Analysis

Knowing that there is a statistically significant difference between the two approaches in adherence results after the programs were implemented is not enough to gain an understanding of what contributes to the difference. This is especially important when there are still many enrollees who are non-adherent even after implementation of the chronic care program. A logistic regression analysis is done to help identify the factors that contribute to changes in adherence. Variables of interest in the regression analysis are variables that are possible factors that impact adherence behaviors. Factors that are included in the analysis are: age; gender; number of co-morbid conditions; number of hospitalizations; number of physicians treating diabetes; and, approach to chronic care management. All factors were entered into the regression analysis to determine the predictive relationship to the dependent variable.

The dependent variables are change in adherence to each of the four recommended screenings. Adherence is categorized into no change in adherence or positive change in adherence over the two and a half years prior to each program being implemented as compared to adherence two and a half years after program implementation. Change in adherence is calculated by taking the number of tests

Table 23. Differences in Nephropathy Screening Adherence from Prior to Post Program

	Adherence Prior to		TOTAL	Adherence Post No	Adherence Post Yes
Adherence to Nephropathy Guidelines - Micro Level Approach (Individual)	No	N	147	138	9
		%		93.9%	6.1%
	Yes	N	3	2	1
		%		66.7%	33.3%
*ns (p=.061)					
Adherence to Nephropathy Guidelines - Micro-Meso-Exo System Level Approach (System)	No	N	154	109	45
		%		70.8%	29.2%
	Yes	N	20	3	17
		%		15.0%	85.0%
*p=.000 X <sup>2</sup> =24.012					

performed according to the guidelines after the program start and subtracting the number of tests performed according to guidelines before program start. In some cases the subjects were adherent both before and after program implementation. Those cases were removed from these analyses resulting in a different sample size for each measurement. The logistic regression is performed for each screening to answer the second research question: Can adherence to selected evidence-based guidelines be predicted by age, gender, co-morbid conditions, number of hospitalizations, evidence of a consistent medical provider, and approach to diabetes management (system-level versus individual-level only)? The research is designed to address the following hypothesis for each of the recommended screenings: Approach to diabetes management is associated with a change

in adherence to select diabetes screenings from pre-program implementation to post program implementation.

### *Regression Results for Adherence to LDL Monitoring*

In relation to LDL monitoring, 115 cases were removed because of consistent adherence from before to after the start of the program, leaving a sample size of 209 subjects in the analysis. Table 24 presents the results of the logistic regression performed. The model being studied, with all independent variables entered into the equation at the same time, was found to be statistically significant for predicting adherence ( $p=.000$ ). The independent variables account for 22.5% of the change in LDL adherence (Nagelkerke  $R^2$ ). Analysis of the predictors shows that three of the variables were not statistically significant predictors of changes in adherence to LDL monitoring. The three were age, number of medical providers treating diabetes and approach to chronic care management. Three of the variables were found to be statistically significant predictors: gender, number of hospitalizations and number of co-morbid conditions. Gender results show that males are less likely to have a change in adherence compared to females. Males were 2.3 times less likely to have a change in LDL adherence as compared to females. The number of hospitalizations is predictive of a decrease in adherence. For every one unit increase in the number of hospitalizations, subjects were 1.79 times less likely to have a change in LDL adherence. The number of chronic conditions is associated with an increase in adherence to LDL. For every one unit increase in the number of chronic conditions, subjects were 1.8 times more likely to show a change in LDL adherence.

Table 24. Logistic Regression Results for Change in LDL Adherence

Predictor	B	p-value	Odds ratio	CI	
				Upper	Lower
Age (continuous)	.018	.272	1.018	.986	1.051
Gender (dichotomous)	-.869	.007	.419	.224	.785
Number of hospitalizations (continuous)	-.575	.004	.563	.380	.834
Number of co-morbid conditions (continuous)	.605	.000	1.832	1.311	2.560
Number of medical provider treating diabetes (continuous)	-.078	.327	.925	.791	1.081
Approach to chronic care management System / Individual (dichotomous)	.463	.136	1.589	.864	2.921
n = 209		p=.000 R <sup>2</sup> =.225			

#### *Regression Results for Adherence to Retinopathy Monitoring*

Logistic regression was conducted to determine the independent variables that are predictive of changes in adherence to the recommended frequency of retinopathy monitoring. This analysis was completed for those subjects who demonstrated a change from prior to program implementation to post program implementation, excluding those subjects that maintained adherence to the recommended frequency throughout the study period. The number of subjects included in this analysis was 284. Forty subjects were excluded. The logistic model with all the variables entered in at the same time was a statistically significant predictor of change in retinopathy screening adherence ( $p=.000$ ). According to the Nagelkerke R<sup>2</sup>, the independent variables account for only 12.8% of the change in adherence. A review of the impact each variable has as a predictor of change shows that only the approach to chronic care management is a statistically significant

factor ( $p=.000$ ). These results are presented in Table 25. Subjects in the plan that implemented the micro-, meso- and exo-level approach are 3.2 times more likely to have a change in adherence.

Table 25. Logistic Regression Results for Change in Retinopathy Screening Adherence

Predictor	B	p-value	Odds ratio	CI	
				Upper	Lower
Age (continuous)	.000	.981	1.000	.971	1.029
Gender (dichotomous)	.436	.113	1.547	.901	2.656
Number of hospitalizations (continuous)	.188	.196	1.206	.908	1.603
Number of co-morbid conditions (continuous)	.154	.217	1.167	.914	1.490
Number of medical provider treating diabetes (continuous)	.083	.202	1.086	.957	1.233
Approach to chronic care management System / Individual (dichotomous)	1.176	.000	3.242	1.832	5.737
n = 284		p=.000			
		R <sup>2</sup> =.128			

#### *Regression Results for Adherence to Hemoglobin A1c Monitoring*

The number of subjects in the analysis was 248, with 78 subjects removed from the analysis because of consistent adherence both before and after program implementation. Just as with LDL and retinopathy adherence, the model was statistically significant for predicting adherence to A1c monitoring ( $p=.000$ ). The independent variables account for only 17.7% of the change in adherence (Nagelkerke R Square). As with retinopathy screening the only factor that is a statistically significant predictor of change in adherence is approach to chronic care management. Table 26 presents these results. Subjects in the micro-, meso-, and exo-level approach are 3.4 times more likely to show changes in adherence than those in the micro-level approach only.

Table 26. Logistic Regression Results for Change in Hemoglobin A1c Adherence

Predictor	B	p-value	Odds ratio	CI	
				Upper	Lower
Age (continuous)	.021	.165	1.021	.991	1.052
Gender (dichotomous)	-.370	.192	.691	.396	1.205
Number of hospitalizations (continuous)	-.170	.275	.843	.621	1.145
Number of co-morbid conditions (continuous)	.226	.125	1.254	.939	1.674
Number of medical provider treating diabetes (continuous)	.083	.233	1.087	.948	1.247
Approach to chronic care management System / Individual (dichotomous)	1.232	.000	3.426	1.968	5.965
n = 248		p=.000 R <sup>2</sup> =.177			

#### *Regression Results for Adherence to Nephropathy Monitoring*

Logistic regression analysis for nephropathy monitoring was conducted in the same way as the previous analyses. There were 300 subjects included in this analysis, with 24 removed because of adherence with the frequency guidelines prior to and post each plan implementing their chronic care program. All independent variables were entered into the analysis at the same time and as with the other results the model was statistically significant in predicting change in adherence (p=.000). The independent variables account for only 10.6% of the change in nephropathy screening frequency. Table 27 presents the contribution each variable contributes to the change in adherence. As with retinopathy and A1c monitoring, only the approach to chronic care management is a predictor of change in adherence. Those that received the mico-, meso-, exo-system level approach were 2.6 times more likely to have a change in adherence.

