THE MEDIATING ROLE OF POSITIVE AND NEGATIVE EMOTIONAL ATTRACTORS BETWEEN PSYCHOSOCIAL CORRELATES OF DOCTOR-PATIENT RELATIONSHIP AND TREATMENT ADHERENCE IN TYPE 2 DIABETES

by

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Dedication

The dissertation is dedicated to my parents, Khaja G. Asghar, Ph.D. and Bilquis Jahan, Ph.D. This one is for you dearest Abba and Amma. Your legacy of scholarship continues.....

Dedication	
List of Tables	
List of Figures	
Acknowledgements	
Abstract	
CHAPTER 1: INTRODUCTION	
Statement of the Problem	21
Assumptions Underlying Existing Compliance Research	
Diabetes	24
Epidemiology	
Pathophysiology	
Diabetes Treatment	
Diet	
Exercise	
Hypoglycemic Agents	
Complications	
CHAPTER 2: LITERATURE REVIEW	
Medical Interviewing	
Styles of Medical Interviewing	
Illness and Disease Frameworks	
Treatment Adherence	
Definition	

Table of Contents

Adherence vs. Compliance	6
Acceptable Rates and Measurement	7
Treatment Adherence in Diabetes	9
Models of Treatment Adherence4	0
Health Beliefs Model	1
Social Learning Theory	2
Self-Efficacy Theory	5
Correlates of Treatment Adherence	.7
Regimen Characteristics	7
Patient Characteristics	8
Provider Characteristics	9
Patient-Provider Characteristics	0
Evolution of Patient-Physician Interaction Process	1
Understanding the Communicative Process	3
Trust	6
Empathy	7
Information exchange	9
Rapport	51
Shared Decision-making	2
Co-morbid Depression	3
Knowledge of the Disease	4
Social Support	6
Intentional Change Theory	7

Positive and Negative Emotional Attractors	
CHAPTER 3: METHODS	
Objective of the Study	75
Hypotheses	
Treatment Adherence Framework	
Sample Size	81
Study Setting and Participants	81
Measures	
Data Analysis	90
Description of Analytical Methods	
Exploratory Factor Analysis	
Confirmatory Factor Analysis	
Baron and Kenny Mediation Analysis	
Classical Baron and Kenny Method (1986)	97
Modified Baron and Kenny Method (1998)	
Bootstrap Procedure	
Mixed Models or Multi-level Modeling	
Assumptions of Multilevel Analysis	
Intra-class Correlation	
2-1-1 Model	
CHAPTER IV: RESULTS	
Sample Demographic Statistics	
Factor Analysis	

Exploratory Factor Analysis of Patient Instrument	
Preliminary Procedures	109
Suitability for Factor Analysis	114
Factor Analytic Procedure	119
Confirmatory Factor Analysis of Patient Instrument	
Exploratory Factor Analysis of Physician Instrument	
Preliminary procedures	128
Suitability for Factor Analysis	130
Factor Analytic Procedure	131
Confirmatory Factor Analysis of Physician Instrument	
Exploratory Factor Analysis of Patient Companion Instrument	
Preliminary Procedures	136
Suitability for Factor Analysis	137
Factor Analytic Procedure	138
Confirmatory Factor Analysis of Patient Companion Instrument	
Mediation analysis	142
Intra-class Correlation using HLM	
Intra-class Correlation using SPSS Mixed Model Function	
Hypothesis Testing: Mediation Analysis and Bootstrap Procedure	
Tests for Hypothesis 1a and 1b	144
Tests for Hypothesis 2a and 2b	145
Tests for Hypothesis 3a and 3b	147
Tests for Hypothesis 4a and 4b	148

Tests for Hypothesis 5a and 5b	
Tests for Hypothesis 6	
Tests for Hypothesis 7a and 7b	151
Tests for Hypothesis 8a and 8b	
Tests for Hypothesis 9a and 9b	
CHAPTER V: DISCUSSION	
Discussion of Findings from Sample Characteristics	
Discussion of Findings from Exploratory Factor Analysis	
Discussion of Findings from Confirmatory Factor Analysis	160
Discussion of Findings from Mediation Analysis	161
Implications for Research	
Implications for Practice	
Limitations	
Future Studies	
Conclusion	
APPENDICES	175
REFERENCES	

List of Tables

Table 1. Summary of variables commonly associated with treatment adherence	. 20
Table 2. Demographic sample statistics	107
Table 3. Descriptive statistics for patient instrument	111
Table 4. Collinearity statistics for patient instrument	113
Table 5. Correlation matrix for patient instrument 1	115
Table 6. Factor loadings for patient instrument 1	122
Table 7. Factor correlation matrix for patient instrument	124
Table 8. CFA Factor loadings for patient instrument	127
Table 9. Descriptive statistics for physician instrument 1	129
Table 10. Collinearity statistics for physician instrument 1	130
Table 11. Correlation matrix for physician instrument	131
Table 12. Factor loadings for physician instrument	133
Table 13. CFA Factor loadings for physician instrument	135
Table 14. Descriptive statistics for patient companion instrument	136
Table 15. Collinearity statistics for patient companion instrument	137
Table 16. Correlation matrix for patient companion instrument	137
Table 17. Factor loadings for patient companion instrument	139
Table 18. CFA Factor loadings for patient companion instrument	141
Table 19. Unconditional model statistics for Intra-class Correlation Image: Displayed statistics	142
Table 20. Bootstrap results for mediated effects Image: Description of the second se	153
Table 21. Hypotheses and Results summary	155

List of Figures

Figure 1. Intentional Change Theory applied to doctor-patient interaction in diabetes 69
Figure 2. Conceptual model
Figure 3. Conceptual model with scales delineated
Figure 4. Baron and Kenny: Total effect
Figure 5. Baron and Kenny: Mediation model
Figure 6. Nested model 101
Figure 7. Cross level mediation: 2-1-1 model 104
Figure 8. Varying intercepts and slopes
Figure 9. Scree plot for patient instrument 120
Figure 10. CFA Measurement model of patient instrument 126
Figure 11. Scree plot for physician instrument
Figure 12. CFA Measurement model of physician instrument
Figure 13. Scree plot for patient companion instrument
Figure 14. CFA Measurement model of patient companion instrument 141
Figure 15. Completely mediated model for empathy and treatment adherence
Figure 16. Completely mediated model for trust and treatment adherence
Figure 17. Partially mediated model for information exchange and treatment adherence 148
Figure 18. Completely mediated model for rapport and treatment adherence
Figure 19. Partially mediated model for physician PNEA and treatment adherence 151
Figure 20. Summary of indirect mediation paths with all variables in the model 154
Figure 21. Relationship between patient PNEA and treatment adherence per doctor 163

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The Mediating Role of Positive and Negative Emotional Attractors between Psychosocial Correlates of Doctor-Patient Relationship and Treatment Adherence in Type 2 Diabetes

Abstract

By

MASUD S. KHAWAJA

Uncontrolled diabetes leads to blindness, amputation, kidney failure, and death. Despite such severe complications, treatment adherence rate for diabetes is low.

This dissertation explores a mediational model of treatment adherence in type 2 diabetics. Mediation analysis goes beyond assessing whether a predictor causes change in an outcome; it examines how that change occurs. Specifically, this research hypothesizes that a patient's positive/negative emotional states, represented by the Lorenz attractors of Positive and Negative Emotional Attractors (PNEA), mediate the relationship between psychosocial correlates of doctor-patient relationship and treatment adherence.

The study was conducted in Karachi, Pakistan. Survey respondents were 375 type 2 diabetic patients and their companions who attended follow-up clinics; and 25 physicians who examined them. Mediation analysis was performed using hierarchical linear modeling techniques to account for nested data. Bootstrapping procedure tested the significance of mediated effects.

Findings confirmed the hypotheses that empathy, trust, information exchange, rapport, physicians' PNEA and diabetes knowledge were associated with treatment

adherence. Patients' PNEA was found to completely mediate the relationships of empathy, trust, rapport and diabetes knowledge with treatment adherence. The relationships of information exchange and physician's PNEA with that of treatment adherence were partially mediated. No association was found between treatment adherence and social support, co-morbid depression or shared decision-making. The results also demonstrated that higher levels of a patient's Positive Emotional Attractor (PEA) were related to higher levels of treatment adherence.

Overall, these findings lend support to the proposition that a patient's emotional state plays a pivotal role in treatment adherence outcome.

Keywords: treatment adherence, treatment compliance, type 2 diabetes, non-insulin dependent diabetes mellitus, positive emotion, negative emotion, positive emotional attractor, negative emotional attractor, helping relationship, doctor-patient relationship, physician-patient relationship, doctor-patient communication, physician-patient communication, positive psychology, patient education, medical education, medical curriculum, hierarchical linear modeling, nested model, mediation analysis, bootstrapping

CHAPTER 1: INTRODUCTION

"We prescribing clinicians continue to struggle with the most basic of problems: how to get our patients to take the pills that we think that they need in the way that we think that they should. As efficacious as medications are in research reports and clinical studies, they cannot be effective without moving from the prescription vial to the patient's body", James Ellison, M.D. (as cited in Shea, 2006, p.3).

The medical profession today has remarkable capabilities to diagnose and treat disease. There are cures for infectious and communicable diseases, technology and medication to improve the quality of lives, and knowledge about behaviors that can promote health. However, in spite of the major advances that medicine has made in the last decades, problems still remain. Specifically, one of those problems is in the area of patient rates of adherence to medical recommendations.

In the course of a typical visit to a doctor's office, patients are given some type of medical recommendation by their physician. These recommendations may be in the form of having one or more prescriptions filled to take medication, discontinuing an activity (e.g., smoking), increasing an activity (e.g., exercise), follow-up with another professional (e.g., a medical specialist, physical therapist, psychologist) or getting laboratory tests done. The inherent reason for a physician to provide a medical recommendation is that by following the recommendation(s), the patient's health outcome may be improved. Health outcome is however dependent upon both the effectiveness of the treatment and the rate of patient adherence to the treatment. While there has been a huge interest in improving medication effectiveness in clinical studies, with pharmaceutical companies pouring in billions of dollars, there remains a dire need to improve patient treatment adherence, which

is alarmingly poor (Ngoh, 2009). Across multiple studies, overall rates of adherence to medical regimens have ranged between 33% and 66% only (Daugherty, Sherenco, Davis, & McClelland, 2003). Given the high rates of non-adherence, it is important to address the variables that may influence patients' intentions to follow medical recommendations.

Treatment non-compliance is an obvious barrier to health care provision (Compton, Rudisch, Weiss, West, & Kaslow, 2005). Clearly, a need exists to understand the conditions under which patients do not follow treatment recommendations, which is so central to the success of medical care. Despite an explosion in research on patient compliance in recent years, the topic is not clearly understood. Nowhere is this truer than for type 2 diabetes. Since adherence tends to decline over time, longer treatment such as in diabetes means that there is more opportunity for episodes of non-adherence to occur (Dunbar-Jacob, Burke, & Puczynski, 1995; Karl, Finklestein, & Robiner, 2006). Also, long-standing habits and lifestyle practices required to be managed in diabetes are frequently resistant to change (Nagelkerk, Reick, & Meengs, 2006; Turk & Rudy, 1991). In fact, for treatment regimens involving behavioral changes, diet or exercise, such as in diabetes, it is not uncommon to find compliance rates approaching zero only a few months after initiating treatment (Haynes & Dante, 1987, as cited by Turk & Rudy, 1991).

A vast majority of existing research on compliance focuses on patients' deviant behavior resulting in non-compliance. This narrow view, however, occludes entire domains of inquiry related to factors other than patient characteristics. Therefore, as an alternative, this project uses the case of diabetes mellitus to redirect that focus by exploring some key psychosocial variables of the doctor-patient relationship. This study identifies a process by which these variables are involved in improving patients' adherence to treatment. Adherence in general term refers to the extent to which the patient follows medical advice (Barber, 2002). The process of adherence typically involves a series of stages such as seeing a physician, receiving treatment instructions (e.g., medication prescription), filling the prescription, and taking the prescription as prescribed. Medical advice can encompass taking medications, following diets, self-monitoring, or making lifestyle changes. As such, non-adherence can take several forms. Individuals may not follow any of the recommendations, they may follow some but not others, or they may make errors. They may also take extra doses; take doses at the wrong times, in the wrong combinations, or without following special instructions for administration of a medication.

Adherence to medical recommendations has been shown to be related to over 200 variables (Cameron, 1996), though most of them inconsistently. Analysis of the adherence literature based on the seminal work of Sackett and Haynes (1976) and Haynes, Taylor, & Sackett (1979) and more recent reviews (Vermiere, Hearnshaw, Royen, & Denekens, 2001; Lehane & McCarthy, 2006; Jin, Sklar, Oh, & Li, 2008; Julius, Novitsky, & Dubin, 2009) using vote counts method (i.e., a count of statistically significant directional findings of studies) suggest that age, education, gender, income, and similar demographic variables do not affect adherence. However, the patient-physician interactive relationship has been found to have a strong correlation to medical recommendation and adherence (Ciechanowski, Katon, Russo, & Walker, 2001; Halkitis, 1998; Haynes, Taylor, & Sackett, 1979; Lehane & McCarthy, 2006; Jin, Sklar, Oh, & Li, 2008; Julius, Novitsky, & Dubin, 2009; Sackett & Haynes, 1976; Vermiere, Hearnshaw, Royen, & Denkens, 2001). More complex factors such as social support and knowledge of the disease also account for a small portion of the variance in adherence behaviors (Dimatteo, 2004; Haynes, Taylor, &

Sacket, 1979; Lehane & McCarthy, 2006; Jin, Sklar, Oh, & Li, 2008; Julius, Novitsky & Dubin, 2009; Sackett & Haynes, 1976; Vermiere, Hearnshaw, Royen, & Denkens, 2001; Tang, Brown, Funnell, & Anderson, 2008). Table 1 presents a summary of the conclusions reached in reviews about the commonly reported variables of treatment adherence. The first column presents the variable of interest. The second column presents a summary of landmark reviews on treatment adherence by Haynes, Taylor, and Sackett's (1979) and Sackett and Haynes' (1976). The third, fourth, fifth and sixth columns represents summary of recent reviews by Vermiere, Hearnshaw, Royen, and Denkens (2001), Lehane and McCarthy (2006), Jin, Sklar, Oh, and Li (2008) and Julius, Novitsky, and Dubin (2009) respectively. As Table 1 suggests, some of the physician-patient communication variables, the patient's knowledge of the disease, and social support available to the patient, have been consistently found across studies spread over three decades to play a significant role in treatment adherence and were used in this study. Patient-provider communication is an umbrella term. I have unpacked the term into five elements, based on the Toronto and Kalamazoo consensus statements (Egnew, Mauksch, Greer, & Farber, 2004; Buyck & Lang, 2002). The elements are empathy, trust, information exchange, shared decisionmaking and rapport. Another important predictor for this research is that of co-morbid depression, which has been shown in recent studies to be detrimental to treatment adherence specifically in diabetes patients (Gonzales et al., 2007, Ciechanowski, Katon, & Russo, 2000). These then are our variables of interest in this study and were used as predictors (Figure 2).

Variable	Haynes, Taylor, & Sackett ('76, '79)	Vermiere, Hearnshaw, Royen, & Donekens ('01)	Lehane & McCarthy ('06)	Jin, Sklar, Oh & Li ('08)	Julius, Novitsky, & Dubin ('09)
Features of the D	isease				
Diagnosis	Yes	Yes	Yes	nr	nr
Disease severity	No	nr	nr	Mixed	nr
Symptoms	Yes	nr	nr	Yes	nr
Concurrent		III	III	105	
illness	No	nr	nr	nr	nr
Family history of the disease	Yes	nr	nr	nr	nr
Dosage frequency	Yes	Yes	Yes	nr	Yes
Complexity	Yes	Yes	Yes	Yes	nr
Duration	Yes	Yes	Yes	Yes	nr
Cost	Yes	nr	Yes	Yes	nr
Clinical setting	No	No	nr	nr	nr
Appointment reminder	nr	No	nr	nr	nr
Side effects	No	Yes	Yes	nr	Yes
Features of the p					
Age	No	No	No	Mixed	Mixed
Gender	No	No	No	No	Mixed
Race	No	nr	No	No	Mixed
Education	No	Yes		No	Mixed
Socioeconomic status	No	Yes	No	nr	nr
Occupational status	No	nr	nr	nr	nr
Religion	No	nr	nr	nr	nr
Forgetfulness	nr	nr	No	Yes	nr
Depression	nr	nr	nr	Yes	Yes
Degree of disability	Yes	Yes	nr	nr	nr
Social Support	Yes	Yes	Yes	Yes	Yes
Features of the p					
Attitude	nr	Yes	Mixed	nr	nr
Respect for	nr	Yes	nr	Yes	nr
patient	nt nuomialau interes	action (
	nt –provider intera				
Patient-provider communication	Yes	Yes	Yes	Yes	Yes
Number of visits	nr	nr	Yes	nr	nr
Satisfaction	Yes	nr	nr	nr	nr
Relationship	nr	Yes	nr	Yes	Yes
Knowledge of disease	Yes	Yes	Yes	Yes	Yes

Table 1. Summary of variables commonly associated with treatment adherence

Yes=relationship present, No=relationship absent, Mixed=both presence and absence of relationship almost equally reported, nr=not reported

Statement of the Problem

Non-adherence to medical recommendations has been construed as a waste of resources and a source of less efficient treatment (Roberts, 2002). The average rate of nonadherence to medical regimens has been found to be a staggering 50% (Gianola, 2007; DiMatteo, Giordani, Lepper, & Croghan, 2002). The rate of non-adherence for chronic diseases such as diabetes mellitus is 30% to 60% and for preventative illnesses is 50% to 80% (Christensen, 2004). Compliance with medical recommendations is a key link to health outcomes (Roberts, 2002). Poor adherence can compromise the effectiveness of treatment. Non-adherence can result in patient and provider frustration and suffering. It can even result in increased mortality. An estimated 125,000 deaths occur every year in the United States due to medication non-adherence (Peterson, Takiya, & Finley, 2003). Despite these relationships between adherence and health outcomes, patients do not necessarily adhere to prescribed treatment after a doctor's office visit (Klingle, 1993; Tudhope, Prinlsoo, Pitt, & Barnes, 2006). Non-adherence can also lead to increased health care costs. Nearly 10% of hospitalizations and 25% of nursing home admissions result from treatment non-adherence (Voils, Steffens, Flint, & Bosworth, 2005). Thus non-adherence, especially in long-term diseases like diabetes, has both negative health and financial implications.

Assumptions Underlying Existing Compliance Research

The role of the physician has been in flux for almost a century (Wynia, 2008; Lasker, 1997). In the traditional biomedical model, all bodily phenomena are considered to have a biological basis and therefore made to fall under the domain of the physician (Kaplan, 1997; Rosenbaum & Stewart, 2002). In this way, even natural biological phenomena have been medicalized. Thus we have seen, for example, a transformation of childbirth in the United States, where women or mid-wives were the primary caregivers as late as the early 1900s, until childbirth was redefined as a medical phenomenon falling under the jurisdiction of medical professionals.

The responsibility of the physician prior to the discovery of microbiological origins for diseases was that of an overseer of illness (Parascandola, 2002) as mostly they were helpless to effect cure for contracted maladies. The physician provided remedies when able, and comfort when remedies were ineffective. In the first half of the twentieth century, the fortunes shifted as a result of an increased understanding of disease-causing microorganisms (Lasker, 1997; Parascandola, 2002). As antibiotics were discovered and able to provide cure, the physician's import increased. They became less of care providers and more of an authority over diseases (Wynia, 2008). Their function was now to identify the problem, and from a seemingly endless choice of effective medical treatments, provide a cure or improve health. However, cure could only happen if the doctor's recommendations are complied with; hence the new found emphasis on compliance/adherence. Thus, implicit in the notion of compliance, is an assumption that the patients must subscribe to modern medicine as their primary, if not the only, source of health care.

There are also assumptions about practitioner authority and patient acquiescence embedded in compliance research. In his classical work on health and illness, The Social System, sociologist Talcott Parsons' (1951) discussion of the sick role is consistent with the rhetorical assumptions about patients and practitioners which underlay the notion of compliance. For Parsons, it was clear that differential authority between patients and practitioners was not only innate to their relationship, but also benefited the larger society by keeping people healthy in as efficient a manner as possible. Thus, the notion was that non-adherence to treatment makes the society less efficient. In the context of research on patient compliance, these clients who are unable and unwilling to comply are therefore deviant, manipulative or recalcitrant (Gianola, 2007).

The state of health care today, however, demands a holistic range of responses from physicians. Disease patterns have changed. In the developed world, people are no longer dying of infectious diseases but are living longer. The challenge for the physician of today is to work with individuals who are subjected to chronic illnesses, or are likely to develop illness as a result of lifestyle habits over the lifespan. Such circumstances demand that the physician interact with individuals on a longer term basis, thus developing a relationship with them. A concomitant issue is that patients are increasingly expecting more from physicians, including open dialogue, respect, and accountability (Dunning, 1999; Thomas, 2009). They are more likely to question the physician's diagnosis of a medical problem and the medical recommendations that accompany the diagnosis. This then calls for making the patient a partner in the therapeutic process.

Diabetes

Epidemiology

Diabetes mellitus is the fastest growing disease in the world today (Faleyimu, Mohammed, & Akinyemi, 2010). About 285 million people in the world suffer from diabetes (World Diabetes Foundation, 2010). It is estimated that the total number of people with diabetes will rise well above 300 million by 2025 (Wild, Roglic, Green, Sicree, & King, 2004). The prevalence in North America and Europe is 8% (International Diabetic Federation, 2009) while two-thirds of the diabetics are in developing countries (Wild et al. 2004). The prevalence of diabetes rises steadily with prosperity (Link & Mckinlay, 2009). Type 2 diabetes is the most common, and accounts for about 90% of all diagnosed cases of diabetes (Purty et al., 2009). The diagnosed cases of diabetes, however, do not fully portray the growing problem facing healthcare. The prevalence of undiagnosed diabetes is significantly greater than had been realized; about 1/3 of the diabetic population living is asymptomatic, undiagnosed and untreated (Centers for Disease Control and Prevention, 2005). Many people do not learn of their diabetic condition until a routine physical exam or as part of evaluation for another known medical problem. Although this may not immediately seem like a cause for concern, these asymptomatic and undiagnosed people are liable to suffer the long-term consequences of diabetes (Valdez, 2009), like their symptomatic counterparts.

The cost of diabetes to the U.S. is around \$177 billion annually (National Conference of Pharmaceutical Organizations, 2009). This figure combines both the direct and indirect costs. Direct costs are the results of usage of increased health care services, including emergency department visits and hospitalizations. Indirect costs include

disability payments, lost work time, and premature death. The largest incidence of the diabetic population occurs in the most economically productive age group, which further adds to the indirect costs (Sicree, Shaw, & Zimmet, 2006).

Controlling diabetes requires round the clock commitment from diabetic patients. The onset of complications due to diabetes can be delayed, and even prevented through effective management. The issue of treatment compliance is critically important to diabetes care because patients are required to independently manage complex daily regimens of medications, glucose testing, diet and exercise. Poor compliance with treatment regimens increases one's likelihood of having chronically high blood sugars and consequent longterm diabetes complications, such as blindness, kidney failure, neurological damage, heart disease, and stroke. Understanding patient non-compliance is therefore imperative in minimizing the calamitous complications of diabetes.

Pathophysiology

In healthy individuals, the body derives its energy from glucose, though to a lesser extent proteins and fats also provide fuel. This glucose, broken down from the more complex sugars in the diet, circulates in the bloodstream where it is carried to cells for metabolism. Ordinarily, the Beta (β) cells of the pancreas secrete the hormone insulin, which facilitates the glucose's uptake from blood into cells. In the diabetic individual, this system fails. Either the Beta (β) cells do not create enough insulin or the body's cells ignore the insulin that is produced. In both situations, the result is an excess of glucose in the blood, which is passed out of the body with urine. Thus even though the blood may be loaded with glucose, cells are unable to access it for fuel and thus forfeit a primary energy source.

There are two primary types of diabetes, insulin-dependent diabetes mellitus (IDDM) or type 1 diabetes, and noninsulin-dependent diabetes mellitus (NIDDM) or type 2 diabetes. Though the etiology for type 1 diabetes is not clearly understood, scientists believe a genetic or viral trigger, combined with age and environment causes a misguided autoimmune response, whereby the immune system turns on itself and destroys Beta (β) cells of the pancreas (Jabbour & Stephens, 2008), so the pancreas produces little or no insulin. Type I diabetes typically afflicts children and young adults. It represents about 10% of all diabetes cases (Purty et al., 2009). Type 2 diabetes is far more common, developing in adults who are usually over age 40 and often overweight. According to many researchers in type 2 diabetes while there is relative Beta (β) cell dysfunction of the pancreas, the main problem is that the cells in the human body fail to acknowledge the presence of insulin; this is termed as insulin insensitivity (Dar & Porries, 2009).

Diabetes Treatment

The cornerstone of diabetes treatment is dietary modification, regular exercise and the use of hypoglycemic agents.

Diet

Prior to the discovery of anti-diabetic drugs and insulin, the treatment of choice for diabetic patients was an extremely restricted diet that essentially amounted to starvation. Even after the discovery of insulin, the diabetic diet was one of restrictions, in that the patient was generally instructed to avoid all simple sugars and eat a low carbohydrate diet (American Diabetes Association, 2008). However, most diabetic management plans currently allow for a small amount of simple sugars in the diet. Dietary recommendations for people with diabetes are now quite similar to those without diabetes, with the majority of calories coming from grains and starches, and the least amount from fats and simple sugars (American Diabetes Association, 2008). Timing and consistency are also important, as it allows for coordinating the meal with the peak action of insulin. Consequently, general recommendations include eating three meals a day and three snacks spaced throughout the day, eating meals and snacks at regular times, eating about the same amount of food each day, and not skipping meals (Farrer, 2008).

Exercise

Another component of the treatment regimen for type 2 diabetes is exercise. Exercise is considered beneficial as it improves insulin action (Babraj at al., 2009) and has been associated with decreased risk of retinopathy and better metabolic control (Seyoum, Estacio, Berhanu, & Schrier, 2006). However, as with diet, exercise routines must be balanced with other regimen strategies. Exercise can lead to hypoglycemia if insulin levels are high compared to the food intake; for example, if the patient under eats. Therefore diabetics need to decide whether or not to engage in physical activity according to food intake.

Hypoglycemic Agents

The Sulfonylurea class of drugs is the most common hypoglycemic agent used in the treatment of diabetes type 2 (Gupta, Ghosh, & Chandra, 2005). Their mode of action is by stimulating insulin secretion from pancreatic Beta (β) cells. They also help in reducing insulin resistance in the peripheral tissues. Sulfonylurea may further increase insulin levels by reducing hepatic clearance of the hormone (Kumar, 2008). The glycemic control that results has been shown to significantly reduce microvascular and macrovascular complications (Stratton et al., 2000).

Complications

The inability to breakdown glucose has severe consequences. Prior to the development of insulin in 1922, a diagnosis of diabetes constituted a death sentence, executed after a short but harrowing existence (Hirsch, 2007). However, with the discovery of insulin and anti-diabetic medications, a medical reprieve was attained from acute metabolic consequences of diabetes. Hence, attention is shifting from the primary causes and acute problems associated with diabetes to the long-term complications of the disease. It is the myriad of secondary effects that is principally responsible for the high costs of diabetes in terms of personal suffering, economic burden, and death.

The long-term health consequences of diabetes are broadly divided into two categories, microvascular and macrovascular complications, with an array of other complications not neatly fitting either category. Microvascular changes refer to the increasing constriction of the smaller blood vessels, which can lead to retinopathy and nephropathy (Creager, Luscher, Cosentino, & Beckman 2003; Giardino & Brownlee, 1997). The primary cause of this narrowing is prolonged exposure to hyperglycemic conditions, though other factors may also contribute to the problem. However it occurs, the result is the same; blood is insufficiently delivered to the affected organs and they begin to fail. The list of potential harms that can occur because of microvascular degradation is extensive. It includes damage to the retinal capillaries which causes swelling and exudates, increasing the risk of cataract, and blindness. In fact, among the 20-74 year old age group, diabetes is the leading cause of blindness in the U.S. (Silva, Cavallerano, & Aiello, 2009) Nerve-tissue can also become demyelinated due to constriction of micro-vessels, leading to sensory and motor control dysfunction.

Macrovascular complications in diabetes are caused by prolonged exposure to elevated glucose levels, which can damage the endothelial linings of the blood vessels (Creager, Luscher, Cosentino, & Beckman 2003). This then makes the larger vessels prone to atherosclerosis and calcification of larger blood vessels, caused by fat and calcium sticking to the vessel walls. This can result in hypertension and stroke. They pose a serious health-risk for the person with diabetes. Exacerbating the normal risks associated with high blood pressure, a diabetic patient may experience increased blood pressure rushing through already compromised nephrons, accelerating the destruction of the kidney's filtration abilities. This can lead to end-stage renal disease (ESRD). Many statistics, estimated and inferred, all support diabetes as a significant contributor to early deaths. In 2003, diabetes was the fourth leading cause of death in most developed countries (International Diabetes Federation, 2009). Over the past three decades, diabetes has become a major contributor of mortality amongst the youth and the middle-aged (Purty et al., 2009). Individuals with diabetes suffering from cardiovascular problems are twice as likely to die as people without diabetes (Kronmalet et al., 2006). This elevated risk remains, even when controlling for other risk factors such as smoking, and cholesterol levels.

CHAPTER 2: LITERATURE REVIEW

In an endeavor to understand and modify adherence behaviors, a vast body of literature on treatment adherence has accumulated. However, little attention has been given to the role which patients play during medical consultations (Thompson, 2007). The consequences of alienating the patient from the process and not understanding how patients come to experience lifestyle change have been costly in both personal and economic terms (National Institutes of Health, 1999). It is only in the recent past that there has been a call to involve the patient, as an active agent in the treatment process (Stone, 1979). As a result, patients' perception on health and illness is now being taken into account in adherence research (Vermeire, Hearnshaw, Royen, & Denekens, 2001). This research study is one such endeavor to assess the patients' perceptions and emotions at the center-stage of the treatment adherence process.

Medical Interviewing

It is well documented that medical interviewing remains one of the most important diagnostic tools (Rouf, Chumley, & Dobbie, 2009). The interview is often the primary source of information leading to the determination of appropriate treatment recommendations. The medical interview serves as a vehicle whereby the patient and the physician influence one another. Unfortunately, there is considerable literature suggesting widespread patient dissatisfaction due to the poor quality of patient-physician communication (Agha, Roter, & Schapira, 2009). This is significant because it has been shown that the quality of dialogue often determines the future doctor-patient interaction

and patient compliance with the treatment regimen (Street, Makoul, Arora, & Epstein, 2009).

Styles of Medical Interviewing

Physicians exhibit differing styles of communication with their patients, which range from doctor-centered (also termed disease-oriented or biomedical) at one extreme to patient-centered at the other (Laine & Davidoff, 1996; Taylor, 2009). The disease-oriented model is doctor led. In this, the physician concentrates on his/her own agenda and essentially seeks to reach a clear diagnosis of the problem, mostly through direct inquiries. The term patient-centered approach refers to the understanding of the complaint offered by the patient, not only in terms of the symptoms but also as an expression of the patient's unique individuality, tension, conflicts, and problems (Balint, Hunt, Joyce, Marinker, & Woodcock, 1970).

The dominant model in medical practice has been the doctor-centered or biomedical approach (Taylor, 2009). It not only requires that disease be dealt with as an entity independent of social behavior, but also demands that behavioral aberrations be explained on the basis of disordered somatic (biochemical or neurophysiologic) processes. This dominant ideology espouses disease focus, objectivity, and social control through authority and technical expertise (Roter & Hall, 2006), and in the process oversimplifies the complexities of sickness. Thus, this biomedical approach reduces sickness to disease (Stewart et al., 2003) where the focus is on the body, not the person. Patient-centeredness, on the other hand, is a framework encompassing both abstract concepts, such as humanism, empathy, and self-awareness, and concrete concepts, such as rational organization of

diagnostic questioning and physical examination (Roter, 2000). Reaching a correct diagnosis is not the sole goal of the physician in such an approach.

In the patient-centered model, the physician creates the secure space to enable the patient to express his/her feelings, ideas and expectations (Jeffrey, 2005). The doctor asks more open-ended questions and approaches the patient with a more empathic attitude. The focus is the person and not the disease. The realization exists that illness and disease may not always co-exist. For instance, people who are worried or grieving may feel ill but have no disease (Stewart et al., 2003). In summary, the doctor-centered model embodies the classic paternalistic doctor-patient relationship in which the disease is the main concern, the doctor is dominant and the patient is expected to defer to the doctor's judgment. The patient-centered model, however, is characterized by a physician's desire for a relationship in which the patient is involved in the decision-making process for a better health outcome, and the whole person rather than the disease is the focus of treatment (Cegala & Post, 2009).

Illness and Disease Frameworks

In order to fully appreciate the patient-centered approach, it is essential to first recognize the distinction between the two conceptualizations of ill-health, that is, disease and illness. According to Nordby (2008), disease can be conceptualized as a health problem that consists of a physiological malfunction that results in an actual or a potential reduction in physical capacities. Ontologically, disease is characterized as an organic phenomenon independent of the subjective experience or social conventions.

Epistemologically, disease is measurable by objective means. Stewart et al. (2003) explain this by noting that disease is diagnosed by objective observation; it is a category, the 'thing' that is wrong with the body-as-machine or the mind-as-computer. Disease is a theoretical construct by which physicians attempt to explain patients' problems in terms of abnormalities of structure or functions of body systems or organs. Illness, on the other hand, is identified as a subjectively interpreted undesirable state of health (Nordby, 2008). Ontologically, it is the subjective feeling of the individual, which is referred to in medical terminology as a symptom. Thus, illness is the personal experience of the feelings, the thoughts, and altered behavior of someone who feels unwell. Epistemologically, this feeling can only be directly observed by the subject and indirectly through her/his reports and eliciting signs during physical examination.

Treatment Adherence

The literature regarding the construct of treatment adherence is vast, of varied methodological quality, fragmented, and complex (O'Donohue & Levensky, 2006). Between 1961 and 1974, only 245 articles were published on the subject. Systematic compliance related research started when David Sackett became interested in the issue around 1972, when he found that hypertensive patients were having unpredictable responses to treatment due to low compliance rates (Vermeire et al., 2001).

Many studies on the subject have been conducted since the first major academic symposium on patient compliance was held at McMaster University in 1974 (Roter et al., 1998). Most of the published studies tend to be fragmented by diagnostic categories and

disciplinary perspectives (Roter et al., 1998), for example compliance difficulties of the headache patients (Rains, Penzien, & Lipchik, 2006), renal failure (Vives et al., 1999), osteoporosis (Lai, Chua, & Chan, 2005), etc. What is disappointing is that often absent from adherence research has been the perspective of the patient (Vermeire et al., 2001). This study helps correct this gaping hole.

Definition

Adherence is a term adopted more recently and is generally used synonymously with compliance, as in this study. The most cited definition (Bosworth, Oddone, & Weinberger, 2006) of adherence/compliance is "the extent to which a person's behavior (in terms of taking medications, following diets, or executing lifestyle changes) coincides with medical or health advice" (Haynes, 1979, p. 1). More recently, it has been defined as the ability and willingness to abide by a prescribed therapeutic regimen (Inkster et al., 2006). Adherence has also been viewed as persistence in the practice and maintenance of desired health behaviors which is the result of active participation and agreement (Cohen, 2009). Concordance is another term that is used synonymously with adherence. Concordance entails a sense of mutual agreement or a frank exchange of information, negotiation, as well as a spirit of cooperation (Mullen, 1997).

Critiquing the compliance approach, Bauman (2000) asserts that the compliance/adherence concept assumes that the existing health problem poses a present danger to the patient and not a possible harm in the future. This approach may work for symptomatic patients. However, it is not suitable for many of those patients who are asymptomatic or diagnosed through routine tests. Such patients do not realize the

imperativeness of adherence to avoid future symptoms and complications. A change of expectations as suggested by Bauman (2000) helps reframe the adherence and compliance model assumption to a constructive approach, where one looks for ways to improve treatment adherence, rather than looking for reasons which hinder the process.

Adherence vs. Compliance

The terms *adherence* and *compliance* are used throughout the literature to describe the degree to which patients' behavior conforms to recommended treatment. Although mostly used synonymously, these terms have different connotations. They reflect different values and beliefs regarding the relationship between the provider and the patient, particularly those related to patient autonomy and freedom of choice (Shay, Siebert, Watts, Sbrocco, & Pagliara, 2009). The term *compliance* connotes a provider-patient relationship in which the provider is cast in the role of expert/authority figure whose direction the patient is expected to follow passively. In contrast, the term *adherence* connotes a patientprovider relationship in which decisions regarding treatment are made collaboratively, with the patient playing an active role (Kerns, Bayer, & Findley, 1999; Saba et al., 2006). Because of the recent popularity of patient-centered care, which is associated with collaboration and is consistent with improved clinical outcome, the term adherence has become the preferred term to describe patients' active conformity to treatment. Adherence has thus been suggested to replace compliance as it is said to connote more empowerment of the patient (Halkitis, 1998; Julius, Novitsky, & Dubin, 2009).

Acceptable Rates and Measurement

Within the literature is a category which deals with adherence measurement and the acceptable rates of adherence. There are various general approaches to objectifying adherence categorically; with those above a certain cutoff considered adherent and those below the cutoff as non-adherent (Karve et al., 2009). A weakness of this approach is that such a cutoff is arbitrary because there is no standard threshold level of adherence necessary for adequate treatment across diseases. Some researchers consider an acceptable rate of treatment adherence to be 80% (Rosen, Spaulding, Greenburg, Palmer, & Newman, 2009). However, acceptable adherence rates vary depending on the regimen prescribed. For example, taking antibiotics for antimicrobial illnesses such as tuberculosis requires close to 100% adherence to the antibiotic regimen in order for treatment to be successful and to prevent recurrence of the infection (Kirkland et al., 2002). The same is true for HIV antiretroviral therapy (Mehta, Moore, & Graham, 1997). Other prescribed treatment regimens, however, such as taking anti-hypertensive medications may yield acceptable results even if the patient is less than 100% compliant with the regimen prescribed (Vermeire et al., 2001).