Table 27. Logistic Regression Results for Change in Nephropathy Screening Adherence

<b>Predictor</b>	<b>B</b>	<b>p-value</b>	<b>Odds ratio</b>	<b>CI</b>	
				<b>Upper</b>	<b>Lower</b>
Age (continuous)	-.004	.758	.996	.969	1.023
Gender (dichotomous)	-.044	.864	.957	.581	1.577
Number of hospitalizations (continuous)	-.248	.137	.781	.563	1.082
Number of co-morbid conditions (continuous)	.187	.126	1.205	.949	1.530
Number of medical provider treating diabetes (continuous)	.026	.669	1.027	.910	1.158
Approach to chronic care management System / Individual (dichotomous)	.967	.000	2.629	1.592	4.342
n = 300		p=.000 R <sup>2</sup> =.106			

#### Additional Analyses

In order to gain an understanding of predictors of change in adherence this research proposed conducting a logistic regression with data from subjects that had a complete change in adherence. These subjects are those who had no evidence of adherence before enrollment in the program and complete adherence according to guidelines after enrollment in the program. This analysis could not be completed, however, since there were an insufficient number of subjects who met the criteria. No subjects had a complete change across all screenings. Few subjects had a complete change in adherence to the individual screenings. LDL had only ten subjects with a complete change. For retinopathy screenings there were only eight subjects with a complete change. Only 11 subjects had a complete change in adherence to hemoglobin A1c monitoring and 21 had a complete change in adherence to nephropathy screening.

## Summary

This study is designed to answer two research questions with four hypotheses associated with each. The first set of four hypotheses presents the null hypothesis, stating that there is no difference in adherence behavior between subjects in the two health plans, each implementing a different approach to chronic care management. The hypothesis is applied to the four screenings that are recommended as a part of appropriate management of diabetes. Chi square analyses were performed. For each of the screenings, LDL, retinopathy, hemoglobin A1c, and nephropathy, there was a statistically significant difference between participants in the two plans, thus the null hypothesis is rejected for all. Table 28 presents these hypotheses and the results.

In order to examine the factors that contribute to the change in adherence, logistic regression analyses were conducted for each of the recommended screenings. The four hypotheses associated with this part of the research stated that the approach to diabetes management was associated with a change in adherence. For three of the four screenings the hypothesis was accepted. Approach to management was associated with changes in adherence to retinopathy, hemoglobin A1c and nephropathy screening. The approach was not a statistically significant predictor of change in adherence to LDL screening. Results are summarized in Chapter 5.

For each of the regression models the effect size is moderate. According to Cohen (1988), R squared can be interpreted for the behavioral sciences as a small effect size when the value is .01; moderate where the value is .09; and large where the value is .25. R squared values ranged from .106 (nephropathy screening) to .225 (LDL), which



represent a moderate effect size. A small to moderate effect size is not uncommon in the behavioral sciences. These results indicate that there is only a moderate correlation between the model and changes in adherence.

## CHAPTER 5: DISCUSSION AND CONCLUSIONS

This chapter presents an overview of the study and a summary of the research findings. Next a discussion of the findings in relation to the research hypotheses is presented. Limitations and implications of the study are next discussed. Finally, policy implications are explored.

### Study Summary

Chronic illnesses continue to be a challenge in terms of the burden to all stakeholders in the health care industry and in relation to the personal burden to individuals who suffer from the conditions. The health care industry has struggled over the years to identify programs and interventions that help in effective management of chronic illnesses. Despite this struggle there has been an increase in the costs related to these conditions and consistently poor evidence of adherence to recommendations for effective management of the conditions (McGlynn, Asch, Keesey, Hicks, and DeCristofaro, 2003; Partnership for solutions, 2004). Diabetes is of particular concern because of the involvement of multiple systems as the disease progresses. The health care cost related to these co-morbid conditions is significant (Gerberding, 2005).

The primary goal of effective chronic care management is to maintain the health of the individuals affected by the conditions and as a consequence decrease the costs to the stakeholders responsible for the payment of care. One step to help prevent the

progression of disease and the occurrence of co-morbidities is to increase the vigilance in relation to early identification of signs of disease progression. Recommended screenings for diabetes relate to the major body systems affected by the disease. Hemoglobin A1c is an overall indicator of how well blood sugar is maintained in an acceptable range over time. Low density lipid (LDL) monitoring helps identify cardiac involvement. Nephropathy screening is performed for early identification of kidney failure and retinopathy screening is performed to identify risk for blindness. Improving adherence to select screenings is a goal of effective management of the condition.

Historically, one of the major approaches to the management of chronic conditions and particularly of diabetes has been disease management. This initiative has focused primarily on individual level approaches to improving management of the disease with the primary avenue of intervention educating the individual on self-management skills. Disease management has been adopted throughout the health care industry by payers and employers who are interested in maintaining costs and improving employee's health and work productivity. Despite adoption of this approach, the control of diabetes is still not adequate; control and management of diabetes is still not adequate; and, costs continue to increase. Explorations have begun into other approaches to improve diabetes management. Programs adopting a systems-level approach have been developed but are not widely implemented and studied.

The focus of this study is to explore the impact of two different approaches on adherence to the recommended screenings for diabetes. The approaches studied were implemented by two health plans, one implementing an individual-level approach and the

other a system-level approach. The theoretical framework for this study looks at the multilevel influences on an individual's behavior and posits that multiple factors at different levels influence health behaviors. This framework extends beyond the individual influences that are the focus of disease management and includes other influences that may impact and individual's health-related behaviors.

### Overview of the Problem

According to the most recent National Institute of Health figures 7.8% of Americans have diabetes and 24% are undiagnosed (National Institute of Diabetes and Digestive and Kidney Diseases, 2008). Medical costs alone for a person with diabetes are three times higher than for those without diabetes (Diabetes Cost Calculator, 2007). These costs do not consider the personal costs in terms of lost wages from absences from work and the cost to employers for absences and decrease productivity. The stakeholders impacted by these costs are the patients who suffer from the illnesses; the employers who are responsible for health care costs for the majority of Americans (Ha, 2004); and the federal and state governments who carry the burden for costs through Medicaid and Medicare.

In addition to the costs of diabetes the clinical burden of the disease is significant, impacting multiple body systems. This impact is the reason monitoring and educating regarding adherence to recommended screening and effective chronic care are key components of diabetes management. Maintaining blood sugar within an acceptable range is essential to prevent the development of complications and involvement of other body systems (Blonde, 2007; Diabetes Control and Complications Trial Research Group,

1993). Individuals with diabetes have double the risk of heart disease and stroke (National Institute of Diabetes and Digestive and Kidney Diseases, 2005). Lowering the LDL can reduce the risk of heart attack by 42% (American Heart Association, 2007). Monitoring LDL is a significant part of diabetes management and is recommended at least annually. Diabetic retinopathy causes 12,000 to 24,000 new cases of blindness every year (National Institute of Diabetes and Digestive and Kidney Diseases, 2008). Annual eye exams are recommended for patients with diabetes in order to identify early signs of retinopathy. Kidney disease leads to significantly higher costs of care and a significant burden on the patient who can end up with kidney failure and subsequently be placed on dialysis. Monitoring for nephropathy is essential for early detection and is recommended at least annually. Improving adherence to the recommended frequency of these screenings is an integral part of most diabetes management programs.