Kerns et al. (1999) emphasize that adherence is rarely an all-or-nothing phenomenon and is usually incremental. This is generally considered a more appropriate way to view adherence because it highlights the fact that adherence is a continuum (Horne, Weinman, Barber, Elliot, & Morgan, 2005). Adherence in this case refers to a range of behaviors and may best be understood to reflect the degree to which patients' behavioral choices approximate the treatment recommendations made by their healthcare providers. On one extreme of this continuum is treatment refusal or premature dropout. In other instances, however, non-adherence may be less clear-cut. In cases involving complex and multifaceted treatment regimens for ongoing self-management of chronic illness, for example, it is not uncommon for a patient to adhere to one aspect of the recommended treatment and not adhere at all to another.

An even more complex, but related issue is the type of method used to measure adherence. There is no gold standard for measurement of treatment adherence (Vermeire et al., 2001). Self-report of adherence to medical recommendations is the most economic and feasible method of indirect assessment (Gozum & Hacihasanoglu, 2009). It is also the most commonly used (Quittner, Modi, Lemanek, Ievers-Landis, & Rapoff, 2008). Other methods of measuring adherence, particularly for medication or dietary regimens, are through serum or urinalysis. Using serum levels as a way of monitoring medication or dietary adherence, however, is expensive, requires a high level of expertise and is technically sophisticated (Liu et al., 2006) and therefore may not be always practical or available. Another method for measuring adherence is through pill or bottle count. This method consists of counting the unused number of pills or the amount of liquid medication in a bottle to presumably identify what the patient has consumed. It has been pointed out that this method is timeconsuming and subject to falsification by the patient should they for any reason feel that it is to their advantage to discard the unused medication (Steel, Joshi, & Paige, 2005). On the surface, it may seem that the best method for measuring adherence to medical recommendations is through the clinical outcome. This, however, may not be true, since unfortunately medication adherence and clinical outcome do not always have a strong relationship (Westbrook, Duggan, Duggan, & Westbrook, 2005).

Treatment Adherence in Diabetes

Shahady (2009) has identified that the illness that physicians find most challenging to treat is diabetes. This is not surprising as Cramer (2004) reports that some studies have found that only 7% of diabetics are fully adherent to their required treatment regimen. Other researchers have offered more optimistic figures of approximately 40% adherence rates (Reinehr, Schober, Roth, Wiegand, & Holl, 2008).

Like most chronic diseases, diabetes demands considerable management and participation by patients and physicians. Without such involvement and partnership, patients with diabetes experience inadequate glycemic control and subsequent poorer health outcomes. The complexity of diabetic treatment regimen makes its study particularly intriguing (Rubin, 2005). No wonder then that diabetes accounts for about one-third of the studies examining adherence within the chronic illness literature; more than any other single chronic illness (Thompson & Gustafson, 1996).

Sustainable lifestyle changes have been found difficult to implement in diabetic patients when a doctor-centered approach is used (Nagelkerk, Reick, & Meengs, 2006). Delamater (2006) therefore argues that the traditional medical approach is inappropriate for diabetes. He asserts that the self-care demands of diabetes necessitate a more interactive relationship between patients and providers. In a study assessing the experience of female diabetic patients through in-depth interviews; it was found that maximizing two-way communication between the doctor and the patient helped improve patient compliant behavior (Matthews, Peden, & Rowles, 2009).

A national initiative, entitled, the *National Diabetes Education Program*, evaluated the role of diabetic patients and their providers (National Institute of Diabetes, & Digestive

and Kidney Diseases, 2006). The program concluded that when informed patients take an active role in managing their illness and providers are prepared, proactive, and supported with time and resources, their interaction is more productive (Bodenheimer, Wagner, & Gmmbach, 2002). Such interactive processes lead to better diabetes care, more efficient and effective practices, healthier patients, and more satisfied patients and providers. Recognizing the adherence challenges faced by diabetics, both the American Diabetic Association (American Diabetes Association, 2003) and the National Diabetes Educational Program (National Diabetes Education Program, 2006) have advocated the need for the healthcare provider to take a patient-centered care approach rather than the traditional doctor-centered approach.

Models of Treatment Adherence

Adherence research derived from physicians' concerns that their medical advice was not being followed (Vermeire et al., 2001). Early explanations viewed non-adherence as deviant behavior on the part of the patient (Gianola, 2007). The underlying assumption was that patients fail to adhere to the medical regimen because they are resistant, lack insight and are careless (Butterworth, 2008; Leventhal, 1993). However, more recent models view adherence as a function of complex psychosocial parameters (Thompson & Gustafson, 1996).

Most of the theoretical models applied to treatment adherence have their roots in social-cognitive perspective which combines aspects of cognitive and behavioral psychology. According to this perspective, behavior results from mental processes such as reasoning, decision-making and problem-solving efforts (Bosworth & Voils (2005). It also assumes that most of the reinforcers of human behavior are social in nature. Thus, Bandura (2004) asserts that human health is a social matter and not just an individual one. Many such social cognitive models that involve the identification of beliefs and cognitions underlying the behavior of an individual have been widely used in studying treatment adherence (Hughes 2004). Some of the models that are commonly used to explain treatment adherence include, the Health Beliefs Model, Social Learning Theory, and the Self-Efficacy Theory. Each of these models is elucidated below.

Health Beliefs Model

During the 1950s and 1960s, health problems began to surface in the United States due to failure to accept immunizations. In order to understand non-acceptance, the Public Health Service under the direction of Rosenstock (1974), developed a conceptual model of preventive health behavior. This theory referred to as the Health Beliefs Model (HBM) proposed that it is the world of the perceiver that determines what one will do (Martin & Degner, 2004; Rosenstock, 2000). The Health Beliefs Model suggests that whether or not an individual will take action to avoid a disease depends on four basic concepts. These concepts are (a) the level of perceived susceptibility to a specific condition, (b) the degree of perceived severity of the consequences that may result from a condition, (c) the perceived risk-benefit ratio in reducing susceptibility, and (d) the perceived barriers related to advocated behaviors (Sharpe & Curran, 2006).

Perceived susceptibility refers to how vulnerable one feels about acquiring or reacquiring an illness and one's confidence in the diagnosis. *Perceived severity* focuses on

how serious the person considers the condition to be, the consequences of leaving it untreated, and the complexity and duration of the problem and treatment. *Risk-benefit ratio* is concerned with an individual's belief that the treatment will effectively improve or correct the problem and outweigh the treatment's risks (Glazer & Byerly, 2008). *Perceived barrier* refers to what one considers are the risks involved with the desired change in behavior.

Olsen, Smith, Oei, and Doughlas (2008) tested a Health Belief Model of adherence in order to determine the contribution of psychological indices in predicting use of continuous positive airway pressure (CPAP) therapy for obstructive sleep apnea (OSA). The results suggested that the patients developed strong beliefs and expectations about obstructive sleep apnoea and continuous positive airway pressure. These beliefs and expectations then predicted their adherence to therapy. A similar study using Health Beliefs Model in 101 dermatological patients was conducted by Fatemi, Arbabi, Reza, and Arash (2008). They found that Health Beliefs Model-based education was effective in improving treatment adherence in acne patients.

Social Learning Theory

Social learning theory (Rotter, 1966) explains how people choose their actions from a variety of options. This theory assumes that people have a choice about how they will behave. Locus of control (LOC) has its origins in Rotter's Social Learning Theory. Locus of Control refers to people's expectations about whether or not their behaviors are reliably linked to outcomes - an internal locus of control is the belief that they are, and an external locus of control is the belief that they are not (Koehler, Koenigsmann, & Frommer, 2009; Williams, Grow, Freedman, Ryan, & Deci, 1996). For example, if the patient took the medication only because his spouse was concerned, he would have an external locus of causality. On the other hand, if the patient took the medication because he wanted to remain healthy for his grandson's marriage, then he would have an internal locus of control. Interestingly disorders such as diabetes in Pakistan are thought by some to be the will of God or punishment for wrong-doing and there is nothing they can do to control it. This concept of External Locus of Control may prevent individuals from seeking information because they nihilistically feel that fate has already decided for them or there is nothing they can do that will help.

The construct of LOC is also based on the concepts of expectancy and reinforcement value (Rotter, 1966). Before any action is initiated, individuals must consider both the value they place on the outcome of their behavior, i.e., reinforcement value and the probability that the outcome will occur, i.e., expectancy (Kormanik & Rocco, 2009). If a person perceives reinforcement as contingent upon his/her own behavior, a resultant positive or negative reinforcement will enhance or lessen the potential for that behavior to recur in a similar situation. If a person perceives that reinforcement to be outside his/her control and dependent upon chance, fate, powerful others or unpredictable events, the behavior is less likely to be strengthened or weakened.

Wallston, Wallston, Kaplan, and Maides (1976) refined or extended the concepts of locus of control to health-related behaviors by developing the concept of Health Locus of Control (HLOC). Health locus of control is a multidimensional concept reflecting beliefs about the extent to which the following three factors control an individual's health (Wallston et al., 1976): 1) Internal Health Locus of Control is the belief that one's health is controlled by one's own actions and behaviors.

2) Chance Health Locus of Control is the belief that health is controlled by luck, fate, or chance.

3) Powerful Others Health Locus of Control is the belief that health is controlled by others such as physicians, nurses, family, and/or friends.

Learning theorists have suggested that perceived HLOC is one important determinant of health-related self-care practice. This social learning perspective suggests that to be optimally effective in self-managed health care practices, patients must believe that their own actions are important in controlling their health status. In other words, one must have a high perceived Internal HLOC in order to act responsibly in matters of health. Based on these beliefs, an imperative goal of health care intervention would be to develop their self-care agency.

Atkins and Fallowfield (2006) in their study of non-adherence among women with breast cancer showed that patients who were intentionally non-compliant had a lower health locus of control. These patients considered themselves to have minimal influence over their own health. Voils, Steffens, Flint, & Bosworth (2005) studied 85 elderly patients with major depression. They clearly found that the relationship between social support and antidepressant medication adherence is moderated by factors related to Health Locus of Control. In another study, O'hea et al. (2005) in a sample population of 109 diabetic type 2 patients found that HLOC is meaningfully related to medical outcomes.

Self-Efficacy Theory

The concept of self-efficacy was developed by Bandura (1977). Self-efficacy is a belief that one has the ability to perform certain actions that can lead to the desired outcome (Williams, Bezner, Chesbro, & Leavitt, 2008). From a health perspective, self-efficacy beliefs center on an individual's confidence in his or her ability to make and maintain necessary changes in health behaviors over time and across a variety of situations. The importance of self-efficacy beliefs has been well documented as determinants of patients' adherence to medical treatment, willingness to accept responsibility for self-management of chronic illness, and to change important health behaviors such as smoking, drug, or alcohol use, exercise habits or dietary practices (Dunbar-Jacob et al., 1995). Self-efficacy is concerned with the performance of a specific behavior in a specific situation (Jones, Hughes, & Kingston, 2007). Patients who perceive themselves as capable of performing the actions they need to perform are most likely to adhere to the recommended treatment (Maddison & Prapavessis, 2004).

The four principal sources of information (Bandura, 1997) from which self-efficacy expectations are developed include (a) performance accomplishment, (b) vicarious experiences, (c) verbal persuasion, and (d) physiological state. Empirical support suggests that *performance accomplishments* are the most influential and powerful of the four sources (Ramirez-Garcia & Cote, 2009) because they rely on one's personal experiences as a source of learning and show how clearly people can bring together the things they need to succeed. This learning is first initiated with simple task accomplishments. Successful mastery of these behaviors provides positive reinforcement for more complex tasks (Ramirez-Garcia & Cote, 2009). Many self-efficacy expectations are derived by observing

people or events that illustrate certain principles. These situations are referred to as models. Models are the second source of efficacy expectation and are known as vicarious experiences. In order to enhance a person's self-efficacy, the models must be seen as overcoming difficulty. Sharing similar characteristics of the models such as age, sex, and ability can improve the effectiveness of symbolic modeling (Bandura, 1997). Verbal *persuasion* comprises the third source of efficacy expectations. This source is frequently used due to its ease and availability. Verbal persuasion informs people that they are capable of accomplishing a specific behavior and attempts to persuade people to put forth greater effort (Ramirez-Garcia & Cote, 2009). The fourth source of influence is a person's perceived *physiological state*. This includes evaluation of one's capability and strength to participate in a behavioral change. Anxious, stressful situations tend to produce a high arousal state which frequently leads to low self-efficacy and usually impairs performance, while conducive environments have opposite effects. In a study by Johnson et al. (2006), measures of medication adherence, provider interactions, and adherence self-efficacy were administered to 2765 HIV-infected adults. It was found that self-efficacy was associated with better adherence to medications. Similarly, Messer et al. (2007) assessed self-efficacy in predicting adherence to pelvic-floor muscle training (PFMT) for urinary incontinence (UI) prevention in a sample of postmenopausal women. The results clearly showed that self-efficacy predicts adherence.

Correlates of Treatment Adherence

Based on the literature review, the correlates of treatment adherence can be characterized by the following factors; (a) regimen characteristics, (b) patient characteristics, (c) provider characteristics, and (d) patient-provider characteristics.

Regimen Characteristics

Researchers have observed that adherence declines as the length of therapy increases (Johnston, Tyler, & Foreyt, 2007). Estimates of non-adherence range from 20% among patients who are required to follow a short-term (e.g., 10-day) treatment for an acute symptomatic problem; to 50% for a long-term chronic condition with symptoms, such as in diabetes; to 70% or more for a long-term asymptomatic condition, such as in hypertension (Sherbourne, Hays, Ordway, DiMatteo, & Kravitz, 1992). Patients are more likely to follow simple recommendations than complex ones. A recent study by Robin, Novack , Covert, Crockett, and Marcic (2007) assessed 62 adults suffering from glaucoma (ophthalmologic condition). They divided the group into those using a single drug for glaucoma and compared it to those using a two-drug regimen for the disease. The results clearly showed that the more complex dosing regimen resulted in poor adherence. Adherence to medical recommendations which demand change in life-style behaviors such as smoking or dietary changes is generally poor (Mapel et al., 2000; Simmons et al., 2000).

It has been found that the perceptual properties of prescribed medication, such as the taste and size of pills, are potentially important variables that affect a patient's acceptance of, and adherence to medication (Halkitis, 1998). Expectation about the color of pills can also influence outcome (Stevens, 2001). An interesting study was conducted by De Craen, Roo, de Vries, and Kleijnen (1996) that showed that the color of the pills affected treatment outcome. The researchers in the study assessed 49 colored pills which affect the central nervous system. Studies on perceived action of colored drugs showed that red, yellow, and orange were associated with a stimulant effect, while blue and green were related to a tranquilizing effect.

Patient Characteristics

A variety of variables related to patient characteristics have been studied. Accurate prediction of adherence based on many demographic variables, has not been supported. Some of the variables investigated which have not been found to have a relationship to patient adherence include age, race, gender, and educational level (Flegal, Kishiyama, Zajdel, Haas, & Oken, 2007; Janicke et al., 2009).

Cognitive factors are important since the patient needs to understand the instructions about treatment and to incorporate them into daily life. It has been estimated that the patient's recall is only 44% (Merckaert, Libert, Bron, Jaevino, & Martiat, 2009). Cognitive declines in the patient can be problematic, especially if complex treatment regimen, such as in diabetes are prescribed (Park & Kidder, 1996).

Decision about adherence is also likely to be a function of beliefs that the patient holds. Belief in the medication's efficacy leads to higher compliance (Horne, Weinman, & Hankins, 1999). In a study by Horne & Weinman (1999) involving 324 patients suffering from four chronic illnesses (cardiac problem, asthma, renal, and oncologic problems) were studied. It was found that compliance was affected by concerns about the medication causing dependence or long-term adverse effects. Past experiences can also affect adherence. Thus, Howard & Gosling (2008) conducted a study with 200 adult orthopedic patients in which all consenting patients were asked to complete a questionnaire which assessed (1) patient attitudes, education, and past experiences relating to health, sport and exercise, (2) whether the patient had received exercise rehabilitation prescription, and (3) compliance to the exercise rehabilitation prescription. The researchers found a significant difference between attitude and past experience scores for the exercise rehabilitation prescription, amongst compliant and non-compliant groups.

Provider Characteristics

Most treatment adherence interventions assume that the healthcare provider treats the patient appropriately, which could be a potentially flawed assumption (Bosworth & Voils, 2005). Thus, in a study on hypertension, Berlowitz et al. (1998) found that 40% of the sample population had poor blood pressure control (>160/90 mm Hg) despite medication adherence by the patients. The study found that the physicians were at fault and they failed to increase the anti-hypertensive dosages or try alternative medications for them.

Provider characteristics such as qualifications and experience, years in practice, practice specialty, or type of practice setting may have an impact on treatment adherence (Tennstedt, 2000). Thus, in a study, Ren, Kazis, Lee, Zhang, and Miller (2002) identified prescriber characteristics that may influence compliance with antihypertensive medications. They found that the type of practice was associated with patient compliance. Health care providers who were fellows in specialty care had patients who were less likely

to be compliant. Similarly LaPointe et al. (2006) conducted a large prospective, randomized study using multifaceted intervention to improve β -blocker medication use in hypertensive patients. The study involved 2631 patients (1701 in 23 intervention practices and 930 in 22 control practices). The study found that the physician's age or race did not significantly affect β -blocker use in the intervention versus control groups.

Kerns et al. (1999) noted that the extent to which patients perceive their health care providers as supportive, has consistently been an excellent predictor of treatment adherence. Physicians' approachability, their signs of friendliness, interest, and respect, has been shown to be related to satisfaction and subsequent adherence (Chewning & Kobulnicky, 2007). Provider skills must therefore include the ability to communicate openly, have a non-judgmental attitude, and be able to transfer knowledge and have adequate teaching skills to ensure treatment adherence (Bosworth & Voils, 2005).

Patient-Provider Characteristics

Human communication serves as a vehicle whereby individuals influence one another. Physicians can significantly influence patients' behaviors by addressing physicianpatient communication factors related to adherence during their medical interaction (Smith, Devellis, Kalet, Roberts, & Devellis, 2005). Communication aspects of consultation have been consistently found across studies to be important predictors of treatment adherence (Vermeire et al., 2001). Patient-provider communication is an umbrella term and its elements constitute the bulk of predictors in this research study. These have been individually discussed later on.

Evolution of Patient-Physician Interaction Process

Parsons (1951) in his book, The Social System, contended that it is up to the physician to direct and set the boundaries of the clinical encounter. The roots of such a doctor-dominated and disease-centered approach can in fact be traced back to Rene Descartes. In 1634, Descartes wrote that "the body is a machine, so built-up and composed of nerves, muscles, veins, blood, and skin, that even though there were no mind in it at all, would not cease to have the same function" (Foss, 2002; p. 37). Descartes' conceptualization of body as a machine laid the foundation of modern day medicine with its emphasis on body physiology.

The nature of the relationships between physicians and patients has changed in the last century and a half. A key factor in the increasing power of the physician was the success of the biomedical paradigm which directly augmented the physician's ability to understand, diagnose, and treat disease (Parascandola, 2002). Lasker (1997) categorized Post World War I as a crucial era for modern medicine. This heralded the start of the biomedical model of medicine with a consequent decrease in interest in the patient's experiences of illness. Medical science started promoting a paternalistic view of patient care whereby physicians were expected to use their wisdom and prudence to decide the best course of patient care (Lazaro, 1999). This wisdom granted physicians social dominance that was particularly evident in the physician-patient relationship, where physicians became the active and technical experts, and the patients were expected to take a subordinate and passive role (Taylor & Field, 2007). Physicians treated disease as an organic problem. This depersonalization of medicine downgraded the importance of the doctor-patient interaction (Stewart et al., 2003). Thus, the prominence of medical

communication in clinical encounters waned sharply with the professionalization of medicine (Stewart, 1995). This remodeled the medical interview as wholly scientific and objective and left no room for the catharsis that the patient felt by telling their narrative to the physician.