In regard to the approaches taken by most chronic care management programs, the literature review identified few results that had a theoretical foundation. An analysis of the literature resulted in the conclusion that most programs focused on theories that were based on individual level influences. These are theories such as the Health Belief Model, the Theory of Planned Behavior and the Transtheoretical Theory of change. These theories posit that as an individual becomes increasingly aware of the impact of the disease they are more likely to engage in change. The perception of risk and their sense of control and ability to change impact the end result. Self-management education, the main focus of most chronic care management programs, is designed to increase the

patient's perception of risk and to help increase their sense of control over being able to change.

The limitations of individual-level approaches have lead to explorations into system-level approaches. The main systems-level approach that was presented in the literature is the Chronic Care Model (CCM) proposed by Wagner, Austin, & Vonkorff, (1996). This approach includes self-management support but points to the support that is needed within the health system for chronic care. The concepts in the CCM correspond to the components of Social Ecology Theory. Social Ecology Theory posits that an individual's health behaviors are impacted by different spheres of influence. The spheres include the individual's internal factors surrounded by the systems and individuals with which they directly interact (microsystem); then surrounded by settings that impact the individual but with which they do not interact (meso- and exo-system). The spheres extend to organizations, policies and cultures that impact the adoption of healthy behaviors (macro-system). This is the theoretical framework of this study.

### Discussion of the Study

This research is a retrospective, descriptive non-experimental study using claims and enrollment data to identify factors that influence adherence to the selected screenings for diabetes management. The subjects were members of two hospital plans, each adopting a different approach to diabetes management. One adopted an individual-level approach providing self-management education and support (micro-system only). The other adopted a system-level approach, providing support across the organization for chronic care management. The components of this approach were consistent with the

components of the Chronic Care Model and the micro-, meso and exo-system levels of Social Ecology Theory. One of the goals of each of the programs was to improve adherence to the recommended screenings. Because of the importance of the screenings the dependent variables of this study are adherence to the recommended screening frequencies.

A review of the literature led to the incorporation of select variables as independent variables. Age and gender have been linked to adherence to diabetes guidelines with results being variable. There was no literature associating gender with adherence to the screenings that are the focus of this study. However, on other measures of adherence in diabetes management, where there was a correlation between gender and adherence females were less likely to adhere (Hertz, Unger, & Lustik, 2005; Korbel, Wiebe, Berg, & Palmer, 2007; McCullum, Hansen, Lu, & Sullivan, 2005). There was no literature on the association between age and the dependent variables in this study. However, as with gender, there were associations between age and adherence to other diabetes guidelines, with varying results. Two studies report opposite results as far as the association between age and adherence (Hartz, et al., 2006; Hertz, Unger, & Lustik). The relationship between the patient and their physician and the corresponding association to adherence has been reported in the literature (Ciechanowski, et al., 2004; Maddigan, Majumdar & Johnson, 2005). Both studies indicate that a consistent and positive patient-physician relationship may be a significant variable associated with adherence behaviors. This study includes an independent variable of the number of physicians involved in the management of diabetes. The assumption is that the more physicians treating diabetes,

the less likely the relationship between patient and physician is consistent and productive. Two other independent variables were included in the study because they are likely associated with an individual's perception of their risk. These variables are the presence of co-morbid chronic conditions and admissions to the hospital during the post program implementation period. They were included in the study with the assumption that individuals who are suffering from other conditions and presenting with other complications may have a higher sense of risk associated with their disease, thus leading to a higher vigilance in relation to managing their disease. The primary independent variable of interest is the approach to chronic care management: micro-system only and micro-, meso- and exo-system approach.

The purpose of this research was to explore the impact of the approach to chronic care management on adherence. The questions addressed by the study were whether there was a difference in adherence between individuals based on the approach and what factors were predictive of changes in adherence from prior to program implementation to post program implementation. The statistical analysis was conducted in three phases. The first involved descriptive analyses of the population as a whole and then a comparison of the two health plans in relation to the descriptive statistics. Chi-square and t-tests were conducted on the independent variables. The second phase explored whether there were differences between the two health plans on adherence post program implementation. Chi-square analyses were conducted on adherence versus non-adherence for categorical variables. The third phase involved exploring which of the independent variables were associated with a change in adherence from pre-program



implementation to post-program implementation. Logistic regression analyses were conducted to determine the predictive value of the model and to identify those variables predictive of a change over time.

### Major Findings and Implications

#### *Descriptive Differences between Participants in the Two Health Plans*

The independent variables for the subjects in the two health plans were compared. There were no statistically significant differences between subjects in the two health plans on the independent variables of age, gender and the number of treating physicians. There were statistically significant differences between the two health plans on the number of hospitalizations since participants were enrolled in the diabetes programs and the number of co-morbid conditions. Subjects in the individual-level health plan had a greater number of hospitalizations (mean = 0.56; range of 0-6) than those in the system-level health plan (mean = 0.31; range of 0-3). However, subjects in the system-level health plan had a greater number of co-morbid conditions (mean = 2.55; range of 0-6) than those in the individual-level health plan (mean = 2.11; range of 0-4). While they are contradictory as indicators of risk for the two health plans, these two variables were included in the analysis as representations of the risk of individuals. According to individual level theories, as an individual's perception of risk increases they are often more likely to change health-related behaviors. Hospital admissions and the presence of other co-morbid conditions are seen as factors that raise an individual's sense of risk.

*Adherence Differences between Health Plans*

The hypotheses and results are listed in Table 28. In relation to the first research question, is there a difference in adherence behaviors of individuals in a health plan that implemented a system level program and those in a health plan that took an individual level approach to chronic care management, this study first examined the differences in adherence among participants before implementation of the programs. For LDL, A1c and nephropathy screenings participants in the two health plans showed a statistically significant difference in adherence before implementation with the system-level approach consistently demonstrating a higher level of adherence. For retinopathy screening, however, there was no statistically significant difference in the level of participant adherence between the two health plans before program implementation.

In relation to the comparison between participant level of adherence in plans with differing approaches after program implementation, the major finding was that for all four screenings there were statistically significant differences between participants in the two different health plans. After program implementation, the health plan with the system-level approach demonstrated a higher level of participant adherence in LDL, retinopathy, A1c, and nephropathy screening. The null hypothesis that there would be no difference was therefore rejected for all four of the hypotheses associated with the first phase of the study looking only at levels of adherence after implementation.

Although the null hypotheses were rejected, it was felt that further investigation into comparisons between the two approaches before and after program implementation was needed. These analyses show that there is a statistically significant difference

Table 28. Hypotheses and Corresponding Results.

<b>HYPOTHESIS</b>	<b>RESULTS</b>
H1. There is no difference in adherence to lipid monitoring of individuals in a health plan that implemented a micro-, meso-, and exosystem approach to chronic care management compared to individuals in a health plan that implemented a microsystem approach alone.	Rejected
H2. There is no difference in adherence to retinopathy monitoring of individuals in a health plan that implemented a micro-, meso-, and exosystem approach to chronic care management compared to individuals in a health plan that implemented a microsystem approach alone.	Rejected
H3: There is no difference in adherence to HbA1c monitoring of individuals in a health plan that implemented a micro-, meso-, and exosystem approach to chronic care management compared to individuals in a health plan that implemented a microsystem approach alone.	Rejected
H4. There is no difference in adherence to nephropathy monitoring of individuals in a health plan that implemented a micro-, meso-, and exosystem approach to chronic care management compared to individuals in a health plan that implemented a microsystem approach alone.	Rejected
H5: Approach to diabetes management is associated with a change in lipid monitoring adherence from pre-program implementation to post program implementation.	Rejected
H6: Approach to diabetes management is associated with a change in retinopathy monitoring adherence from pre-program implementation to post program implementation.	Accepted
H7: Approach to diabetes management is associated with a change in HbA1c adherence from pre-program implementation to post program implementation.	Accepted
H8: Approach to diabetes management is associated with a change in nephropathy monitoring adherence from pre-program implementation to post program implementation.	Accepted

between adherence before and adherence after for both plans for all dependent variables except nephropathy screening. For the health plan that implemented the individual level approach there was no statistically significant difference in adherence after as compared

to before. In this case the null hypothesis that there is no difference between the before and after adherence for nephropathy screening would be accepted. However, since two cells in the output had expected counts less than five, there is a risk in this part of the analysis of accepting the null hypothesis when it is false (type 2 error).