In the later portion of the 20th century, health care delivery witnessed the advent of changing perspectives. A new attitude towards doctors began to develop. People began to question the authority and power of physicians (Dunning, 1999). Even the courts became concerned and drafted the first set of patients' rights. In the past 25 years, a call for more humane form of medicine has been made which has created a renewed interest in patientphysician communication. It has lead to the introduction of interviewing and interpersonal skill courses in medical teaching (Wagner, Lentz, & Heslop, 2002). In parallel with this trend in medical education has come the increased sociological interest in doctor-patient interaction aspects over the last two decades (Ploeg, Winthereik, & Bal, 2006). Thus, Balint, Hunt, Joyce, Marinker, & Woodcock (1970) introduced the concept of patientcentered medicine. However, since its conceptualization, patient-centered medicine has been viewed by scholars and researchers as a soft-science. Few people give credence to its role in modern scientific medicine (Stewart, 1995). While it is obvious that there is tremendous gain to be had from a more egalitarian relationship between physicians and patients, paradigm shifts do not generally occur smoothly.

The biomedical model of disease largely remains the standard by which medical students are educated (Hojat, Mangione, Nasca, Gonnella, & Magee, 2005). As a result of a strong focus of the physicians' learned comfort with the organic basis of illness, the patient remains depersonalized. As one new physician stated, "we're taught to look for diseases,

they just happen to be attached to people" (Rittelmeyer, 1993, p. 657). Although an increasing emphasis is now being placed on perspectives that incorporate the biopsychosocial aspects of patient care (Engel, 1989), newly trained physicians are often uncomfortable to make an effort to discuss problems with patients that are of a psychosocial nature (Levinson, Dunn, Parker, & Kaufman, 1988).

Understanding the Communicative Process

Patient-physician interaction has been characterized as a dynamic, creative, socially constructed event (Street, 2003). Although certain technical activities transpire, such as a physical examination, *talk* is considered the primary activity in which the physician and patient exchange information about health-related concerns, share decision-making, and preferably develop sustainable relationships characterized by rapport and respect (Street, 2003). Research on the physician-patient relationship underscores the importance that these relationships contain elements such as trust and empathy (Altice, Mostashari, & Friedland, 2001). During such an interactive process which is patient-centered, both the physician and the patient negotiate to achieve their individual and mutual goals (Burke, Earley, Dixon, Wilke, & Puczynski, 2006).

Aspects of patient-provider communication can be either empowering or demeaning, such that patients can either feel in control and in partnership or ashamed (Roter & McNeilis, 2003). Likewise, providers can act as facilitators or hindrances to patients' behavior change. Charon (2001) challenges those involved in patient-provider communication to consider that "a scientifically competent medicine alone cannot help a patient grapple with the loss of health or find meaning in suffering. Along with scientific ability, physicians need to listen to the narratives of the patient, and "be moved to act on a patient's behalf" (Charon, 2001, p. 1897). In such a relationship, the patient's autonomy and "fundamental right to self determination" need to be acknowledged (Vermeire et al., 2001, p. 337). Patients feel comfortable expressing their feelings and setting goals and learning how to best care for themselves (Burke et al., 2006). This unique interaction involves vulnerability on the part of patients to trust that the information shared will be heard and valued. It also assumes that the information received from providers will be appropriate given the specific needs of the patient and presented in a way that is respectful and compassionate (Ong, De Haes, Hoos, & Lammes, 1995).

Patient-provider communication is especially significant for adults with type 2 diabetes because findings from the National Diabetes Education Program (National Institute of Diabetes, Digestive & Kidney Diseases, 2006) suggest that informed patients need to take an active role in managing their diabetes. Patient-centered interaction has been shown to lead to better diabetes care, more efficient and effective practices, healthier patients, and more satisfied patients and providers (National Institute of Diabetes, Digestive & Kidney Diseases, 2006). Physicians and educators play a pivotal role in providing patients with the assistance and resources to care for themselves and to prevent the onset of additional morbidity or associated complications. Leaders of health professional organizations and care facilities, as well as policy makers would benefit from understanding how doctors and educators can best interact with diabetic patients to assist them in caring for themselves (Golin, DiMatteo, & Gelberg, 1996).

Understandably, interdisciplinary research and collaborations among many health professionals and patients is needed to champion the role of patients and providers involved in patient-physician interaction. Healthy People 2010 (Department of Health & Human Services, 2000) objectives established a national goal to increase the proportion of persons who report that their health care providers have satisfactory communication skills. Two major conferences were also held in Toronto, Ontario (1991) and Kalamzoo, Michigan (1999) to discuss patient-physician communication. In the light of the Toronto and Kalamazoo consensus statements (Egnew, Mauksch, Greer, & Farber, 2004; Buyck & Lang, 2002) and the reviews written on them, the following elements of communication in a medical encounter have been consistently found to be the central theme in patient-centered communication:

Trust

Empathy

Information exchange

Rapport

Shared decision-making

Furthermore, the variables of Knowledge of the disease, and Social support which have been consistently found across studies to be predictors of adherence (Table 1) will also be discussed here, along with co-morbid depression which is a significant predictor of diabetic treatment adherence (discussed earlier). All these modifiable factors can be targets for interventions to improve adherence and are the predictor variables in the study.

Trust

Interpersonal trust is a key ingredient in cooperative relationships (Schlinder & Thomas, 1993). It is considered essential to the physician-patient relationship (Agarwal, 2008). The most widely quoted definition of trust is by Rotter (1967), who states that "trust is an expectancy held by an individual or a group that the word, promise, verbal, or written statement of another individual or group can be relied upon" (Rotter, 1967, p. 651). Anderson and Dedrick (1990) have defined interpersonal trust within the physician-patient relationship as "a person's belief that the physician's words and actions are credible and can be relied upon" (p. 1092). Implicit in this definition, the significant factor in trusting one's physician is the belief that the physician will act in the individual's best interest and will provide support and assistance concerning treatment and medical care. Trust in the physician has been described more recently as a condition in which the patient views the physician as credible, honest, and benevolent (Fugelli, 2001). Patients go to the physician because they trust that the physician is the best person to take care of their medical problem. Therefore, Hall, Dugon, Zheng, and Mishra (2001) consider trust as "an optimistic acceptance of a vulnerable situation in which the trustor believes the trustee will care for the trustor's interests" (p.615).

Thom & Campbell (1997) found that both technical competence and interpersonal behavior contribute to the patient's trust in the physician. This means that since patients cannot objectively evaluate a physician's competence, they make a subjective assessment of it. Thus patients usually assess from an emotional perspective whether the physician can be trusted. Davies & Rundall (2000) contend that trust lies at the core of doctor-patient relationship. Their study shows that a trusting relationship leads to loyalty to the physician and this can result in better treatment compliance. They contend that the benefits of a high trust therapeutic relationship include a more enriched information exchange, patient loyalty, and better treatment compliance. Patients' trust in their physician has been shown to predict adherence to medical regimen (Mechanic, 1998; Safran et al., 1998). More recently, a study of hypertensive patients' adherence to medication recommendations found that patients who do not trust their physicians have a lower level of treatment adherence (Hopfield, Linden, & Tevelow, 2006).

Empathy

The word empathy was not introduced in behavioral research until the twentieth century. It originates from the German word *einfuhlung*, in which, *ein* means one and *fuhlung* means feeling (Snyder, 2009). Thus, the literal translation of empathy is one who receives another's feelings. Empathy was also a fundamental tenet of Carl Rogers' (1975) theory. Rogers' early speculations on the nature of the construct were as follows, "the state of empathy, or being empathic, is to perceive the internal frame of reference of another with accuracy and with the emotional components and meanings which pertain thereto as if one were the person" (as cited in Rogers, 1959, p. 210-211). Implicit in Rogers' definition is the interaction between two individuals in which both are invested in each other. Empathy is claimed to be the basis of all human interaction and an essential constituent in all psychological phenomena (Kohut 1959, as cited in Aragno, 2008). It is a common observation that a patient often needs moral and emotional support from the healthcare provider. Thus, Halperm (2003) suggests that patients seek empathy from the physicians.

This is especially true when an emotional situation occurs, such as a physician disclosing to a patient the diagnosis of a chronic illness. Historically, there has been a controversy over defining whether empathy is an affective or cognitive construct or both. Lemerise and Arsenio (2000) emphasize the cognitive process of empathy whereas Sams and Truscott (2004) consider it to be a primarily affective construct. Lamm, Batson, and Decety (2007) have defined empathy to consist of both, that is, a cognitive informational aspect and an affective motivational component.

An interesting study conducted by Marci, Ham, Moran, and Orr (2007) measuring physiological concordance, showed that patient perception of empathy displayed by the physician leads to enhancement of social and emotional patient-physician interaction. Patient perceived empathy has been linked to the patient's ability to cope with and understand his or her illness (Reilly, 2001). This ability to cope with and understand one's illness was termed enablement in Reilly's study. Reilly (2001) surveyed 200 patients immediately after a physician's visit. Measures included a patient enablement instrument, a measure of the perception of physician empathy, and a measure of knowing the physician well. Results indicated that the patient's ability to cope and understand their illness was directly related to the patient's perception of physician empathy. Notably, no relationship was found between a patient's sense of enablement and length of time spent with the physician. A myth exists that showing empathy to patients is time-consuming (Schattner, 2009; Virshup, Oppenburg, & Coleman, 1999). This notion was disproved by Levinson, Gorawara-Bhat, and Lamb (2000) who found that in surgical and primary care settings, physicians who missed opportunities to demonstrate understanding and empathy to their patients had longer visits with the patient.

Kim, Kaplowitz and Johnston (2004) assessed the relationships of physician empathy and related constructs to patient satisfaction and adherence. In this study, 550 outpatients at a large university hospital in Korea were interviewed. It was found that patient-perceived physician empathy significantly influenced patient satisfaction and adherence. LeSure-Lester (2000) investigated whether empathy was related to behavior adherence of abused youth within the natural living context of a group home environment. The results suggested a strong, positive relationship between empathy and higher rates of behavior adherence.

Information exchange

A physician usually seeks information so as to reach the correct diagnosis and to help formulate a treatment plan. The patient, on the other hand, seeks information from the doctor so as to understand the nature of the illness and to get relief from the symptom, and to some extent, to have catharsis by verbalizing the problems. Various studies have revealed that the information-seeking desire by patients is especially great when suffering from chronic illnesses like cancer or diabetes (Starke & Moller, 2002). The level of anxiety in patients is mitigated if they perceive that they have received adequate information from their physician (House & Stark, 2002). It has been shown that a greater patient participative role in the medical encounter improves satisfaction and treatment compliance (Loh, Leonhart, Wills, Simon, & Harter, 2007). It is therefore imperative that doctors encourage patients to speak up about the aspects of the disease about which they want to receive communication. Garden (2009) found that a patient-centered approach takes this into account and allows for patients to openly discuss their feelings about the problems that they are encountering.

Patient adherence is also increased when physicians communicate in a manner that reduces discrepancies in instructions and promotes a commonality of expectations (Vervoort, Borleff, Hoepelman, & Grypdonck, 2007). Halkitis (1998) found that in HIV patients, treatment adherence is enhanced when doctors provide clear explanations, describe medications' full side effects and possible interactions with other medications.

Adequate information exchange helps a patient to understand the problem, and make informed and shared decisions, which can lead to better treatment adherence (Ishikawa & Yano, 2008). In a study by Chew, Bradley, Flum, Corina, and Koepsell (2004), 332 patients were interviewed at a pre-operative clinic. They administered a health literacy test and collected socio-demographic data. When patients returned for their scheduled surgical procedures, adherence to preoperative instructions was assessed. It was evident from the study that poor information exchange was associated with lower adherence to preoperative medication instructions. In another study, data were obtained for 103 patients visiting thoracic surgery or oncology clinics in a large Veterans Affairs hospital for initial treatment recommendation for suspicious pulmonary nodules or lung cancer (Gordon, Street, Sharf, & Souchek, 2006). The results showed that poor information exchange between the physician and the patient lead to communication problems which were associated with lower adherence to treatment recommendations.

Rapport

A strong therapeutic relationship is considered an important outcome of a patientphysician interaction (Safran et al. 1998). The Kalamazoo consensus statement of 1999 endorsed the patient-centered approach to rapport building as a fundamental communication element between the doctor and the patient (Makoul, 2001). Relationship is also the cornerstone of Boyatzis' (2006) Intentional Change theory (described later), which is the overarching concept of this research study.

Roter (2000) suggests that strong relationship building occurs when both the doctor and the patient explicitly convey emotional content. Radwin (2000) found that knowing personal information about health providers makes the patients feel closer to them. The presence of such a high quality relationship also leads to advantageous physiological changes in the human body (Heaphy & Dutton, 2008). Heaphy and Dutton (2008), found that such a relationship between individuals has the potential to positively impact the cardiovascular, immune, as well as the neuroendocrine systems of the body. Lack of rapport building communicative process contributes to adherence problems (Cooper et al., 2003). During the initial phase of the medical interviewing process, one of the tasks of the physician is to build rapport and establish an atmosphere of trust that is conducive to the patient's feeling comfortable, to be able to share his or her concerns, thoughts, and feelings openly (Miller & Rollnick, 2002). Although building and maintaining rapport is an ongoing task in medical interviewing, initial steps that the therapist can take towards starting the session in the right manner include (a) eliciting the patient's feelings about the visit referral directly (Zweben & Zuckoff, 2002), and (b) affirming the patient for coming to the session (Miller & Rollnick, 2002). In a related study, Gilbert and Hayes (2009) video-recorded

visits of 31 nurse practitioners and 155 patients. The quality of patient-provider communications during the visits was measured using the Roter Interaction Analysis System. The results showed that better treatment adherence is related to relationship building components within the patient-provider interactions.

Shared Decision-making

In the traditional paternalistic model of the decision-making process, the physician commands the patient to follow a certain treatment modality, based on the diagnosis he/she has made. In their study of physician-patient interactions, Geist and Dreyer (1993) have maintained that the biomedical communication system advances hegemony that "establishes a system of values, attitudes, and beliefs that restricts the layperson's participation in scientific decision-making" and also "suppresses the types of dialogue that facilitate understanding in provider-patient relationships" (p. 233). No wonder then that a high proportion of patients do not even remember what their doctors inform them about diagnosis and treatment (Ettner, 1999), this then obviously leads to treatment non-compliance. In a patient-centered medical interviewing approach, the physician is expected to offer to the patient the option to partake in the decision-making process. Thus, for example, in prescribing an antibiotic course for a bacterial infection, the patient and the physician may collaboratively decide on a once-a day or twice daily regimen, size and color of the pill.

Shared decision-making benefits health care outcomes. A number of research studies have clearly shown that patients are more likely to comply with medical advice when they participate in decision-making (Whitney et al., 2008). In a study, 30 patients

were assessed using non-steroidal anti-inflammatory drugs (Cames, Anwer, Underwood, Harding, & Parsons, 2008). The researchers found that shared decision-making encouraged adherence to the treatment process. Goldring, Taylor, Kemeny, and Anton (2002), conducted a study with 218 patients diagnosed with inflammatory bowel disease. The patients reported on their physician-patient relationship, general and disease-specific quality of life, and intentions to take drug. Those who shared a decision-making relationship with their physician showed greater intentions to adhere to the treatment.

Co-morbid Depression

Depression is said to be common amongst diabetics. Studies suggest that major depression is two times more prevalent in type 2 diabetes patients than in the general population (Ali, Stone, Peters, Davies, & Khunti, 2006). Some of the risk factors in diabetes for co-morbid depression include long-term diabetes, high and sustained blood sugar levels, female gender, and ethnic minority status (Katon, Korff, & Ciechanowski, 2004).

The etiology of co-morbid depression amongst diabetics is not known and both psychological and physiological causations have been put forward. It is thought that comorbid depression in diabetes has multi-factorial origins (Ali, Stone, Peters, Davies, & Khunti, 2006). The high number of stress factors that diabetics have to deal with is an obvious predisposing factor. However, advances in neurochemistry have shown that neurotransmitter changes in the brain may have a role to play in the causation of co-morbid depression in diabetics (Lustman & Clouse, 2002). The mechanism by which clinical depression might negatively affect medication adherence could be multifaceted. Poor cognition, attention deficit, forgetfulness, and lack of self care may lead to poorer treatment adherence.

In spite of the high rates of depression among diabetes patients, it is infrequently recognized as one of the diabetic complications. This could be particularly problematic because co-morbid depression can lead to further diminished treatment adherence, which is already low amongst diabetics. In a well cited research study, Ciechanowski, Katon, and Russo (2000) examined the impact of depressive symptoms on adherence in patients with diabetes. Their findings showed that diabetes patients with higher level of depressive symptoms had poorer adherence to medical regimens. A recent study (Gonzales et al., 2007) involving 879 type 2 diabetic patients, found that major depression was a predictor in decline of both medication adherence, and frequency of glucose monitoring. The study concluded that alleviation of depressive symptomatology could lead to better treatment adherence.

Knowledge of the Disease

For some patients, non-adherence could be the result of lack of knowledge about the illness and treatment regimen. Although healthcare providers believe that they spend adequate time to give patients relevant information; observational studies generally show that they spend little to no time in giving patients information (DiMatteo, 1995). Many times they just assume that the patients are aware of the information (Miller et al., 2003). Even when healthcare providers do give information, it is often confusing or inadequate (McLane, Zyzanski, & Flocke, 1995). Various studies have shown that a patient's level of knowledge about the disease and prescribed regimen is directly proportional to adherence behavior (Lee, 2008). When patients are more knowledgeable about the regimen, they are more adherent to treatment. Traditional patient education programs use the same assumption when hoping to directly influence adherence behaviors by increasing the patient's level of knowledge.

Sherbourne, Hays, Ordway, DiMatteo, and Kravitz (1992) argue that the patient's knowledge of the treatment regimen is an essential prerequisite to cooperation. Detailed patient education programs are considered essential for patients with AIDS to increase adherence with the medication prescribed in their treatment regimen (Ickovics & Meisler, 1997). Support programs to enhance patients' problem-solving abilities have been generally found to be beneficial. In chronic patients, such as diabetics it was clearly found that the relationship between patient knowledge and adherence is significant (Dimatteo, 2004). Cameron (1996) stated that under some conditions, provision of knowledge about the disease information may enhance adherence. For motivated patients, who are ignorant of the correct procedures, additional information should be beneficial. However, for the knowledgeable, but insufficiently motivated patients, increase of information may not improve adherence (Cameron, 1996).

Social Support

Stewart et al. (1997) defined social support (within a health context) as interactions with family members, friends, peers, and health professionals who communicate information or aid the patient. Social support is said to help buffer effects of a stressful illness by facilitating coping efforts of the individual and enabling individuals to perceive the event as less stressful (Penninx et al., 1998). High levels of social support have been associated with greater treatment adherence, more positive health and lifestyle changes (Lewandowski & Drotar, 2007; Martin, 1996). It influences recovery from illness by enhancing motivation to adhere to difficult treatment regimens (Kim, Sherman, & Taylor, 2008) and helps recipients develop greater self-confidence and feelings of autonomy. On the other hand, inadequate social support has been reported to adversely affect the motivation of patients to stay actively involved in diabetes management (Wallhagen, 1999).