In all cases where there is a significant difference between before program implementation adherence and after implementation adherence (LDL, retinopathy, A1c screening for both plans) there was a greater percent of participants who moved from non-adherence to adherence for the health plan that had adopted the micro-, meso, and exo-level approach than the plan that adopted the micro-approach only. In each of the before and after comparisons the number of subjects in each cell ranged from one to 154. Due to the small number of subjects in the cells it is difficult to draw conclusions on the significance of these results.

The literature provides no information on studies that compare adherence to these diabetes guidelines based on the approach to management. The only studies found in the literature regarding a systems level approach were those that implemented only some of the components of the Chronic Care Model (Bodenheimer, Wagner, & Grumbach, 2006; Piatt et al., 2006; Siminerio, Piatt, & Zgibor, 2005) or those that reported on findings over time for patients and physician practices (Siminerio, Zgibor & Solano, Jr., 2004; Siminerio, et al., 2006). No studies compared changes in adherence to any diabetes guidelines between traditional individual-level approaches and system-level approaches. This study expands the available literature by exploring the impact of implementation of all components of the CCM on adherence to select diabetes guidelines and comparing

changes in adherence for those receiving this approach versus those receiving a traditional individual-level approach.

### *Predictors of adherence*

The second major finding of the study answers the research question: Can adherence to selected evidence-based guidelines be predicted by age, gender, co-morbid conditions, number of hospitalizations, evidence of a consistent medical provider, and approach to diabetes management (system-level versus individual-level only)? The multivariate model, including age, gender, number of hospitalizations, number of co-morbid conditions, number of physicians treating diabetes and approach to chronic care management is a statistically significant predictor of changes in adherence over time in all four areas of adherence studied in this research.

The independent variable of interest in this study is the approach to chronic care management. For three out of the four screenings the approach to management was a statistically significant predictor of changes in adherence and was the only independent predictor. Lipid monitoring is the only screening that did not have the same result. The hypothesis that approach to chronic care management is associated with a change in adherence to lipid monitoring was rejected. Since lipid monitoring is a significant screening associated with other chronic conditions, the approach to management may play less of a role than other factors for this screening. For the other three screenings (hemoglobin A1c, retinopathy and nephropathy screenings), participants who were in the plan with the systems-level approach were more likely to exhibit a change in adherence than participants in the plan with an individual level approach. The hypotheses that the

approach to chronic care management was associated with a change in adherence were accepted for each of these analyses.

Studying a systems-level approach to chronic care grounded in Social Ecology Theory and the implications on adherence behaviors is in its infancy. The approach to studying the impact of implementing the CCM has been to either report on results associated with implementation of only some of the components (Bodenheimer, Wagner, and Grumbach, 2006) or to report on pre and post implementation results (Piatt et al., 2006; Siminerio, Piatt, & Zgibor, 2005). The results in these analyses varied with the ones reported by Bodenheimer, Wagner, and Grumbach (2006) and the ones conducted by Piatt et al. (2006) and Siminerio, Piatt, & Zgibor (2005). Bodenheimer, Wagner, and Grumbach reported improvement in at least one adherence or clinical measure based on CCM implementation. Piatt et al. and Siminerio, Piatt, & Zgibor reported no statistically significant correlation between CCM implementation and adherence behaviors. Until this research there are no studies that compare a systems-level approach to a standard of care approach in which individual level interventions only are implemented. Of significance is the fact that most of the research reported in the literature on the CCM involves measuring results for those programs that implemented different components of the CCM and not all of the CCM. The two components that are excluded from many of the studies are those components that represent full involvement at a system level: organizational changes and the integration of community resources (Bodenheimer, Wagner, and Grumbach, 2006).

This research reports on an approach that incorporates all components of the CCM. The results suggest that there is a statistically significant relationship between implementation of a full systems-level program and changes in adherence. These results are consistent with research reported in relation to other health behaviors (Hopkins, Husten, Fielding, Rosenquist & Westphal, 2001; Patrick, Intille & Zabinski, 2005). Although this research suggests a correlation between implementation of all components of the CCM and changes in adherence the correlation coefficients indicate that only a small percentage of the change in adherence are explained by the regression models.

In addition, although there was a statistically significant change in adherence levels based on approach to chronic care management, adherence levels for both health plans are lower than what is reported in the literature where national adherence levels are known. The national adherence level for A1c monitoring is 64.3 to 68.8% (Centers for Disease Control, 2007) while the adherence level for the plan that implemented the micro-level only approach was only 16.7% after the diabetes program and adherence levels for the plan that implemented the micro- meso - exo level plan was 60.3%. National adherence levels for retinopathy screenings was reportedly 60.6% (Centers for Disease Control, 2007). However, adherence levels for the health plan that implemented the micro-system approach only was 19.3% after program implementation and for the health plan that implemented the micro- meso - exo system approach the adherence level after program implementation was 30.5%. It is unclear why adherence levels were so much lower than nationally reported levels. There are no national adherence levels for the other two screenings.

In relation to individual predictors, change in adherence to lipid monitoring was the only model where different results than the other three screenings studied were found. For lipid screening, gender was predictive of change whereby males were less likely to have a change in adherence. This result differs from the literature on gender and its association with adherence to other diabetes guidelines. In relation to medication and diet adherence to improve glucose levels, Hertz, Unger, & Lustik, (2005); Korbel, Wiebe, Berg, & Palmer, (2007); and McCullum, Hansen, Lu, & Sullivan, (2005) reported that females were less likely to demonstrate adherence. Since monitoring lipid levels and consistently adhering to medications and diet are different actions it may not be appropriate to draw any conclusions about the discrepancy between this result and what is reported in the literature. Gender was not a significant predictor of adherence for the other three screening dependent variables.

Number of hospitalizations and number of co-morbid conditions are also statistically significant predictors of change in adherence to lipid monitoring. With an increase in the number of hospitalizations and the number of conditions there is an increased likelihood of change in adherence. These were not however statistically significant predictors of adherence for the other three dependent variables. Unlike the three other screenings, monitoring lipid levels is an important component of managing other conditions such as coronary artery disease, hypertension, hyperlipidemia, and heart failure and individuals with diabetes may also be diagnosed with these conditions. Therefore, the association found may be related because participants who received these screenings may also have had other conditions that require these screenings. This may be



the reason that lipid screenings were associated with more hospitalizations and a greater number of co-morbid conditions, but the other screenings were not.

However, given the tenet of individual level theory that raising an individual's awareness of risk leads to action, it is significant that hospitalizations and the number of co-morbid conditions are not predictive of change in adherence behavior in the other three recommended screenings. Central to the Health Belief Model, the Transtheoretical Model of Change, the Theory of Planned Behavior, and the Information-Motivation-Behavioral Skills Model are the concepts of perception of risk and the patient weighing the pros and cons of not changing one's behavior (Ajzen, 2002 ;DiClemente, Crosby, & Kegler, 2002 ;Glanz, Lewis, & Rimer, 1997; & Prochaska & DiClemente, 1983). Hospitalizations and the presence of complicating co-morbidities are seen as triggers that would raise the patient's awareness of their risk and the impact that poor management of the disease can have on their health. This research suggests, however, that these risks are not alone associated with changes in adherence.

The literature suggests that a strong patient-physician relationship is significantly associated with diabetes outcomes such as diet and exercise adherence (Ciechanowski, et al., 2004; Maddigan, Majumdar & Johnson, 2005; Rothman & Wagner, 2003). The literature does not address fragmentation that might occur as the numbers of physicians involved with the patient rises, but it does address patients' perceptions of their relationship with their physician and their sense that their physician collaborates with them. This research uses a proxy to measure the patient-physician relationship. This proxy is the number of physicians involved in the management of diabetes. Being unable

to measure the exact nature of the patient-physician relationship, the number of physicians involved in the care was used, since it is assumed that as the number of physicians increases it is less likely patients have a strong, consistent relationship with one treating provider. The possibility for fragmentation of care is assumed to be present as the number of treating physicians rises. It is significant that in this research the number of medical providers is not predictive of changes in adherence in any of the four dependent variables. A better measure of the patient-physician relationship may have been more predictive.

#### Suggestions for Future Research

Social Ecology Theory and the CCM help to inform suggestions for future research. Both frameworks include individual level approaches as a part of a full system approach. The micro-level approaches are informed by individual level theories. In the quest to discover what impacts a person's engagement in healthy behaviors, these individual level theories should be further explored by including all components of the theories in the development of programs and in the analyses of the impact of these programs. All of the individual level theories point to the importance of the patient's perception of risk. Most of the interventions examined in the literature and used in programs based on individual level approaches focus on raising awareness of the disease; the risk associated with the disease; the benefits of action; and the risk of inaction. Since this research suggests that triggers (hospital admissions and co-morbid conditions) that should contribute to a high perception of risk are not statistically significant predictors of

changing one's behavior, there may be better measures of the components of individual level theories that can be researched in relation to a system-level approach.

A major tenet of the individual level theory presented in Chapter 2, Information-Motivation-Behavioral Skills Model (IMB), is that behavioral skills are enhanced by focusing on the individual's ability and perceived ability to perform the sequence of behaviors required in the management of one's health (DiClemente, Crosby, and Kegler, 2002). Research that has focused on this approach has been primarily limited to HIV and AIDS management. The IMB focuses more on the behavioral skills of the patient than the other individual level theories do (Fisher, Fisher, Williams, & Malloy, 1994). Other individual level theories focus on educating and motivating patients. Further research on impacting the individual's behavioral skill level and its relationship to levels of adherence to chronic care guidelines can add to understanding how to improve patient adherence. Components of behavioral skill building can be integrated into system-level approaches and studied to determine the impact in relation to system-level interventions.

Another individual level factor reported in the literature as positively impacting health outcomes is patient-physician relationship. While this research indicates that the number of physicians involved in diabetes care is not predictive of positive outcomes, a better measure of this relationship would help to inform programs designed to improve diabetes outcomes. Is the number of physicians an appropriate measure of relationship? While it measures the lack of a consistent provider, other measures such as the patient's and physician's perception of relationship might be a better measure of that relationship. The World Health Organization (2003) focuses on the significance of the patient-provider

relationship and the need to organize health systems to support that relationship.

Casalino (2005) points to the fact that most physicians lack the time to focus on the needs of patients with chronic illnesses. He indicates that while disease management programs generally focus on direct outreach to the patient, excluding the physician from that approach, the chronic care model incorporates the physician in the management of the patient. Additional research on the strength of the patient-physician relationship would help to inform programs designed to improve diabetes outcomes. Such research could explore adherence to diabetes guidelines in relation to the quality of the patient-physician relationship; the features of that relationship; and the support of that relationship by the health system.

No previous published research compares health and behavioral outcomes for individuals receiving interventions from the two approaches presented. Additional research that compares other system level approaches to individual level approaches would add to the body of knowledge on what may improve adherence to diabetes guidelines. It is significant that all of the published research on CCM implementation reports on programs that implemented only some aspects of the CCM. The components that were implemented involve only micro- and meso-system levels and do not extend to the exo-system. This excludes organizational support for chronic care management. Additional research on programs that implement all components of the CCM will help the health care industry to identify more effective ways to impact diabetes outcomes.

There are increasing numbers of programs that report implementing all components of the CCM. Such programs include the Mayo Clinic (Smith, et al., 2008)

and Intermountain Healthcare (Dorr, et al., 2006). The federal government, through the Health Resource and Services Administration and specifically the Health Disparities Coalition, has begun to support initiatives for implementing the Chronic Care Model (Health Resources and Services Administration, [ca. 2007]). The initiative supports Federally Qualified Health Centers that implement the model. The coalition indicates that the six components of the model interact with each other and must be addressed to achieve significant change. As these health centers implement programs based on the model opportunities for further research will be available.

The macro-level, as reflected in Social Ecology Theory, is the overall context in which all levels exist. The CCM, as it originally was designed, does not include the larger community and policy context but rather approaches chronic care management from an organization level. However, the World Health Organization and the McColl Institute for Healthcare Innovations have joined to expand the CCM to the Innovative Care for Chronic Conditions framework. Policy and wider community interventions are integrated into the framework to provide a more comprehensive milieu for chronic care management (Epping-Jordan, Pruitt, Bengoa & Wagner, 2004). The authors indicate that a wider support for chronic care management needs to include leadership and advocacy for chronic care; policy changes designed to decrease fragmentation and redundancies in care; financial commitment for chronic care; and partnerships between private sector, government and community organizations. This development will lead to multiple opportunities for research.

### Study Limitations

There are four major aspects of the study that result in limitations beyond the methodological limitations that were discussed in Chapter 3. The first is related to the characteristics of the study population, as well as what is not known, that makes it difficult to conclude that these results would be reflected in other populations. The subjects involved in this study sample were employees and dependents of two hospital systems in Maryland who were enrolled in employer health plans. While no literature found indicates that hospital employees are any more or less likely to adhere to diabetes guidelines, the use of hospital employees and their dependents limits the ability to conclude that the results might be the same or similar for other populations. Thus, the sample does not reflect the entire population with diabetes. This fact limits the ability to conclude that the results could be applied to individuals who are uninsured or insured by public programs.

In addition, no information on socioeconomic status or race was available for individuals in this study. The Center for Health Care Strategies reports that members of racial and ethnic minority groups experience poorer quality of care; greater barriers to accessing necessary services; and consequently poorer adherence to evidence based care for diabetes (Martin, 2007). In the absence of information on socio-economic, racial and ethnic characteristics there are no conclusions that can be drawn regarding other barriers to accessing appropriate care and ways to impact adherence to recommended guidelines that address these barriers. Since all of the subjects in this study were employed or dependents of employed individuals and are covered by private insurance there are

limitations in the conclusions that can be drawn on how the approach to chronic care management would impact the uninsured or those insured under public insurances, such as Medicare or Medicaid. The geographical location of the hospital systems also limits generalizability. The hospitals are located in more rural parts of one state. Additional research on other groups in other locations would need to be conducted in order to strengthen the usefulness of the results.