Researchers evaluated the possible relationship between adherence and marital status. It has been found that marital status may be a source of support for a chronically ill patient. Married patients are generally more likely to follow medical recommendations than patients who were unmarried, separated or divorced (Chung, Moser, Lennie, & Riegel, 2006). Independent living is affected by fluctuating mental conditions (Vauth, Loschmann, Rusch, & Corrigan, 2004). In a study of 156 patients 70 years of age or older (Rich, Gray, Beckham, Wittenberg, & Luther, 1996), compliance was lower in patients living alone. The investigators in this study concluded that a spouse or other caregiver might increase compliance through medication reminders or by direct supervision of medication administration.

Social support has been clearly found to play a role in diabetes-specific selfmanagement practices (Tang, Brown, Funnell, & Anderson, 2008). It increases the probability of adherence in diabetes to self-care regimens, including physical activity (Chlebowy & Garvin, 2006). Glasgow, Toobert, and Hampson (1995), examined supportive and non-supportive family behaviors in relation to adherence in diabetic patients. The subjects consisted of 18 adolescents and 54 adults. All were diagnosed as having diabetes mellitus. Subjects and their families participated in two interviews 6 months apart, in which they completed psychosocial measures. The subjects completed a 24-hour diet recall and provided a blood sample for glycosytated hemoglobin (Ghb) analysis. For a period of one week, they also monitored their glucose levels. A strong correlation was established in this study between negative family behavior and poor adherence.

Intentional Change Theory

The reason why patient-centered interviewing can help create positive affect in the patient leading to a desired change in treatment compliance can be explained by Intentional Change theory (Boyatzis, 2006). Intentional Change theory (ICT) describes the essential components and processes that encourage sustained, desired change to occur in a person's behaviors, thoughts, feelings, and perceptions (Boyatzis, 2006). The change in the ICT model is termed desired change because the person wishes for it to occur. This desire is in the person's consciousness or self-awareness (Goleman, Boyatzis, & Mckee, 2002). Such change is sustainable as it can endure for a long period of time. In a patient-centered

patient-physician relationship, it is the patient's desired change that the physician needs to tap into.

The theory includes five phases or discontinuities, called discoveries (Boyatzis, 2006; Goleman, Boyatzis, & McKee, 2002). The five phases include: (1) the Ideal Self, i.e., the image of a desired future, (2) the Real Self, i.e. the current self-image, (3) creation of a Learning Agenda and Plan focusing on the desired change, (4) Experimentation and Practice with new behaviors, thoughts, or feelings outlined in the Learning Plan, and (5) Relationships. The starting point in the process of intentional change is the discovery of who we want to be (Boyatzis, 2006). This is our Ideal Self, which is an image which emerges from our dreams and aspirations (Boyatzis & Akrivou, 2006). Once a sense of *Ideal Self* has been built, the next stage is the awareness of the Real Self. This is the person as others see him/her and with whom they interact (Boyatzis, 2006). The *Real Self* helps us identify our strengths and weaknesses. The third discovery is that of the formation of an Agenda. The focus of this agenda is to achieve the desired future. This may call for development of a plan in which one may have to engage in activities which is out of his/her comfort zone. The next emergent awareness comes in the form of Experimenting and *Practicing* with planned behaviors (Boyatzis, 2008). All these stages are made possible if there exists a *Relationship* (fifth discovery) amongst those involved in the process.

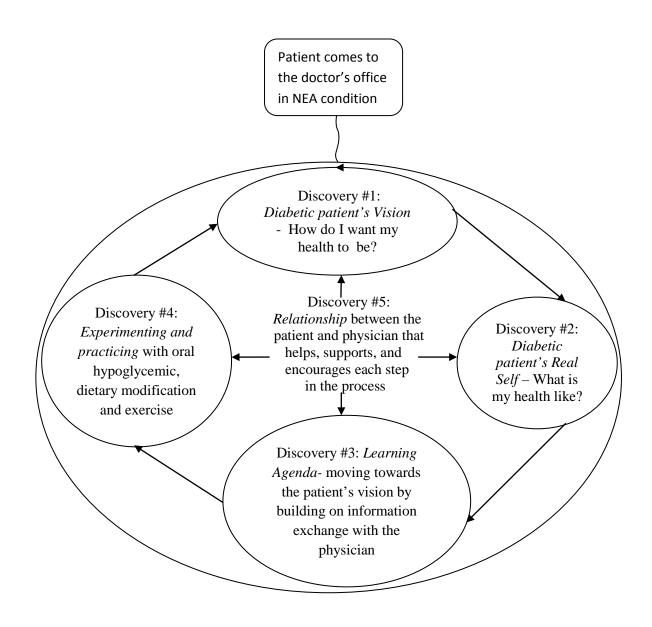


Figure 1. Intentional Change Theory applied to doctor-patient interaction in diabetes

Figure 1 (adapted from Boyatzis, 2006) illustrates the ICT model, as it applies to the patient-physician interaction in diabetes. Doctor-patient interactive relationship may help a patient to realize his/her desired image of a healthy self (first discovery), understand his/her current medical situation (second discovery), help formulate a plan to achieve the ideal health state (third discovery) and adhere to prescribed medication, dietary and exercise regimen (fourth discovery). All of these discoveries are, however, possible only if there is a relationship (fifth discovery) between the patient and the physician; as it is the physician who can help the patient to navigate the various stages, towards realization of a healthy future. With regard to the patient-centered approach to medical care, it is important to recognize the critical role of relationships, which is in the center of the model (Figure 1). According to Boyatzis (2006) a person will not experience more than one discovery in intentional change if the relationship does not exist. For example identification of one's Ideal Self by the physician requires a deep conversational exchange during patientphysician communication, and this can only occur if there is a relationship between the physician and the patient (Boyatzis, Howard, Rapisarda, & Taylor, 2004). A critical stage with regard to this research study is the first discovery, or hope of a desired future. Maikranz, Steele, Dreyer, Stratman, and Bovaird (2007) state that recently, health professionals have become increasingly interested in the correlates and consequences of hope, which is also a central aspect of the positive psychology movement. According to McKee, Tilin, and Mason (2009), hope enables us to believe in an attainable and optimistic vision of the future. It is the energy within, which moves us and others to believe in a better future. Maikranz et al. (2007) conducted an interesting study in which they examined the associations among hope, illness-related uncertainty, anxiety, depression, and adherence. Their study population consisted of 70 renal and liver transplant recipients and their caregivers who participated in a three month study. The results of the study clearly showed that there was an association between hope and adherence, which was mediated by depressive symptoms. Hopefulness has been directly associated with a more positive

attitude toward medication-taking (Godin, Cote, Naccache, Lambert, & Trottier, 2005). Carver, Lehman, and Antoni (2003), argued that hopefulness keeps patients involved and engaged in treatment goals, leading to an improved psychological well-being. A number of studies have shown that those who have hope have more active and problem-focused coping responses (Strutton & Lumpkin, 1993). A study found that hopeful heart patients exercise for a greater period of time in cardiac rehabilitation program than those who were not hopeful (Shepperd, Morot, & Pbert, 1996). It was concluded that patients who are hopeful focus on positive aspects of treatment and are more likely to adhere to prescribed treatment. Overall, hopefulness predicts a better quality of life (Carver et al., 2005).

Positive and Negative Emotional Attractors

According to Boyatzis (2008), intentional change is a sustainable, desirable change which is iterative and cyclical in nature. Intentional change engages the cycle through selforganizing properties. The context of the self-organizing process is determined by Positive Emotional (PEA) and Negative Emotional Attractors (NEA) (Boyatzis, 2008). These are Lorenz attractors that pull people towards them (Mackenzie, 2005). The process of helping a person to focus on future possibilities and instilling hope, pulls that person towards his or her Ideal Self. This is also linked to better cognitive functioning and opens new avenues for understanding and learning (Boyatzis, 2006). In such a condition, the possibilities for helping others learn, change, and grow are tremendous. This emotional and psychological arousal is called the Positive Emotional Attractor, PEA state (Boyatzis, 2006). As opposed to the above, a Negative Emotional Attractor state (Boyatzis, 2006) is elicited when a person prepares to deal with fear, fight, and flight. In the Negative Emotional Attractor (NEA) state, the cognitive distortions and lack of concentration that feelings of hopelessness and despair create can impair an individual's ability to process thought. If a person remains in the Negative Emotional Attractor (NEA) state for long, then the process of change does not happen.

Evidence from medical studies have also lead Boyatzis, Smith, and Blaize (2006) to attribute that PEA pulls the person toward his or her Ideal Self. As the person focuses on possibilities, a person's parasympathetic nervous system (i.e., PSNS) is aroused. In this PSNS state, the person is calm, and the immune system is up-regulated (Richman et al., 2005), which helps renew the body. Positive emotions may also speed internal homeostatic processes (Fredrickson & Levenson, 1998) and so reduce any stress. According to Howard (2006), the changes initiated when PEA is high are more successful. The NEA on the other hand arouses the sympathetic nervous system (SNS), which helps human beings deal with threats. Functional approaches to emotion have conventionally centered on the adaptive value of negative emotions. Negative emotions are said to serve the purpose of coping with a threat or an imbalance between the individual and his or her environment (Ekman, 1999). Thus, when faced with a threat, the NEA pulls a person towards such defensive protection (Boyatzis, Smith, & Blaize, 2006). When the body's defense mechanism is activated, all non-essential functions are shut down (Boyatzis, Smith, & Blaize, 2006). This also results in the down-regulation of the immune system (Kiecolt-Glaser et al., 1993).

In the light of Gottman's (1993) seminal work on relationships, both NEA and PEA may play an important role in a particular relationship. Gottman (1993) refers to the mathematics of the predator-prey model to prove that negativity is as necessary as

positivity. According to him, negativity and negative affect have a positive, pro-social role in relationships. They may play a role in balancing opposing qualities and may also serve a role in keeping attraction alive, as the persons involved are able to feel the two opposing emotions (positive and negative). A relationship that is totally positive may therefore be as undesirable and unstable as one that is all negative. Considering that an ailing patient is likely to be in the NEA state because of ill-health, patient-centered interviewing can help lead to eliciting of a PEA state in the patient. Once in the PEA, a patient is more likely to be open to the views of the physician and more willing to adhere to advice. This can help sustain the change effort (Casti, 1994) towards better treatment adherence.

Various studies have proved a clear link between positive emotions and such perceptual openness. Fitzpatrick, Janzen, Chamodraka, & Park (2006) conducted a study involving 20 patients in which they found that positive feelings inspired openness to exploration. The researchers also concluded that patient openness to exploration and positive emotional response moves forward the relationship between the patient and the healthcare provider. In another study involving 108 undergraduate university students, it was found that positive emotional dispositions were closely associated with openness to experience (Shiota, Keltner, & John, 2006). Further analysis revealed that openness was most strongly associated with positive emotion, which was experienced during patient-provider information exchange. Optimistic beliefs have also been linked to greater processing of health-risk information (Aspinwall & Brunhart, 1996). There is also a well-established link between emotional state and general cognitive functioning. Positive affect have been shown to lead to creative and flexible ways of approaching a problem (Schellenberg, Nakata, Hunter, & Tamoto, 2007). It has been proved to improve memory

recall in word association tasks (Isen, Johnson, Mertz, & Robinson, 1985). Positive emotion can also enhance the scope of visual spatial attention processes and improve the selection of visual targets (Rowe, Hirsh, & Anderson, 2007).

CHAPTER 3: METHODS

Objective of the Study

Based on the conclusions reached from the review of literature, variables related to doctor-patient interactive relationship, knowledge of the disease, co-morbid depression and the social support available to the patient, were considered to be the key antecedents for treatment adherence. The purpose of this study was to explore these key psychosocial variables and identify the process by which these antecedents affect treatment adherence in type 2 diabetes patients.

The study builds on Boyatzis' (2006) Intentional Change Theory. According to this model, if the physician and the patient are able to build a relationship with each other, then the physician may be able to help focus the patient on images of a healthy future and instill hope of a speedy recovery. Such hope would result in the patient being more open to possibilities to experiment with prescribed treatment and thereby adhere to the treatment regimen, to achieve the desired future. Specifically, this study assesses if the patient's Positive Emotional Attractor (PEA) and Negative Emotional Attractor (NEA) mediate the relationship between these variables of the doctor-patient relationship with that of treatment adherence. This is the first study to evaluate such a mediational model. The focus of this approach is to understand patients' perception of their interactive relationship with the physician, and the emotions generated as a result, which may lead to treatment adherence. The study envisages bridging the fields of organizational behavior, psychology, and medicine, in the realm of treatment adherence.

Hypotheses

I hypothesize that if physicians use the elements of patient-centered style of interaction, then the patients will adhere more to their physicians' treatment recommendations. Patients' knowledge about the disease and available social support will also help improve treatment adherence. Conversely, co-morbid depression will inhibit treatment adherence. Previous studies (described above) have led to the belief that such direct relationship exists. I hypothesize that all the direct relationships will be mediated by the patient's PEA/NEA (PNEA). Furthermore, the physician's PEA/NEA will also have an effect through the mediator variable of patient PEA/NEA on treatment adherence.

The following then are the hypotheses for this study.

Hypothesis 1a: Patient perception of empathy increases treatment adherence.

Hypothesis 1b: Patient PNEA mediates the relationship between empathy and treatment adherence.

Hypothesis 2a: Patient perception of trust increases treatment adherence.

Hypothesis 2b: Patient PNEA mediates the relationship between trust and treatment adherence.

Hypothesis 3a: Patient perception of information exchange increases treatment adherence.

Hypothesis 3b: Patient PNEA mediates the relationship between information exchange and treatment adherence.

Hypothesis 4a: Patient perception of rapport increases treatment adherence.

Hypothesis 4b: Patient PNEA mediates the relationship between rapport and treatment adherence.

Hypothesis 5a: Patient perception of shared decision-making increases treatment adherence.

Hypothesis 5b: Patient PNEA mediates the relationship between shared decision-making and treatment adherence.

Hypothesis 6: Patient PNEA mediates the relationship between physician PNEA and treatment adherence.

Hypothesis 7a: Co-morbid depression in the patient decreases treatment adherence.

Hypothesis 7b: Patient PNEA mediates the relationship between co-morbid depression and treatment adherence.

Hypothesis 8a: Patient perception of social support increases treatment adherence.

Hypothesis 8b: Patient PNEA mediates the relationship between social support and treatment adherence.

Hypothesis 9a: Patient knowledge of the disease increases treatment adherence.

Hypothesis 9b: Patient PNEA mediates the relationship between knowledge of the disease and treatment adherence.

Treatment Adherence Framework

The crucial factor in adequate health care and in the treatment of chronic illnesses, such as type 2 diabetes, is patient self-management. The physician prescribes treatment medication and gives advice regarding health behavior, such as diet and exercise. However, treatment adherence by the patient, or lack thereof, occurs outside the healthcare provider setting, e.g. at home, and is thus beyond the physician's control. The primary responsibility of adhering with doctor's prescription lies with the patient.

A patient's non-compliant behavior could be a reaction to the physicians' inability to situate the illness within the patient's larger context. This includes patients' hopes and aspirations for life and the current social situation. Non-adherence could also be a negative reaction against the authoritative and patronizing style of the physician's biomedical approach to medicine that fails to integrate the patient in a collaborative therapeutic process.

The present study looks at the key variables that were consistently found across reviews to predict compliance. For the most part, the quality of doctor-patient interactive relationship can determine whether Positive Emotional Attractor would be evoked in the patient, which may then lead to treatment adherence. Figure 2 below, presents the conceptual model for the study. The figure illustrates some of the elements of patient-centered communication involved in the doctor-patient interactive relationship as perceived by the patient, the patient's knowledge of diabetes, the patient's available social support, co-morbid depression in the patient and the PEA/NEA of the physician as the independent variables, and treatment adherence as the dependent variable.

I expect the PEA/NEA of the physician to only indirectly affect treatment adherence through the mediator variable of patient PEA/NEA. This is so, because it is really the patient who is the ultimate determinant of adherence, as it is the patient who finally takes action to ingest the prescribed medications, make dietary modification or follow the exercise regimen. For example, since the patient takes medication while at home or at work, where no interaction with the physician takes place, it is really the patient's PEA/NEA which influences the patient's decision to take the medication or not. The doctor's PEA/NEA cannot possibly directly affect treatment adherence of the patient. The doctor's PEA/NEA will, however, affect the formation of the patient's overall PEA/NEA and thereby indirectly affect treatment adherence.

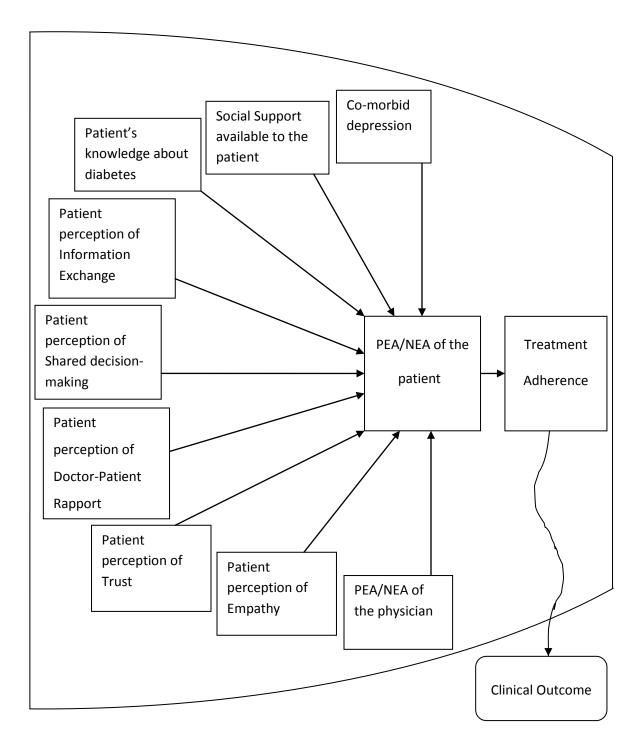


Figure 2. Conceptual model

Sample Size

Before embarking on data collection, probable sample size needs to be ascertained. According to Singh (2009), power analysis plays an important role in research design for determining sample size. Based on the variables included in this study, a power analysis was conducted. In order to have sufficient power with an anticipated medium effect size of 0.3 (Cohen, 1992) at an alpha of 0.05, about 250 participants were desired for this study. However, this study had a multilevel structure and required two levels of sample sizes. Unfortunately, according to researchers, sample size estimation for multilevel (hierarchical linear models) models generally cannot be determined with precision (Boyle & Willms, 2001). Different adequate sample size estimates, as rules of thumb have been suggested by investigators. Recently researchers of multi-level model have discussed a rule of thumb of 15 level-2 groups with at least 15 level-1 nested observations, as the minimum sample size for Hierarchical linear modeling (HLM) studies (Huang & Lu, 2007). This study had a sample of 25 level-2 groups with 15 level-1 nested observations (a total of 375 levellobservations). Thus, the sample of 375 patients and their companions, nested in 25 physicians was adequate in this case.

Study Setting and Participants

This study was conducted in Karachi, Pakistan. Surveys were administered in seven diabetic centers in the urban and suburban areas of Karachi across diverse socio-economic localities. The centers included hospital settings and private clinics. All surveys were administered in the outpatient departments. The approval of the Institutional Review Board at Case Western Reserve University was obtained before starting the data collection process.

Participants in this study were adult patients in diabetic consultation facilities, and their adult household companions who had come to the facility with them. Physicians who interviewed these patients were also surveyed. If the patient was not accompanied by an adult household companion, then such a person was not recruited for the study.