The second area that contributes to study limitations is the use of administrative data. Administrative data are obtained for purposes other than research, such as medical claims payment. Although the literature indicates that data from claims are acceptable, particularly for identifying utilization patterns, there were no means to assess validity and reliability of the data. Assumptions are made that, since the same TPA and claims management systems are used for both groups, comparisons between the two on the dependent variables (utilization patterns that indicate adherence or non-adherence) have comparable levels of accuracy. For the measurement of the independent variables, the data available may be limited representative measures of the variable of interest. For instance, assumptions were made that an increase in numbers of hospitalizations and the number of co-morbid conditions raise a person's awareness of risk. Other measures of awareness of risk may better represent individual perceptions. Similarly, assumptions were made that the number of physicians involved with a patient in the care of diabetes is an adequate measure of patient-physician involvement. Fewer physicians involved in the care of individuals with diabetes was seen as a proxy for a more consistent and effective relationship. Other measures may more accurately represent this relationship. Patients'

and physicians' perception of the relationship, measured by survey results, may be better measures of the predictive value in relation to improvement in adherence.

The third area that may be considered a limitation is the sample size. The second phase of the study, in which comparisons were conducted between the two approaches on adherence pre - and post-program implementation, all subjects were included in the analysis (324). This sample size was adequate for the chi-square and t-tests performed in this phase. Initially, the same sample size would be maintained for the logistic regression analysis as well. The analysis of adherence change lead to a determination that some of the subjects had to be removed since they were adherent throughout the study period. As a result, sample sizes were different for each dependent variable. Sample size met the 300 subject criteria for nephropathy screening. For the other three screenings sample size ranged from 209 to 284. The lower than initially accepted sample size can lead to an over-estimation of the odds ratio and a possible type 2 error (Nemes, Jonasson, Genell, & Steineck, 2009).

The fourth area is related to the effect sizes in the regression analyses. The results indicate the regression models account for only 10.6% to 22.5% of the change in adherence, a moderate effect size. These should be considered in relation to resources that are expended in implementing and sustaining a system-level approach to chronic care management. Additional research with a larger number of subjects and more specific measurement of the variables of interest may lead to a larger effect size.



## Conclusions

Chronic illnesses and particularly diabetes continue to challenge the health care industry to identify ways to improve care. The management of chronic conditions is seen as a major challenge for the 21<sup>st</sup> century. Since the early 1990s employers and governments have supported and implemented disease management programs in the hope that these programs would slow chronic illness progression. Employers and governments hoped that these programs would have a positive impact on individuals and payers who feel the burden in terms of poor health, increased health care costs, and decreased productivity. These programs focused exclusively on individual level approaches to change behavior. The main focus of these programs was on raising an individual's awareness of the disease, the impact of in-action, and self-management skills.

Outcomes from an individual approach only to address behavior change have been varied. In an effort to find other, more successful ways to impact chronic illnesses a system level approach based on Social Ecology Theory was proposed by Wagner, Austin, & Vonkorff (1996). The Chronic Care Model (CCM) has 6 components which span most of the Social Ecology Theory levels. The CCM integrates the micro-, meso- and exo-system levels into the model. The components include organizational support for chronic care management, acknowledging that most care in the current health system is geared towards acute care. Very little research has been conducted on the impact of the CCM on adherence to screenings that are recommended for individuals with diabetes. Wagner (1997; p. 702) called for research on new models of care, stating that "Following the failure of health care reform, we are experiencing unprecedented, unevaluated tinkering

with basic care models and values”. The published research did not evaluate the difference between the more traditional approach to chronic care management (an individual level approach) and a system-level approach such as the CCM. In addition, where there was research on the CCM, it primarily addressed programs that implemented only some of the features of the model. However, as the Health Disparities Coalition pointed out, the six components of the model interact with each other and all must be addressed to achieve significant change.

The study supports the conclusion that an approach to diabetes management that incorporates all six elements of the CCM has a greater impact on adherence than the traditional individual level approach. The research went on to examine the factors that are associated with changes in adherence from before program implementation to after program implementation. Along with the type of approach to chronic care management, individual level variables were included in an assessment of adherence to screenings. For all but LDL monitoring, the study suggests that a system approach to chronic care management was a statistically significant predictor of change in adherence.

This research is a step in understanding effective diabetes management. The strategies discussed here can be applied to other programs for chronic illness management. With the challenges of chronic illnesses, including obesity, looming ahead of us and the struggles to find what motivates a person to change, this research sheds some light on ways to impact positive outcomes. Individual-level approaches can be enhanced through support and processes that are implemented at a system level and that are designed to impact chronic illness care.

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## APPENDIX A

### Adherence Guidelines Used by Both Plans

The following are the adherence guidelines that are excerpted from the medical management software used by both plans both plans to educate the participants with diabetes on adherence to diabetes guidelines.

#### Hemoglobin A1c -

##### ADHERENCE TO FREQUENCY OF A1C SCREENING

The recommendation of the ADA is performance of the A1C test at least two times a year in patients who are meeting treatment goals (and who have stable glycemic control).

Since the A1C provides insight into the average glycemic control over the previous 2-3 months it is most efficacious to evaluate these results to determine whether metabolic control is within range. Quarterly evaluation then is recommended in patients whose therapy has changed or who are not meeting glycemic goals.

The MMO staff obtains information from the managing physician on the recommended frequency of HgbA1c and also obtains information on the last date of HgbA1c. From this information a determination of adherence is made. It is essential that the staff determines adherence to guidelines or physician recommendations for HgbA1c frequency. If the participant is not having HgbA1c done according to these recommendations an issue will be triggered to the care plan so that the MMO staff can work with the participant to improve adherence.

#### LDL -

##### ADHERENCE TO FREQUENCY OF LIPID SCREENING

*Based on the guidelines below regarding the frequency of monitoring lipid levels, the physician's recommendations for frequency and the frequency that the lipid levels are being done, the case manager determines adherence to the guidelines / recommendations. An answer that indicates gaps in adherence will trigger an issue to the care plan so that the case manager can work with the physician and the participant to improve the participant's understanding of the importance of monitoring lipids and to improve adherence to the recommendations for frequency.*

In adult patients with diabetes, test for lipid disorders at least annually and more often if needed to achieve goals. In adults with low-risk lipid values (LDL <100 mg/dl, HDL >40 mg/dl, and triglycerides <150 mg/dl), repeat lipid assessments every 2 years.

In children >2 years of age, perform a lipid profile after diagnosis of diabetes and when glucose control has been established.

## Nephropathy -

### ADHERENCE TO FREQUENCY OF MICROALBUMIN SCREENING

*Based on the guidelines below, recommendations from the managing physician and the date of the last microalbumin the MMO staff determines the level of adherence to the recommendations. An answer that indicates there are gaps in adherence will trigger an issue to the care plan so that the case manager can work with the physician and participant in order to help the participant understand the importance of monitoring the microalbumin and to assist in improving adherence to the recommendations.*

Persistent microalbuminuria and albuminuria have been shown to be the earliest stage of nephropathy in type 1 diabetes and is a marker for the development of type 2 diabetes.

To reduce the risk or slow the progression optimize glucose control and optimize blood pressure control. Consider a low dose ACE inhibitor or ARB even if client is normotensive.

Consider adding a nephrologist to the treatment team. Early referral for such patients has been shown to reduce costs and improve quality of care by delaying more adverse outcomes.