A convenience sample of 375 patients along with their companions, and 25 physicians who interviewed them, were surveyed. 15 patients per physician were solicited. Convenience sampling method was chosen because it is easier and relatively time efficient as compared to random sampling.

Permission from the consultant physician for the study was taken several weeks prior to the start of the research study. However, on the day of the consultation session, the concerned physician was again approached by the researcher before the start of the clinic session and verbally asked for permission. The physician was handed the information sheet (appendix-xv) which provided details about the study. If there was consent to participate, then the physician was requested to complete the physician survey form (appendix-xii). The physicians filled out the survey forms in one of the clinic rooms when they were alone. This survey took about 2-3 minutes to complete. Each physician filled out this survey only once and returned it to the researcher.

Next, as the patients went into the examination rooms, the researcher approached them with the information sheet for the patient. The patient was asked initial screening questions about type 2 diabetes status, the number of follow-ups they had with the doctor (<10 visits), and if there was an accompanying household adult. Qualifying patients were requested to read the information sheet (appendix-xiv), so that they may participate in the study. Participating patients were handed the patient survey form (appendix-xi). While the patient filled out the survey form in the examination room, the researcher remained outside the room to be available to the patient in case any clarification was required about the survey. Upon completion of the surveys, they were returned to the investigator by the patient. Similarly, the patient's companion, if an adult and living in the same household, was solicited to fill out a separate survey. An information sheet (appendix-xiii) was provided to the patient companion (attendant). Participating patient companions were given the patient attendant survey form (appendix-x), which was completed and returned. The investigator did not hover around the respondents while the survey was being completed, but remained available at a distance to respond to any query.

Generally, the waiting times in the consultant physician's examination room in Karachi, Pakistan, were very long. This is because of huge patient load in consultant physicians' offices. Therefore, the patients usually had sufficient time to fill the survey while they were waiting for the examination by the physician. In case of the companion, it did not take them more than 1-2 minutes to fill out the short survey. The survey forms were collected by the researcher as soon as they were completed by the participants.

Measures

Only well-validated scales (appendices i to ix) were used in the survey. These scales have been previously used extensively in research studies. The different scales used

are mentioned below. Also, a repeat of the model figure with the scale developer's name along with each variable is presented at the end of this section.

Information Exchange: Hausman's (2001) measure was used to assess the perception of information exchange by the patient, in the doctor-patient interaction. The scale consists of 5 items (appendix i), and has been shown to possess good psychometric properties in previous studies. In a study conducted on 239 patients, the Cronbach's alpha for the scale was reported as 0.80 (Hausman, 2001).

Rapport: Gremler and Gwinner's (2000) measure of rapport was used which consists of 5 items (appendix iii). The notion of rapport is based on the patient's perception of affiliation with the doctor in the dyadic relationship. In a study involving 484 dental patients, the scale was found to have good internal consistency (α =0.93) (Gremler & Gwinner, 2000).

Diabetes Knowledge: The 8-item diabetes knowledge questionnaire (appendix vii), was adapted from the instrument developed by Garcia, Villagomez, Brown, Kouzekanani, and Hanis (2001). The instrument was developed by Garcia et al. (2001) following a 4 year longitudinal study of 502 type 2 diabetic and non-diabetic individuals. The instrument was found to be a reliable measure of diabetes knowledge, with an internal consistency of 0.78 (Garcia et al., 2001).

Shared Decision-making: Hausman's (2001) measure was used to assess the patient's perception of shared decision-making, in the doctor-patient interaction. The scale consists of 5 items (appendix ii). In a study by Hausman (2001) conducted on 239 patients, the Cronbach's alpha for the scale was reported as 0.87.

Trust: The Trust scale (appendix iv), was adapted from the compassion scale developed by Boyatzis (2008). It measures patient's perceived trust of the doctor, in the dyadic

relationship. In a study involving 231 individuals, the 6-item scale was found to have good internal consistency (α =0.85) (Mahon, 2009).

Social Support: A social support scale (appendix viii), developed by Dalgard (1996) was used. It measures the extent of perceived availability of social support to the patient. This can be a protective factor during stressful times, such as ill-health. A Cronbach's alpha of 0.60 has been reported for the 3-item social support scale (Dalgard, 1996).

Empathy: Boyatzis & Goleman's (2007) measure from the Emotional and Social Competency Inventory (ESCI), was used to assess empathy. Empathy encompasses the ability to perceive the feelings and perspectives of others, as well as taking active interest in their concerns (Boyatzis, 2007). The scale consists of 6 items (appendix v), and has been shown to possess good psychometric properties in previous studies. In a study of the Emotional and Social Competency Inventory (ESCI), involving 5638 managers, executives and professionals in private and government sectors across several countries, the empathy scale was reported to have a Cronbach's alpha of 0.70 (Boyatzis, 2009).

PNEA: The PNEA (Positive and Negative Emotional Attractor) measure (appendix vi), was adapted from the instrument developed by Boyatzis' (2008). The measure which was used consists of 13 items and assesses the dimensions of vision and overall mood. The 7-item PNEA-vision subscale assesses the respondent's focus and alignment with the healthy future of the patient (Clayton, 2009). The 6-item PNEA-overall mood subscale assesses the global disposition of the respondent. Internal consistency of 0.91 was reported for both the PNEA-vision subscale and for the PNEA-overall mood subscale by Mohan (2009) in a study involving 231 subjects.

Treatment Adherence: The 6-item treatment adherence scale (appendix ix), was adapted from the measure formed by Morisky, Green, and Levine (1986). The scale was developed following an 18-month longitudinal study of 400 hypertensive patients in two outpatient clinics, of a large American teaching hospital. According to Morisky, Green, and Levine (1986), the measure is designed to "facilitate the identification and addressing of problems and barriers to adequate compliance" (p. 72). The scale was found to be a reliable measure of adherence, with an internal consistency of 0.61 (Morisky, Green, & Levine, 1986).

The patients' survey form included items related to the following scales: Rapport, Diabetes knowledge, Information exchange, Shared decision-making, Trust, Empathy, PNEA and Social support. The patient's companion survey form included items related to Treatment adherence scale. The physicians' survey form included items related to the PNEA scale. Certain factors are more trait-like (Lilly styles) while there are others which are more state-like. A physician was surveyed only once, as I believe that a physician's PEA/NEA state is more trait-like; a view that finds support from several studies (Nelson, 1978; Evans, 1992; Halpern, 2001; Greenburg, 2009). Thus, a physician's PNEA is stylistic, and does not vary by patient. Therefore, since there were 15 patients nested in each physician, it was appropriate to conduct one survey of the physician trait-like PNEA state which holds good for the 15 nested patients.

The self-reported Morisky scale assessed patients' adherence history. One might argue the advantages of assessing a direct physiological measure of treatment compliance in type 2 diabetes patients, such as a physiological measurement of HBA1c and other serum assays to identify average plasma glucose concentration or by monitoring the medication bottle caps which are opened. However, such methods are not only more expensive to measure but also have their limitations such as the requirement of a high level of expertise and technical sophistication (Liu et al., 2006), which was beyond the scale/scope of this study. For example, Medication Event Monitoring System (MEMS) caps have their own limitations because the number of cap openings may not necessarily reflect the number of pills ingested by the patient (Whooley et al., 2008). In any case, while these direct measures might be possible in developed countries, it must be considered that in underdeveloped countries like Pakistan, some follow-up diabetic patients do not even get simple random and fasting blood sugar levels assessed on time. The reasons include cost of laboratory testing involved, laboratory facilities not being available in the local area, or the lack of transportation. These limitations were deemed to especially hold true in this study, since it was multi-center in nature and surveyed diabetics of varying socio-economic status. Adherence measured by the Morisky scale is the most commonly used subjective compliance measure (Liu et al., 2001). In a number of studies, this scale has been validated as a reliable predictor of health outcomes (Whooley et al., 2008). The Morisky scale has been used across many chronic diseases, including diabetes, and has demonstrated good reliability and predictive validity (Day et al., 2005; Mann, Ponieman, Leventhal, & Halm, 2009). However, self-reports by patients have been criticized in general for over-estimating adherence (Osterberg & Blaschke, 2005). The patients therefore did not fill out the Morisky instrument. Physicians in many studies have also been shown to consistently overestimate their patients' adherence, usually more than the patients themselves (Crepo-Fierro, 1997; Dimatteo, 2004; Gianola, 2007; Leuppi et al., 2006), and so they too were not asked to give information about patient's adherence. In any case, this would have been a report of a self-report from the patient, and would not have served much purpose. In this

study, the patient's companion, who was living in the same household as the patient, reported on the patient's treatment adherence. This was expected to be a relatively unbiased subjective assessment of patient's treatment adherence.

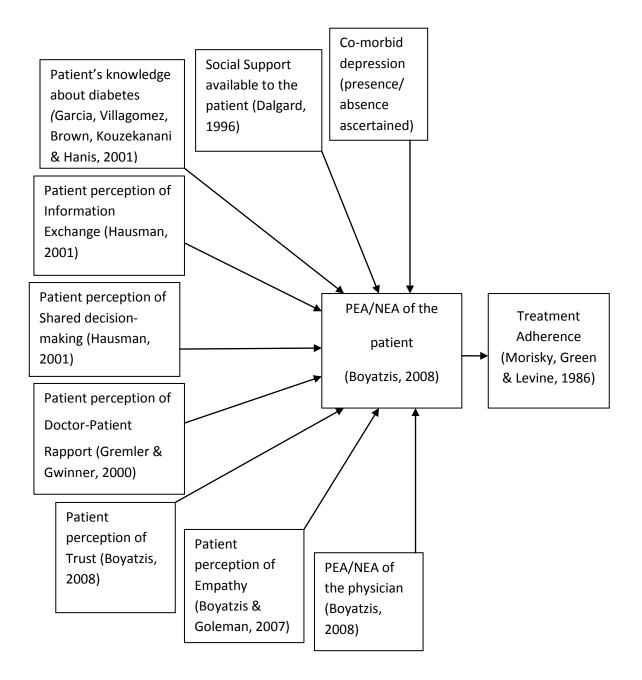


Figure 3. Conceptual model with scales delineated

Data Analysis

This section primarily consists of two parts. The first part presents description of the data analytic procedures for Exploratory and Confirmatory Factor Analysis, and the second part presents details about Mediation analysis.

Analyses were performed using the software packages of Statistical Package for the Social Sciences (SPSS) for Windows version 15.0, AMOS version 17.0 and HLM version 6.0. Unless otherwise noted, an alpha level of .05 was used in all analyses.

Description of Analytical Methods

Exploratory Factor Analysis

Exploratory Factor Analysis (EFA) was conducted using SPSS, to assess the factor structures of different scales used. Although, only well validated measures were used in this study, some of these instruments, such as the PNEA scale, had never been used in research outside of the United States. Scales used in different populations and cultures can show varying psychometric properties. Thus, Exploratory Factor Analysis provided a good opportunity to evaluate the item integrity and factor structure, in a population foreign to the United States.

Exploratory Factor Analysis is the best known statistical procedure for investigating relations between latent and observed variables (Byrne, 2010), and identifying the minimal number of factors (Byrne, 2010). Before conducting the analysis, it should be ascertained whether assumptions for the analysis are met. Hair, Anderson, Tatham, and Black (1998) argue that the important assumptions of factor analysis are both statistical and conceptual

in nature. At the very minimum, an underlying structure must be assumed to exist amongst the selected variables. This assumption was easily met since the surveys used only those scales which were well-validated and rooted in theory and research. Prior to submitting the indicators to a factor analysis, it should also meet the assumption of a reflector model (Kercher, 2005). A reflector model is one in which the items are the outcome, effect or consequence of the underlying latent construct (Kercher, 2005). The indicators of the constructs used in this study, met the assumption of a reflector model. Furthermore, one may check for the following before running EFA (1) variability of the variables, (2) sample distribution, (3) miscoding, (4) missing data, (5) sample size, (6) Bartlett's test of sphericity, (7) and the Kaiser-Meyer-Olkin (KMO) measure of Sampling Adequacy. The KMO provides an index for comparing the magnitude of the observed correlation coefficients to the magnitude of the partial correlation coefficients. It produces an index on a range from zero to one. Higher values for the KMO statistic indicate that the data is well suited for factor analysis, whereas smaller values indicate that the data may not be appropriate. Hair et al., (1998) has provided the following calibration to describe the interpretation of the KMO index in terms of the appropriateness for factor analysis: 0.80 or above=meritorious, 0.70-0.79=middling, 0.60-0.69=mediocre, 0.50-059=miserable, below 0.50=unacceptable.

The other measure to assess suitability of data for factor analysis is the Bartlett's Test of Sphericity which produces a chi-square statistic, testing the null hypothesis that the population correlation matrix is an identity matrix. An identity matrix is a matrix where all diagonal terms are 1.0 and all off-diagonal terms are zero (Stevens, 1996).

H₀: Correlation matrix = Identity matrix

H₁: Correlation matrix \neq Identity matrix

When the significance is <.05, one can reject the null hypothesis and conclude that there are correlations that can be factor analyzed. Results of these tests can be found in Chapter 4.

Upon meeting the assumptions that guide factor analysis, the method of extracting the factors and the number of factors selected to represent the underlying structure were determined. There are two basic models utilized to obtain factor solutions: Principal Components Analysis and Principal Axis Factoring. Principal Axis Factoring, seeks to extract the least number of factors necessary to account for a significant portion of the common variance of a set of variables. This analysis is preferred by many statisticians over principal component analysis because the factor solution it computes is uncontaminated by error variance and unique variance (Tabachnick & Fidell, 2001). It is used when the factor structure is set up as a reflector model (Kercher, 2005). For the study data, Principal Axis Factoring was used as the primary method of extraction. The factors were rotated using an oblique rotation method called Direct Oblimin. Oblique rotation is employed when correlation amongst factors is assumed (Tabachnick & Fidell, 2001), as was the case in this study.

Since this study used only well-validated scales, we already had a prior idea of the probable number of factors in an instrument. Additional information was taken from the Scree test, which helped identify the optimum number of factors that could be extracted (Hair et al., 1998). This was done by plotting the number of factors against the latent roots (generated by SPSS) and retaining all factors up to where the curve begins to level off,

which is referred to as the elbow, and then forms a straight line with an almost horizontal slope.

Since EFA is concerned with the extent to which the observed variables are generated by the underlying latent constructs, the strength of the paths from the factors to the observed variables, also called the factor loadings, is of interest (Gliem, 2003). The selections of the final factor solution were primarily based upon the size of the factor loadings. There is no agreement amongst scholars as to the acceptable factor loadings. Some investigators consider 0.6 (Nunnally, 1978) as the lower limit, whereas there are others who deem 0.4 as the minimum acceptable (Lu, 2006). A liberal boundary of 0.4 was chosen for this study. Also, any secondary factor loading of more than 0.3 was closely examined.

Reliability for each of the factors was measured by Standardized alpha, which is Cronbach's alpha based on standardized items. This is a widely used form of determining the internal consistency of a scale (Vogt, 1999). This statistical procedure is dependent on the number of items included in the instrument, consistent variance across items, and the mean inter-item correlation (Miller, 2003). Alpha coefficients range from 0 to 1.0 and Vogt (1999) maintains that a score above 0.7 suggests that the instrument is reliable. Reliability analysis in SPSS also assessed whether the reliability of a given scale may increase by dropping any of the items. However, a strong theoretical ground was also deemed necessary to justify dropping an item, regardless of the reliability results.

Confirmatory Factor Analysis

Confirmatory Factor Analysis (CFA) was conducted to substantiate the results of the Exploratory Factor Analysis (EFA). CFA determines if the relationships between the variables in the hypothesized model are similar to the relationships in the observed data. Since the CFA model links the underlying factors with their measured indictors, it is also termed as the measurement model (Byrne, 1998). The current study used AMOS 17.0 software to conduct CFA.

The CFA yields several different statistics for determining how well the hypothesized model fits the data. However there is a lack of consensus in determining the best tests to assess the fit of the models (Van Laaar, Edwards, & Easton, 2007). Therefore a combination of multiple tests is recommended to assess model fit (Hu & Bentler, 1999). These statistics are referred to as goodness-of-fit statistics. According to Burant (2008), some of the commonly used fit statistics include chi-square goodness of fit, Comparative Fit Index (CFI), Tucker-Lewis Index (TLI) and the Root Mean Square Error of Approximation (RMSEA).

Although chi-square is the classic goodness-of-fit index and is routinely reported in CFA, it is considered by many researchers to be an unreliable test (Brown, 2006). Chi-square tests the hypothesis that the pattern of covariance among the observed variables, the observed covariance matrix, is not significantly different from the pattern of covariance among the variables that result from the parameter estimate produced by the CFA based on the hypothesized model, the reproduced correlation matrix (Stevens, 2001). Low scores and non-significant p-values of chi-square statistic represent that the model is not different from the data (Burant, 2008).

The values of CFI (Comparative Fit Index) and TLI (Tucker-Lewis Index) indicate the proportion of the improvement of the fit of the hypothesized model relative to a null model (Kalichman et al., 2002). Thus a CFI or TLI of 0.80 indicates that the relative overall fit of the model is 80% better than that of the null model of the data. Hu and Bentler (1999) propose that CFI and TLI values greater than 0.90 indicate reasonably good fit of the proposed model to the data.

The Root Mean Square Error of Approximation (RMSEA) is also an indicator of model fit. RMSEA takes into account the parsimony of a model in relation to the degrees of freedom (Taylor & Todd, 1995). According to some researchers, for appropriate fit the RMSEA score should be less than 0.08 (Burant, 2008; Hu & Bentler, 1999). However, other investigators suggest a more liberal cutoff of 0.10 (Brown & Cudeck, 1993; Meyers, Gamst, & Guarino, 2006). Brown and Cudeck (1993) have proposed the following criteria for interpreting the RMSEA values: less than 0.05=close fit, between 0.05 and 0.08=reasonable fit, between 0.08 and 0.10=mediocre fit, and greater than 0.10=poor fit.

Baron and Kenny Mediation Analysis

Baron and Kenny Mediation analysis was conducted using multilevel modeling software (HLM 6.0). The analytical approach to Baron and Kenny's mediation analysis using HLM applied in this study is similar to that used by some other investigators (Lynne, 2008).

A variable is called a mediator if it can account for the relation between the predictor and the criterion variable (Baron & Kenny, 1986). Mediation analysis examines how a variable mediates the effect of predictors on outcome variables. Thus, a mediational structure represents a specific conception of the method through which a predictor variable might affect a criterion variable, not directly, but rather through an indirect route, captured by the mediator variable (Iacobucci, 2008). Thus, in a structure such as

$$X \longrightarrow M \longrightarrow Y$$

the X variable helps predict the Mediator M, which in turn helps predict the variable Y. Researchers usually make causal statements when testing mediational relationships, and indicate that temporally the predictor, the mediator and then the outcome variable occur in a causal pathway; however, some investigators suggest that it is better to avoid causal inferences (Iacobucci, 2008). Thus, in the above structure it may be better to suggest that X variable affects the Mediator M, which in turn affects the variable Y.

Classical Baron and Kenny Method (1986)

Early work on mediation was done by Baron and Kenny. In their paper published in 1986, they proposed the steps to establish mediation. According to Baron and Kenny (1986), the following four steps should be assessed:

Step 1: Regressing the Dependent variable (Y) on the Independent variable (X) to show that the Independent variable is correlated with the dependent variable (estimating path c in Figure 4). This is referred to as the Total effect (and by some investigators as Direct effect).