**Perform an annual test for the presence of microalbumin in type 1 and type 2 diabetic patients.**

## Retinopathy -

### ADHERENCE TO FREQUENCY OF RETINOPATHY SCREENING

The MMO Staff educates the participant on the importance of regular dilated and comprehensive eye examination by an ophthalmologist or optometrist. For type 1 and type 2 diabetic patients the goal is to have examinations repeated annually by an ophthalmologist or optometrist who is knowledgeable and experienced in diagnosing the presence of diabetic retinopathy and is aware of its management.

Examinations will be required more frequently if retinopathy is progressing.

Screening for retinopathy should be done in the first trimester for diabetic patients who become pregnant

## APPENDIX B

### Participant Level Claims Information

The following is a sample of a patient synopsis report that organizes claims to provide information on adherence practices in relation to clinical guidelines. This information is used by the nurses providing self-management support. This was also by the plan that implemented the system-level approach to provide feedback to the treating physicians.

Report Run Date: 03/07/2010

Report Time Frame: 01/01/2008 - 01/25/2010

Patient Name: XXXXXXXXXX  
 Address: XXXXXXXXXX  
 Contact Numbers: H: (XXX)XXX-XXXX  
 PCP:  
 First PCP Visit Date:  
 Personal Nurse:

ID: XXXXXXXXXX Gender: Age: DOB:  
 XXXXXXXXXX XX XXXXX  
 O: (XXX)XXX-XXXX  
 Contact Number:  
 Last PCP Visit Date: 01/18/2010 99213  
 Contact Number:

## Diagnostic Summary - 5 Most Frequent Diagnoses

Total ICD-9 Diagnoses = 32

ICD-9	Description	Duration	Responsible Provider	Encounters
436	CVA	10/16/2008 - 02/16/2009	JASON MARX MD (521703696) - PULMONOLOGY	41
584.8	ACUTE KIDNEY FAILURE OT	03/21/2008 - 01/25/2010	Quest Diagnostics Inc (F0991) - FACILITY	36
327.23	OBSTRUCTIVE SLEEP APNEA	01/30/2009 - 01/24/2010	Johns Hopkins Pharmaquip, (P18532) - OTHER	27
342.9	HEMIPLEGIA UNSPECIFIED	02/23/2009 - 09/21/2009	Howard Co General Hospital (P6631) - FACILITY	24
V57.89	OT REHABILITATION	10/16/2008 - 11/16/2009	GOOD SAMARITAN HOSPITAL PHYS (520591607) - ORTHOPAEDIC SURGERY	11

ER Encounters = 1

Inpt. Admits. = 4

Prescription History Last 120 days(0) Total Prescriptions = 0 Total Unique = 0

## Top 5 Physicians Visited for E&amp;M

Total Physicians = 31

Total E&amp;Ms = 197

Taxid	Name	Specialty	First Date	Last Date	Encounters
520595110	Johns Hopkins Univ Med Ctr, (P1209)	HOSPITAL	11/21/2008	06/24/2009	64
521886012	THE NEPHROLOGY CENTER OF MD (521886012)	CLINICAL SOCIAL WORKER	11/23/2008	02/27/2009	27
521703696	JASON MARX MD (521703696)	PULMONOLOGY	10/17/2006	11/14/2008	27
521311775	St Joseph Physician Enterprise Inc, (P18766)	GROUP PRACTICE	10/18/2008	11/21/2008	14
521965533	KHALID ALTALIB MD (521965533)	CLINICAL SOCIAL WORKER	10/29/2008	11/08/2008	9

## Primary Clinical Indicators

Indicator	Value	Date	Indicator	Value	Date
Height	UNK		Chol. (mg/dL)	142	04/27/2009
Weight (lbs)	extreme obesity, Class III	10/28/2009	HDL (mg/dL)	47	04/27/2009
BMI (kg/m²)	UNK		LDL (mg/dL)	75	04/27/2009
BP	120/78	10/28/2009	Trig. (mg/dL)	103	04/27/2009
HCT (%)	UNK		HbA1c (%)	4.2	04/27/2009
Creat. (mg/dL)	UNK				

## Preventive Screenings

Colonoscopy	UNK	PSA	UNK
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## Evidence Based Medicine Compliance - 03/02/2010 93%

## Cerebral Vascular Accident &amp; Transient Cerebral Ischemia

- Patient with a LDL cholesterol test in last 12 reported months. YES
- Patient with most recent LDL result < 100mg/dL. YES
- Patient with most recent LDL result < 70mg/dL. (Observational) NO

## Chronic Kidney Disease

- Adult with a HDL cholesterol test in last 12 reported months. YES
- Adult with a LDL cholesterol test in last 12 reported months. YES
- Adult with a triglyceride test in last 12 reported months. YES
- Patient meeting the threshold of CrCl < 60ml/min, Cr >= 1.5mg/dL for women or Cr >= 2.0mg/dL for men, that had a hemoglobin or hematocrit in last 12 reported months. YES
- Patient meeting the threshold of CrCl < 60ml/min, Cr >= 1.5mg/dL for women or Cr >= 2.0mg/dL for men, that had a serum calcium in last 12 reported months. YES
- Patient meeting the threshold of CrCl < 60ml/min, Cr >= 1.5mg/dL for women or Cr >= 2.0mg/dL for men, that had a serum phosphorus in last 12 reported months. YES
- Patient that had a serum creatinine in last 12 reported months. YES
- Patient that had a serum potassium in last 12 reported months. YES
- Patient that had an annual physician visit. YES
- Patient with evidence of Stage 1 disease. (Observational) NO
- Patient with evidence of Stage 2 disease. (Observational) NO
- Patient with evidence of Stage 3 disease. (Observational) YES
- Patient with evidence of Stage 4 disease. (Observational) NO
- Patient with evidence of Stage 5 and end stage renal disease. (Observational) NO
- Patient with indications that had a urine microalbumin or protein test in last 12 reported months. YES
- Patient with indications that had nephrology consultation in last 12 reported months. YES

## Colorectal Cancer Screening (National Standard)

- Patient 50-80 years of age that had appropriate screening for colorectal cancer. NO

## Diabetes Mellitus

- Adult aged 18-75 years with diabetes who had their blood pressure documented in the past year less than 140/80 mm Hg. (Observational) NO
- Adult that had a serum creatinine in last 12 reported months. YES
- Adult with a HDL cholesterol test in last 12 reported months. YES
- Adult with a LDL cholesterol test in last 12 reported months. YES
- Adult with a triglyceride test in last 12 reported months. YES
- Adult with diabetic retinopathy and a dilated macular or fundus exam who had level of severity of retinopathy and presence of macular edema documented. (Observational) NO
- Adult with most recent LDL result < 100mg/dL. YES
- Adult with most recent LDL result < 70mg/dL. (Observational) NO
- Adult with most recent triglyceride result < 150mg/dL. (Observational) YES
- Adult with most recent triglyceride result < 50mg/dL. YES
- Adult with the most recent HDL result > 40mg/dL. YES
- Patient that had an annual screening test for diabetic retinopathy. YES
- Patient that had an office visit for diabetes care in last 6 reported months. YES
- Patient that had at least 2 HbA1c tests in last 12 reported months. YES
- Patient with most recent HbA1c result < 8.0%. (Observational) YES