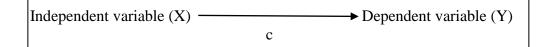


Figure 4. Baron and Kenny: Total effect

Step 2: Regressing the Mediator (M) on the Independent variable (X) to show that the Independent variable (X) is correlated with the Mediator (M) (estimating path a in Figure 5). This step essentially involves treating the mediator as if it were an outcome variable.

Step 3: Steps 3 and 4 are estimated in the same regression equation. Step 3 involves regressing the Dependent variable (Y) on both the Independent variable (X) and on the Mediator (M), to show that the Mediator (M) and the Dependent variable are correlated (estimating path b in Figure 5). The Independent variable (X) is controlled in establishing this effect of the Mediator (M) on the Dependent variable (Y).

Step 4: To show that the Independent variable (X) relates to the Dependent variable (Y) indirectly through the Mediator variable (M). Step 4 attempts to establish a change (c'<c)

in the relationship between the Independent variable (X) and the Dependent (Y) variable (estimate path c' in Figure 5). Path c' denotes Direct Effect. The reduction in relationship may be such that the relationship is no longer significant (complete mediation) or significant (partial mediation).

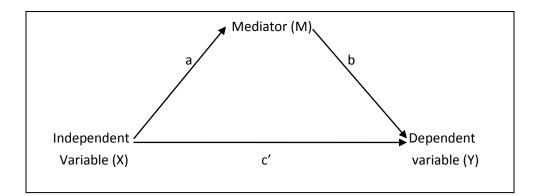


Figure 5. Baron and Kenny: Mediation model

Modified Baron and Kenny Method (1998)

The four steps of Baron and Kenny (1986) mediation analysis have received considerable criticism from researchers. Many investigators (Collins, Graham, & Flaherty, 1998; Shrout & Bolger, 2002) argue that Step 1 is not required since the initial correlation between the Independent Variable (X) and Dependent Variable (Y) is not essential. This argument was subsequently also accepted by Kenny (Kenny, Kashy, & Bolger, 1998), who was one of the two original authors of the mediation analysis method. Kenny accordingly updated the steps of the mediation model (Kenny, Kashy, & Bolger, 1998). Kenny, Kashy, and Bolger (1998) clearly state that, "Step 1 is not required, but a path from the initial variable to the outcome variable is implied if Steps 2 and 3 are met" (p. 260). Thus, they

accepted that the original Baron and Kenny's steps can be modified, which we refer to in this study as the Modified Baron and Kenny method (1998). Accordingly, based on Kenny, Kashy, and Bolger (1988), the Modified Baron and Kenny mediation analysis method is: Stage 1: If a significant relationships exist between the Independent variable (X) and the Mediator (M) (path a assessed in original Step 2); and also between the Mediator (M) and the Dependent variable (Y) while controlling for the Independent variable (X) (path b assessed in original Step 3); then this would imply that a relationship exists between the Independent variable (X) and the Dependent variable (Y) (Kenny, Kashy, and Bolger, 1998).

Stage 2: If stage 1 is met, then one could proceed to assess if this relationship is partially or totally mediated. According to Kenny, Kashy, & Bolger (1998, p. 260), "If Step 2 (the test of a) and Step 3 (the test of b) are met, it follows that there necessarily is a reduction in the effect of X (independent variable) on Y (dependent variable)". In such a case, partial mediation would occur if the Independent variable (X) relates to the Dependent variable (Y), indirectly through the Mediator (M), such that the relationship is significant (Kenny, Kashy, & Bolger, 1998; Ekas, 2009). However, complete mediation would occur if the Independent variable (Y), indirectly through the Mediator to the Dependent variable (Y), indirectly through the Mediator (M), such that the relationship is significant (Kenny, Kashy, & Bolger, 1998; Ekas, 2009). However, complete mediation would occur if the Independent variable (Y), indirectly through the Mediator (M), such that the relationship (Y), indirectly through the Mediator (M) is insignificant (Kenny, Kashy, & Bolger, 1998).

In practice this modified mediation analysis technique in which Step 1 of the Baron and Kenny (1986) method is omitted in estimating the mediation model is being used by many scholars (e.g., Schneider, Ehrhart, Mayer, Saltz, & Niles-Jolly, 2005; Yang, 2008).

In this dissertation study also the above explained Modified Baron and Kenny method was used for mediation analysis using HLM 6.0 software.

Bootstrap Procedure

A number of researchers also recommend an additional step in mediation analysis. That is to test the significance of the mediated or indirect effect. This is usually done by procedures such as the Sobel test or Bootstrapping method (Shrout & Bolger, 2002). Sobel test is used in linear modeling procedures, but it is considered inappropriate for use in multilevel models (Zhao, Lynch, & Chen, 2010). The other alternative is the Bootstrapping procedure (Shrout & Bolger, 2002). Basically, Bootstrapping involves repeated random sampling of observations with replacement from the data set, while the statistic of interest is computed in each resample (Shrout & Bolger, 2002). This procedure calculates the Bootstrap estimate, standard error, and 95% confidence intervals (CI). If zero is not located between the upper and lower limits of the confidence interval, then the result is considered significant. Although the Bootstrapping was used in the data analysis, one needs to be cautious about its results, since according to some investigators, its validity in multilevel models is not well established (Hox, 2002).

Mixed Models or Multi-level Modeling

Life imposes on individuals to be embedded within groups such as communities, socio-economic status etc. Similarly, in outpatient healthcare settings, a hierarchical structure exists such that patients are nested within physicians.

In this study population, 15 patients belong to each of the 25 physicians. It is reasonable to assume that the characteristics of a population of patients belonging to a specific physician differ from those of the population of patients related to another physician. These differences can, for instance, stem from the locale in which the physician is practicing, personality characteristics of the physician, etc. In a multilevel structure, it is therefore said that the observations that are made by the patients are clustered within the physician (Figure 6, adapted from Twisk, 2006), and such observations within a physician are correlated.

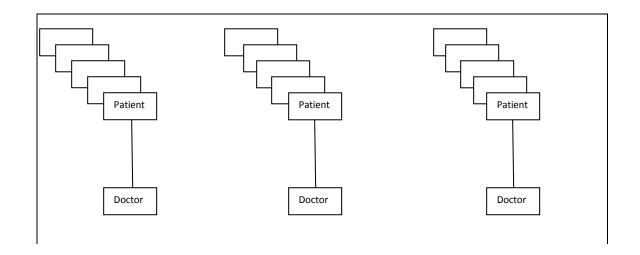


Figure 6. Nested model

Owing to such a clustering in this study, it can be assumed that there is a two level structure of the data; the observation of the patients is the lower level while the physician is the higher level. Due to the fact that lower and higher levels exist within the data, Multilevel Modeling is also referred to as Hierarchical Linear Modeling.

In the realm of the doctor-patient relationship, researchers have previously analyzed data by using linear regression either at the patient level or at the physician level, neither of which is appropriate (Twisk, 2006). Before multilevel analysis was developed, the observations in nested data were tackled primarily in two ways: by ignoring the fact that

the observations are correlated or by combining the correlated observations into one value. Both these incorrect methods are still frequently used. In the latter, simple aggregation of individual data can eliminate much of the individual variability on the outcome variables, which can lead to incorrect estimation of the observed relationships between variables (Twisk, 2006). The alternative method used is to ignore that the observations are correlated. By doing so, traditional Ordinary Least Squares (OLS) analysis, which does not take into account the interdependence of individual-level observations nested within higher-level structure, produces estimates of standard errors that are biased (overestimated), and test statistics may not be valid (underestimated).

Assumptions of Multilevel Analysis

Since multilevel analysis is an extension of standard linear regression analysis, some of the assumptions for standard linear regression analysis also hold for multilevel analysis (Twisk, 2006). These include that the continuous outcome variable should be approximately normally distributed. Also, for multilevel analysis, variables should be reasonably correlated. Before conducting HLM analysis for this study, the assumptions had already been tested as part of Exploratory Factor Analysis (EFA).

Intra-class Correlation

The standard measure employed to assess group effects is the Intra-class Correlation (ICC) (Julian, 2001). The Intra-class Correlation can be viewed as the amount of variance in the individuals' scores that is due to the group. For this study, it can be conceptualized as an indication of the correlation of the observation of patients who belong to the same physician. Thus, it gives the inter-dependence of patient observations within the physician. In this study, we initially analyzed a fully unconditional model, in which neither the patient-related variables nor physician-related variables were specified. This first step can indicate whether the study needs an HLM or whether a single-level analytic method is appropriate. Only when the value of ICC is more than trivial (i.e., generally greater than 5% of the total variance in the outcome) does the investigator need to consider multilevel methods (Johnsrud & Rosser, 2002). In this study, it was found that a substantial proportion of the total variance in treatment adherence was within physicians (discussed in result section), thus confirming that HLM was the right analytic strategy to use.

2-1-1 Model

For HLM analysis, the patients' perception of information exchange, trust, empathy, rapport, shared decision-making, and social support, along with their knowledge of diabetes, co-morbid depression, PEA/NEA state and the treatment adherence were specified as level 1 variables, while physician was specified as a level 2 variable. Such a multilevel model, in which there are independent variables at both levels, but the mediator and the outcome variable are at lower levels, has also been termed Cross-level mediation (Mathieu & Taylor, 2007), and a 2-1-1 model (Bauer, Preacher, & Gill, 2006). In such a 2-1-1 model structure, the influence of both upper and lower level predictors, on lower level outcome, is mediated by lower level mediator (Figure 7).

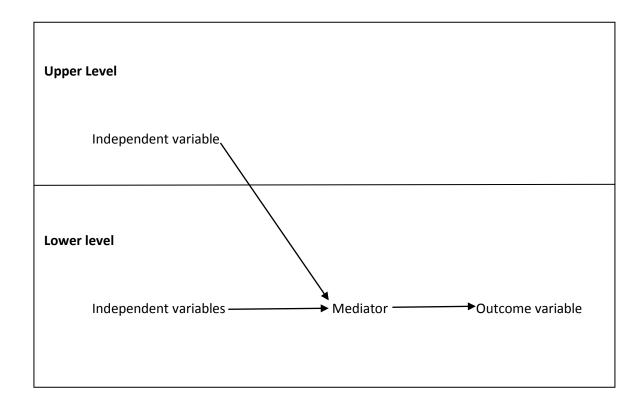


Figure 7. Cross level mediation: 2-1-1 model

In a multi-level model, variables can be fixed or random (Raudenbush & Byrk, 2002). In Hierarchical Linear Modeling, the fixed effect coefficient is the same as the regression coefficient itself. This Fixed effect of a variable is the average effect of the entire population, which is the same across individuals (Raudenbush & Byrk, 2002) and is expressed by the regression coefficient. A multi-level model always has fixed effect analysis of all explanatory variables under consideration (Snijders, 2005). A variable may also be random, meaning that the relationship is different for the individuals in the study (Snijders, 2005). Thus, random variables in multilevel modeling can be conceptualized as a source of variability (Luke, 2004).

The HLM model allows the regression intercepts and slopes to vary across levels (Luke, 2004), as illustrated in Figure 8. Such a model is also known as Random-interceptsand-slopes model and assumes that the explanatory variables for each individual can have a unique intercept or slope (Nguti et al., 2005).

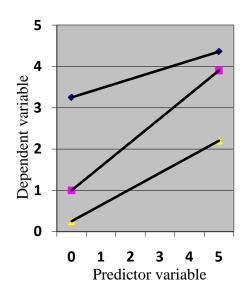


Figure 8. Varying intercepts and slopes

Hofmann and Gavin (1998) recommend that level-1 predictors and level-2 predictors should always be grand-mean-centered, as it has been empirically shown to reduce potential problems in the predictors, such as multicollinearity. In practice, many researchers always grand-mean-center the predictors when using HLM. Following the recommendation of Hoffmann and Gavin (1998), the predictors were accordingly grand-mean-centered for HLM analysis. The HLM software helps to automatically grand-mean-center the variables.

CHAPTER IV: RESULTS

This chapter firstly provides a summary of the demographic sample statistics, followed by two sections of findings concerning Factor analysis and Mediation analysis. The first section explores and confirms the latent constructs in the instruments through SPSS. The second section presents the finding of Modified Baron and Kenny mediation analysis using a Mixed models software (HLM 6.0). The statistical analysis for this study was run in conjunction with Dr. Chris Burant, faculty member and statistical expert, at Case Western Reserve University.

Some data entry errors were found on examination of the raw data. These were removed before running the analysis. Since the initial coding of some of the variables were such that higher scores represented lower values, therefore, firstly, these variables were reverse coded so that higher scores represented higher values. Thus all the study variables were in the same direction.

Sample Demographic Statistics

The data collection for this study took place between December 2009 and March 2010. A total of 375 patients, and their companions, who had come for clinic visit were surveyed, along with their 25 physician consultants. Sample descriptive statistics were analyzed using the Statistical Package for the Social Sciences (SPSS) version 15.0. The mean, standard deviation, minimum value and maximum value for the age and sex of the patient, physician and patient companion, patient household income, number of adults in

the patient household, presence of co-morbid depression and number of previous doctor visits were analyzed. Table 2 presents these descriptive statistics.

Demographic variable	N	Mean	SD	Min. or %	Max. or %
Age			I	I	
Patient	374	54.94	10.45	19	78
Physician	25	44.24	12.37	27	76
Patient companion	355	38.61	15.28	16	80
Gender		I	I	I	<u> </u>
Patient	371			54% (M)	46% (F)
Physician	25			76% (M)	24% (F)
Patient companion	355			49% (M)	51% (F)
Co-morbid depression	343	0.24	0.42	24% (Yes)	76% (No)
Household Income (Rupees)	367	5.57	2.39	1	10
Adults in household	372	7.06	3.47	1	19
Previous doctor visits	367	3.20	1.6	1	8

Table 2. Demographic sample statistics

Household Income (in Rupees): 1=<5K,2=5-9.9K,3=10-14.9K,4=15-19.9K,5=20-24.9K,6=25-29.9K, =30-39.9K,8=40-59.9K,9=60-79.9K,10=80K+

The patient respondents (N=371) ranged in age from 19 to 78 years, with an average age for the sample of about 55 years (SD = 10.45). Men formed the majority of the patient sample (54%). A dichotomous response item (yes, no) asked whether the patient had diagnosed co-morbid depression along with diabetes. 24% of the diabetic patients in the study reported that they had co-morbid depression. A ten level (1-10) scale was used to assess the monthly household income of the patients in Pakistan Rupees (1=<5K, 2=5-

9.9K, 3=10-14.9K, 4=15-19.9K, 5=20-24.9K, 6=25-29.9K, 7=30-39.9K, 8=40-59.9K, 9=60-79.9K, 10=80K+). The mean household monthly income was about Rupees 22500 (US \$262 approx). Patients in this study had an average of approximately 7 adult members living in their household. All the patients who were surveyed were on follow-up visits and most of them had been to the physician more than thrice. The physician respondents (N=25) ranged in age from 27 to 76 years, with an average age for the sample of about 44 years (SD = 12.37). Men formed the majority of the physician sample (54%). The ages of the patients' companions ranged from 16 to 80 years (N=355, M=38.61, SD=15.28) and the majority of them were female (51%).

Factor Analysis

There were three types of respondents in this study, i.e., patients, physicians and patients' companions. Factor analysis was performed on the instrument used by respondent groups. Participants had the option to omit responding to the items in the survey, and not all of the participants chose to answer every item of the demographic profile or the questionnaire. About ten percent of observations were missing from the survey data. The omitted responses were missing randomly. Missing data were not an issue for this study since the main statistical package used in the analysis, HLM 6.0, can easily handle missing data and has the ability to automatically use maximum data (West, Welch, & Galecki, 2006). When missing data are present, robust but complicated procedures, such as Maximum likelihood (used in AMOS software for Confirmatory Factor Analysis) and Direct maximum likelihood techniques can be used. Easier methods are that of listwise and pairwise deletion, and also of mean imputation (Allison, 2009). A number of researchers

consider listwise deletion to be a good option (Kercher, 2005). However, for Exploratory Factor Analysis using SPSS, listwise deletion was not applied, since by eliminating whole cases, it can cause further loss of data (Allison, 2009). Conversely, by using pairwise deletion, the maximum amount of available data is retained for analysis (Pigott, 2001). According to several investigators though, pairwise deletion may sometimes produce bias, especially when the sample size is small (Gallagher, Ting, & Palmer, 2008). Pairwise deletion method has however been used to conduct Exploratory Factor Analysis (EFA) in many recently published studies (e.g. Gregory, 2010; Schulte, Mongrain, & Flora, 2008; Lin, Anderson, Chang, Hagerty, & Loveland-Cherry, 2008). The EFA results of this study, when using pairwise deletion, were found to be comparable to those when using mean imputation (Field, 2006), but not with those of listwise deletion. Furthermore, the results of the EFA obtained through pairwise deletion were generally in accordance with the established factor structures of the validated scales which were being used in this research.

Exploratory Factor Analysis of Patient Instrument

Preliminary Procedures

Firstly, univariate statistics were analyzed to insure that the data was not miscoded, variables had reasonable sample size, the variables varied, and that they were normally distributed. To examine these, the mean, standard deviation, skewness, kurtosis, minimum and maximum values for each variable were evaluated. These descriptive statistics are presented in Table 3. With a Likert scale range from 1 to 5, one would ideally like to see standard deviations of about 1.0, indicating variability (Kercher, 2005). This generally held

true for this dataset. All the variables were normally distributed as they were neither highly skewed (<+/-3) nor kurtotic (<+/-8) (Kline, 2005).