## Diabetes, Comprehensive Care (National Standard)

- Patient 18 - 75 years of age that had a HbA1c test in last 12 reported months. YES
- Patient 18 - 75 years of age that had an annual screening test for diabetic retinopathy. YES
- Patient 18 - 75 years of age that had annual screening for nephropathy or evidence of nephropathy. YES
- Patient 18 - 75 years of age with a LDL cholesterol in last 12 months. YES
- Patient 18 - 75 years of age with evidence of good diabetic control, defined as the most recent HbA1c result value less. YES

than 7.0%.	
● Patient 18 - 75 years of age with evidence of poor diabetic control, defined as the most recent HbA1c result value greater than 9.0%.	NO
● Patient 18 - 75 years of age with most recent LDL result < 100mg/dL.	YES
<b>Hypertension</b>	
● Patient taking an NSAID medication.	NO
● Patient that had a serum creatinine in last 12 reported months.	YES
● Patient that had an annual physician visit.	NO
● Patient with either systolic blood pressure $\geq$ 140 mm Hg or diastolic blood pressure $\geq$ 90 mm Hg with documented plan of care for hypertension. (Observational)	NO
● Patient with hypertension who had their blood pressure documented in the past year less than 140/90 mm Hg. (Observational)	NO
● Patient with hypertension who had their blood pressure recorded in the last 12 months. (Observational)	NO
<b>Influenza Vaccination (National Standard)</b>	
● Patient 50 years of age and older that received the influenza vaccine. (Observational)	YES
● Patient 50- 64 years of age that received the influenza vaccine.	YES
<b>Obesity and Overweight</b>	
● Adult with a HDL cholesterol test in last 12 reported months.	YES
● Adult with a LDL cholesterol test in last 12 reported months.	YES
● Adult with a triglyceride test in last 12 reported months.	YES
● Adult with the most recent HDL result $\geq$ 40 mg/dL.	YES
● Adult with the most recent LDL result < 100 mg/dL. (Observational)	YES
● Adult with the most recent LDL result < 160 mg/dL.	YES
● Adult with the most recent triglyceride result < 150 mg/dL. (Observational)	YES
● Adult with the most recent triglyceride result < 500 mg/dL.	YES
● Patient that had a blood glucose test in last 12 reported months.	YES
● Patient with bariatric surgery in last 24 reported months. (Observational)	NO
** Italicized compliance results indicate an EBM value was overridden by a MMOTS Protocol response.	
<b>Risk Stratification</b>	
<b>As Of 03/02/2010 Level = High - Score = 138.10</b>	

## APPENDIX C

### Quality Report Card for Data

The Report Card Tool checks for all information, summarizes information in different ways to spot errors or incomplete data. Below is a sample page for the two plans. This report card is run every time a claims or eligibility load is received by the Third Party Administrator.

Log No	Log Seq	Group No	Group Name	Data Source	Conv By
26823	21	7762	PLAN B	0 - InforMed	Engine
Prev Log Seq		Next Log Seq		Select Red ONLY	
Record Count		Beg Paid Date		End Paid Date	Total Paid Amount
9,940		1/1/2007		1/31/2007	889,240.51

### Individual Group Information

	Count	Paid Amt	Pct		Count	Paid Amt	Pct
Paid Amt > Charge Amt	0	0	0.0	MDC Id	8666	889,241	100.0
Allow Amt > Charge Amt	0	0	0.0	Diagnosis2	4337	573,951	64.5
Paid Date < From Date	0	0	0.0	Negative Paid Amount	0	-76,094	-8.6
To Date < From Date	0	0	0.0	Valid POS Id	8554	881,570	99.1
Co-Pay/Ded Amount	1886	121,809	13.7	Invalid POS Id	112	7,670	0.9
Co-Insurance Amount	4264	464,024	52.2	Valid POC Specialty Id	7907	809,348	91.0
Invalid Procedure Id	15	6,036	0.7	Invalid POC Specialty I	759	79,892	9.0
CPT Procedure Id	5351	378,988	42.6	In Network Flag	8548	884,163	99.4
HCPC Procedure Id	416	37,206	4.2	Valid Provider Names	8666	889,241	100.0
REV Procedure Id	2789	464,673	52.3	Invalid Provider Names	0	0	0.0
ADA Procedure Id	0	0	0.0	Invalid Anesthesia	29	2,087	0.2
UK Procedure Id	95	2,337	0.3	Invalid Relationship Id	0	0	0.0
Valid Modifier Id	1213	90,654	10.2	Invalid Assignment	0	0	0.0
Invalid Modifier Id	0	0	0.0	Zero Allowance Claims	1274	0	12.8
Procedure2	0	0	0.0	Duplicates	9	1,172	0.1
Invalid Procedure2	0	0	0.0				
DRG	0	0	0.0				
Invalid DRG	0	0	0.0				

Close Options ( All Log Seq )

☐ Alpha  
☐ Beta  
☒ Prod

Log No	Log Seq	Group No	Group Name	Data Source	Conv By
26823	22	7981	PLAN A	0 - InforMed	Engine
Prev Log Seq		Next Log Seq		Select Red ONLY	
Record Count		Beg Paid Date		End Paid Date	Total Paid Amount
13,905		1/1/2007		1/31/2007	1,325,254.52

### Individual Group Information

	Count	Paid Amt	Pct		Count	Paid Amt	Pct	
Paid Amt > Charge Amt	0	0	0.0	MDC Id	10332	1,191,482	89.9	
Allow Amt > Charge Amt	0	0	0.0	Diagnosis2	4023	702,430	53.0	
Paid Date < From Date	0	0	0.0	Negative Paid Amount	0	-10,271	-0.8	
To Date < From Date	0	0	0.0	Valid POS Id	11613	1,275,286	96.2	
Co-Pay/Ded Amount	2707	256,385	19.3	Invalid POS Id	74	16,424	1.2	<a href="#">View</a>
Co-Insurance Amount	3126	482,540	36.4	Valid POC Specialty Id	9921	1,138,489	85.9	
Invalid Procedure Id	23	42,968	3.2	Invalid POC Specialty Id	411	52,993	4.0	<a href="#">View</a>
CPT Procedure Id	7601	627,437	47.3	In Network Flag	11044	1,218,460	91.9	
HCPC Procedure Id	1048	147,125	11.1	Valid Provider Names	12133	1,325,255	100.0	
REV Procedure Id	2265	419,394	31.6	Invalid Provider Names	0	0	0.0	<a href="#">View</a>
ADA Procedure Id	1191	85,703	6.5	Invalid Anesthesia	25	3,763	0.3	<a href="#">View</a>
UK Procedure Id	5	2,628	0.2	Invalid Relationship Id	0	0	0.0	
Valid Modifier Id	1050	105,569	8.0	Invalid Assignment	0	0	0.0	
Invalid Modifier Id	0	0	0.0	Zero Allowance Claims	1772	0	12.7	
Procedure2	0	0	0.0	Duplicates	11	751	0.1	
Invalid Procedure2	0	0	0.0					
DRG	0	0	0.0					
Invalid DRG	0	0	0.0					

[Print Report Card](#)
[Claim File Information](#)

[Add Comments](#)

Close Options ( All Log Seq )
 

☐ Alpha  
☐ Beta  
☒ Prod

[Close](#)

## VITA

Mary Ellen (Spellman) Gervais was born on November 14, 1950 in New Haven, Connecticut and is an American Citizen. She graduated from Sacred Heart Academy in Hamden, Connecticut in 1968. She received her Bachelor of Science degree in Nursing magna cum laude from University of Connecticut, Storrs, Connecticut in 1977. She received her Master of Science in Nursing Administration with a focus on managed care from University of Maryland, Baltimore, Maryland in 1999. She has presented nationally and locally on medical management outcomes. She currently serves as Vice President of Clinical and Technical Development at InforMed Health Care Solutions and serves as a member of a team of experts developing an integrated medical management software which guides case managers in evidence-based case management and which incorporates mechanisms to measure both intermediate and end outcomes.