1							Max.
1	338	3.60	1.195	-0.631	-0.671	1	5
2	337	3.56	1.219	-0.612	-0.708	1	5
3	334	3.60	1.230	-0.606	-0.751	1	5
4	335	3.60	1.229	-0.698	-0.553	1	5
5	319	3.56	1.254	-0.613	-0.750	1	5
6	310	2.25	1.188	0.944	0.059	1	5
7	332	2.21	1.173	0.838	-0.086	1	5
8	335	2.21	1.158	0.964	0.315	1	5
9	336	2.10	1.167	1.048	0.414	1	5
10	324	2.13	1.176	1.069	0.354	1	5
11	323	3.53	1.347	-0.539	-0.975	1	5
12	346	3.50	1.204	-0.549	-0.744	1	5
13	344	3.48	1.280	-0.532	-0.815	1	5
14	345	3.44	1.315	-0.505	-0.943	1	5
15	335	3.43	1.248	-0.455	-0.928	1	5
16	329	3.90	1.175	-0.774	-0.495	1	5
17	320	4.03	1.287	-1.058	-0.181	1	5
18	325	3.91	1.340	-0.981	-0.338	1	5
19	323	3.90	1.421	-0.960	-0.566	1	5
20	318	3.85	1.483	-0.907	-0.714	1	5
11	327	3.83	1.409	-0.896	-0.638	1	5
12	334	3.43	1.205	-0.301	-1.079	1	5
13	347	3.37	1.269	-0.370	-0.998	1	5
14	348	3.40	1.301	-0.378	-1.010	1	5
15	341	3.37	1.217	-0.334	-1.012	1	5
16	344	3.39	1.185	-0.369	-0.961	1	5
17	343	3.36	1.250	-0.427	-0.870	1	5
18	317	3.66	1.292	-0.586	-0.818	1	5
19	322	3.68	1.423	-0.708	-0.864	1	5
30	319	3.55	1.426	-0.563	-1.054	1	5
31	321	3.43	1.467	-0.420	-1.224	1	5
32	323	3.45	1.497	-0.457	-1.229	1	5
33	322	3.65	1.364	-0.627	-0.852	1	5
34	319	3.70	1.321	-0.716	-0.644	1	5
35	321	3.35	1.467	-0.315	-1.299	1	5
35	323	3.35	1.490	-0.366	-1.279	1	5
37	322	3.16	1.530	-0.143	-1.449	1	5
38	311	2.99	1.539	0.000	-1.501	1	5
39	321	3.25	1.510	-0.260	-1.385	1	5
40	302	3.25	1.499	-0.305	-1.334	1	5
40	302	3.83	0.886	-0.403	-0.401	1	5
41 42	328	3.78	0.760	-0.403	0.016	1	5
	329	3.78	0.878	-0.491	0.149	1	5
43				-0.491 -0.512	0.149		
44	329	3.68	0.814			1	5
45	328	3.74	0.807	-0.268	0.000	1	5
46	326	3.77	0.894	-0.545	0.357	1	5
47	324	3.78	0.817	-0.263	-0.250	1	5
48	329	3.71	0.692	-0.108	-0.166	2	5
	330	4.35	0.630	-0.648	0.526	2	5
49 50	357	4.32	0.717	-0.966	1.258	1	5

 Table 3. Descriptive statistics for patient instrument

As a screen for the violation of the assumptions of Exploratory Factor Analysis (EFA), absence of multicollinearity in this dataset was also examined. If multicollinearity is strong, then EFA would not run. In the inter-item correlation matrix (Table 5), none of the correlations were above 0.90, thereby indicating that multicollinearity was not present (Tabachnick & Fidell, 2007). Multicollinearity was further examined by running regression analysis on the data to analyze tolerance statistics. A cut-off value of greater than 10 for the Variance Inflation Factor (Craney & Surles, 2002; Simons & Saginor, 2006), and less than 0.1 for tolerance (Hair, Anderson, Tatham, & Black, 1995; Zhou et al., 2010), was used for multicollinearity. The statistics (Table 4 below) show that multicollinearity was not present in the patient instrument data. Also, influential outliers were examined by running Cook's D statistic (Iyigun & Owen, 2002) and none were found (Cook's D<1).

Item	Tolerance	VIF
1	0.189	5.286
2	0.207	4.819
3	0.210	4.763
4	0.183	5.457
5	0.189	5.301
6	0.445	2.249
7	0.414	2.414
8	0.416	2.406
9	0.418	2.390
10	0.435	2.297
11	0.151	6.614
12	0.196	5.102
13	0.176	5.693
14	0.131	7.605
15	0.149	6.698
15	0.435	2.301
10	0.318	3.143
18	0.353	2.835
19	0.328	3.046
20	0.228	4.378
11	0.229	4.369
12	0.141	7.086
13	0.195	5.136
13	0.200	4.998
15	0.164	6.112
15	0.129	7.736
10	0.163	6.140
18	0.262	3.823
19	0.395	2.529
30	0.474	2.110
31	0.395	2.529
32	0.416	2.406
33	0.397	2.519
34	0.350	2.854
35	0.222	4.509
36	0.245	4.086
37	0.273	3.663
38	0.275	3.610
39	0.277	3.677
40	0.195	5.119
40	0.376	2.660
41 42	0.418	2.394
42	0.418	2.015
43	0.505	1.980
44 45	0.512	1.980
45	0.496	2.015
40	0.490	2.013
47	0.269	3.713
48	0.528	1.895
50	0.605	1.654
50	0.605	1.615
51	0.019	1.013

 Table 4. Collinearity statistics for patient instrument

Suitability for Factor Analysis

Prior to applying factor analytic techniques, it is necessary to evaluate whether the data set is appropriate for the analysis. Three statistical evaluations were used to determine suitability of factor analysis: (1) the inter-item correlation matrix of the items, (2) the Kaiser-Meyer-Olkin (KMO) Measure of Sampling Adequacy, and (3) Bartlett's Test of Sphericity. Factor analysis is appropriate if the observed variables are related to each other (West, 2010). Each indicator is expected to have reasonable (0.3 and above) correlation with at least some of the other indicators (West, 2010; Kercher, 2005). Table 5 shows the zero-order correlation table of the items in the patient instrument.

Item	1	2	3	4	5	6	7	8	9	10	11	12	13
1	1												
2	.793**	1											
3	.781**	.786**	1										
4	.824**	.822**	.791**	1									
5	.798**	.789**	.814**	.797**	1								
6	.133*	.114*	.142*	.144*	.163**	1							
7	.153**	0.087	.155**	0.100	0.100	.560**	1						
8	.195**	.187**	.190**	.182**	.132*	.485**	.574**	1					
9	.125*	.127*	.115*	.142*	0.106	.430**	.447**	.619**	1				
10	.192**	.131*	.156**	.145*	.156**	.520**	.481**	.483**	.595**	1			
11	.732**	.707**	.726**	.728**	.724**	.125*	0.090	.216**	.130*	.216**	1		
12	.720**	.730**	.714**	.706**	.714**	0.101	0.098	.151**	0.109	.164**	.823**	1	
13	.731**	.704**	.728**	.723**	.707**	.147*	.119*	.164**	0.097	.212**	.810**	.790**	1
14	.737**	.726**	.719**	.738**	.741**	0.074	0.094	.188**	.128*	.178**	.877**	.819**	.822**
15	.742**	.745**	.727**	.746**	.752**	0.065	0.077	.133*	0.062	.146*	.798**	.800**	.844**
16	.409**	.419**	.451**	.441**	.412**	0.044	.132*	0.097	0.078	0.116	.442**	.457**	.426**
17	.576**	.568**	.614**	.617**	.567**	0.041	.116*	.133*	0.095	0.093	.542**	.554**	.536**
18	.590**	.595**	.586**	.613**	.607**	.137*	0.059	0.103	0.111	.159**	.599**	.594**	.599**
19	.643**	.589**	.590**	.638**	.602**	0.079	0.060	0.096	0.031	0.111	.594**	.582**	.612**
20	.648**	.607**	.621**	.648**	.606**	0.102	.140*	.151*	.139*	.125*	.595**	.595**	.590**
21	.658**	.635**	.656**	.658**	.646**	0.100	.125*	.173**	.123*	.151*	.646**	.616**	.627**
22	.709**	.687**	.680**	.704**	.709**	.180**	.152**	.252**	.150**	.190**	.732**	.722**	.731**
23	.666**	.662**	.644**	.681**	.668**	0.076	0.101	.170**	0.073	.131*	.709**	.702**	.696**
24	.684**	.662**	.637**	.691**	.655**	.146*	.136*	.171**	0.089	.187**	.701**	.688**	.715**
25	.698**	.671**	.656**	.688**	.665**	.136*	.143*	.195**	0.097	.177**	.737**	.712**	.739**
26	.740**	.716**	.710**	.728**	.734**	.156**	.119*	.195**	.117*	.189**	.761**	.737**	.746**
27	.709**	.673**	.680**	.712**	.687**	.149*	0.102	.175**	0.087	.162**	.741**	.735**	.723**
28	.634**	.591**	.586**	.635**	.586**	0.100	0.066	.164**	0.070	.133*	.639**	.622**	.631**
29	.598**	.562**	.591**	.635**	.606**	0.099	0.060	.161**	0.115	.154*	.620**	.584**	.620**
30	.539**	.463**	.470**	.511**	.456**	0.050	0.035	.122*	0.048	.146*	.481**	.484**	.512**
31	.578**	.520**	.534**	.540**	.530**	0.059	.140*	.171**	0.025	.142*	.570**	.576**	.569**
32	.565**	.508**	.516**	.528**	.533**	0.073	0.103	.161**	0.055	.120*	.587**	.545**	.582**
33	.538**	.537**	.509**	.533**	.493**	0.054	.147*	.128*	0.016	0.043	.550**	.528**	.545**
34	.518**	.536**	.532**	.528**	.502**	0.053	0.091	.154**	0.034	0.115	.581**	.547**	.579**
35	.664**	.638**	.625**	.678**	.636**	.142*	0.073	.117*	0.045	0.062	.642**	.656**	.631**
36	.644**	.604**	.622**	.669**	.601**	.138*	0.030	0.081	0.007	0.051	.647**	.642**	.593**
37	.615**	.584**	.631**	.619**	.585**	.144*	0.062	.156**	0.052	0.065	.633**	.631**	.595**
38	.574**	.552**	.553**	.577**	.575**	.197**	0.079	.127*	0.049	.155*	.566**	.548**	.529**
39	.627**	.597**	.611**	.628**	.597**	.141*	0.062	.184**	0.069	0.081	.580**	.576**	.554**
40	.576**	.618**	.606**	.637**	.557**	.134*	0.044	.143*	0.019	0.060	.659**	.640**	.629**
41	.130*	.144*	.159**	.157**	.130*	-0.065	-0.053	-0.003	0.047	0.018	.161**	0.105	.118*
42	.216**	.200**	.171**	.190**	.139*	-0.032	0.018	0.057	0.070	0.083	.228**	.153**	.160**
43	.145*	.156**	.147*	.167**	.145*	0.029	0.110	0.085	0.111	0.029	.212**	.201**	.151**
44	.215**	.209**	.207**	.226**	.192**	0.097	0.071	.159**	.128*	0.100	.185**	.130*	.185**
45	.188**	.167**	.159**	.160**	.146*	0.040	0.033	0.087	0.088	0.086	.191**	.163**	.140*
46	.163**	.161**	.189**	.180**	.181**	-0.098	-0.078	-0.071	-0.076	-0.051	.239**	.165**	.209**
47	.214**	.226**	.197**	.262**	.238**	-0.003	0.004	0.011	0.022	-0.029	.229**	.149**	.193**
48	.290**	.321**	.299**	.309**	.284**	0.039	0.081	0.100	0.085	0.094	.266**	.234**	.241**
49	0.106	.122*	.136*	.165**	.118*	0.025	0.029	0.082	.116*	0.082	0.110	.128*	0.059
50	0.100	0.110	.138*	.136*	0.088	-0.044	0.060	-0.013	0.022	-0.053	0.076	.130*	0.095
51	0.034	0.041	0.069	0.072	0.050	0.062	.135*	0.087	.168**	0.098	0.025	-0.001	0.023

Table 5. Correlation matrix for patient instrument

**p<.01, *p<.05

Item	14	15	16	17	18	19	20	21	22	23	24	25	26
1													
2													
3													
4												ł	
5													
6												ł	
7													
8													
9													
10												ł	
												ł	
11												1	
12													
13	1												
14	1		 									 	
15	.852**	1										ļ	
16	.456**	.440**	1									<u> </u>	
17	.590**	.561**	.546**	1									
18	.616**	.574**	.551**	.598**	1								
19	.634**	.611**	.571**	.606**	.632**	1							
20	.639**	.594**	.585**	.747**	.632**	.662**	1						
21	.676**	.637**	.560**	.684**	.704**	.661**	.778**	1					
22	.752**	.771**	.438**	.560**	.592**	.608**	.639**	.670**	1				
23	.715**	.725**	.422**	.549**	.562**	.585**	.611**	.642**	.808**	1		-	
24	.740**	.720**	.392**	.555**	.540**	.533**	.646**	.639**	.828**	.770**	1		
25	.745**	.744**	.448**	.567**	.572**	.571**	.645**	.652**	.841**	.810**	.797**	1	
26	.769**	.773**	.419**	.575**	.600**	.604**	.651**	.670**	.869**	.824**	.827**	.851**	1
27	.754**	.739**	.367**	.552**	.578**	.552**	.622**	.647**	.815**	.829**	.808**	.834**	.846**
28	.630**	.681**	.317**	.467**	.484**	.494**	.534**	.575**	.686**	.642**	.608**	.646**	.690**
29	.598**	.623**	.285**	.440**	.481**	.454**	.465**	.567**	.633**	.598**	.584**	.623**	.641**
30	.481**	.502**	.204**	.403**	.396**	.400**	.390**	.441**	.508**	.489**	.510**	.508**	.513**
	.575**	.588**	.215**	.361**	.436**	.400	.435**	.479**	.572**	.551**	.536**	.552**	.513
31	.575	.560**	.215	.301	.430	.423	.435	.465**	.566**	.538**	.530	.571**	.555
32	.559	.547**	.275**	.400**	.414	.389	.440	.403	.500	.558	.521	.515**	.549**
33		-	-					-					
34	.568**	.562**	.223**	.421**	.380**	.360**	.445**	.483**	.573**	.550**	.544**	.574**	.584**
35	.677**	.666**	.409**	.560**	.532**	.565**	.586**	.622**	.691**	.687**	.645**	.695**	.688**
36	.651**	.651**	.473**	.531**	.566**	.561**	.571**	.597**	.674**	.664**	.658**	.678**	.671**
37	.625**	.624**	.477**	.578**	.532**	.542**	.581**	.581**	.628**	.630**	.602**	.597**	.642**
38	.584**	.589**	.339**	.454**	.496**	.485**	.521**	.505**	.593**	.598**	.570**	.609**	.651**
39	.595**	.608**	.354**	.486**	.483**	.519**	.545**	.552**	.647**	.648**	.615**	.647**	.679**
40	.631**	.644**	.454**	.517**	.523**	.509**	.550**	.546**	.695**	.707**	.663**	.686**	.688**
41	.161**	.199**	.115*	.129*	0.092	.161**	.181**	.124*	.221**	.157**	.194**	.147*	.165**
42	.211**	.174**	.179**	.132*	.145*	.204**	.270**	.173**	.201**	.184**	.208**	.278**	.220**
43	.183**	.201**	0.100	.144*	.171**	0.109	.170**	.129*	.185**	.154**	.175**	.207**	.154**
44	.176**	.161**	.118*	.150*	.142*	.125*	.192**	0.102	.161**	.116*	.123*	.168**	.117*
45	.206**	.208**	.152**	.159**	.146*	.207**	.212**	.136*	.211**	.171**	.170**	.181**	.159**
46	.256**	.282**	0.104	.177**	.186**	.139*	.199**	.249**	.200**	.200**	.213**	.208**	.224**
47	.187**	.207**	.189**	.207**	.230**	.198**	.247**	.168**	.201**	.155**	.170**	.224**	.157**
	.265**	.269**	.163**	.153**	.175**	.258**	.250**	.159**	.285**	.214**	.241**	.279**	.240**
48	0.103	0.069	.207**	.133	.163**	.157**	.165**	.152**	.173**	0.099	.126*	.146*	.126*
49	0.103	0.069	.308**	.217**	.195**	.157	.105	.152**	.173	.150**	.120*	.140	.126*
50		-0.090	0.065	0.082	0.094	0.109	.121*	0.084	0.037	-0.038	0.025	0.040	0.035
51	0.041												

Table 5. Correlation matrix for patient instrument (contd.)

Item	27	28	29	30	31	32	33	34	35	36	37	38	39
1													
2													
3													
4													
5													
6													
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8													
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10													
11													
12													
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18													
19													
20													
21													
22													
23													<u> </u>
24													
25													
26													
27	1												
28	.645**	1											
29	.623**	.662**	1										
30	.532**	.616**	.544**	1									
31	.539**	.597**	.493**	.511**	1								
32	.576**	.648**	.558**	.514**	.573**	. 1							
	.531**	.635**	.528**	.545**	.517**	.581**	1						
33	.559**	.653**	.520	.507**	.615**	.534**	.596**	1					
34	.701**	.510**	.509**	.379**	.433**	.429**	.413**	.371**	1				
35	.687**	.510	.486**	.364**	.399**	.432**	.413	.346**	1 .772**	1			
36	.653**	.491**	.480	.304	.399	.432	.360**	.334	.726**	.733**	1		──
37	.627**	.491**	.458**	.337**	.382***	.402***	.360**	.334**	.726**	.733***	.717**	1	──
38	.627**	.445**	.413**	.346**	.404**	.344***	.339**	.315**	.743**	.702**	.679**	 .718**	<u> </u>
39			.439**										1
40	.694**	.486**		.346**	.400**	.373**	.384**	.354**	.766**	.759**	.712**	.708**	.77
41	.211**	.181**	.128*	.173**	0.108	.142*	.235**	.243**	.162**	.222**	.191**	.158**	.14
42	.238**	.144*	.156**	.172**	.172**	.138*	.203**	.226**	.226**	.268**	.227**	.215**	.228
43	.191**	.150*	.130*	.130*	.143*	0.092	.213**	.213**	.180**	.210**	.153**	.165**	.170
44	.149**	.190**	.147*	.221**	.156**	.125*	.176**	.177**	.224**	.182**	.214**	.221**	.163
45	.177**	.168**	.141*	.189**	.185**	.118*	.206**	.162**	.173**	.182**	.184**	.201**	.150
46	.252**	.203**	.202**	.165**	.178**	.144*	.198**	.207**	.222**	.232**	.221**	.160**	.198
47	.228**	.134*	.167**	.127*	0.102	0.107	.212**	.212**	.297**	.322**	.300**	.240**	.22
48	.251**	.289**	.234**	.253**	.162**	.149*	.210**	.254**	.288**	.296**	.291**	.302**	.26
49	.153**	0.106	0.079	0.099	0.056	0.084	0.106	.124*	.200**	.223**	.187**	.189**	.213
50	.174**	0.070	0.073	0.044	-0.049	0.041	0.038	0.073	.184**	.203**	.196**	.119*	.190
51	0.013	0.075	0.030	0.027	0.022	-0.021	0.009	0.032	0.095	0.083	0.064	0.076	0.1

Table 5. Correlation matrix for patient instrument (contd.)

Item	40	41	42	43	44	45	46	47	48	49	50	51
1												
2												
3												
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5												
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11												
12												
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13												
15												
16		ļ		ļ	ļ		ļ		ļ			
10		ļ		ļ	ļ		ļ		ļ			
17												
18												
20												
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21												
22												
24												
25												
26												
27												
28												
29												
30												
31												
32												
33												
34												
35												
36												
37												
38												
39	1											
40		4										
41	.142*	1	4	<u> </u>	<u> </u>							
42	.203**	.480**	1	4								
43	.161** .163**	.530**	.431** .347**	1 .369**	1							
44		.407**			1	4						
45	.121*	.563**	.519**	.348**	.366**	1						
46	.188**	.547**	.394**	.453**	.281**	.385**	1					
47	.255**	.473**	.525**	.434**	.345**	.382**	.384**	1				
48	.248**	.510**	.602**	.548**	.622**	.446**	.453**	.556**	1			
49	.192**	.198**	.169**	.202**	.149**	0.040	0.109	.254**	.249**	1		
50	.189**	0.108	.112*	.118*	0.075	0.049	0.034	.134*	.161**	.487**	1	
51	0.109	0.074	0.023	0.028	0.065	0.015	0.060	.111*	.110*	.484**	.324**	1

Table 5. Correlation matrix for patient instrument (contd.)

**p<.01, *p<.05

The Bartlett test of sphericity and the Kaiser-Meyer-Olkin Measure (KMO) of Sampling Adequacy help determine the appropriateness of the data for factor analysis (Dziuban & Shirkey, 1974). The KMO is an index that compares the magnitude of the observed correlation coefficients to the magnitude of the partial correlation coefficients. The index ranges from 0 to 1 and can be interpreted using the following guidelines by Hair et al. (1998): 0.80 or above, meritorious; 0.70 or above, middling; 0.60 or above, mediocre; 0.50 or above, miserable; and below 0.50, unacceptable. The KMO statistic for the patient instrument was 0.959, which is considered "meritorious" (Hair et al., 1998).

Bartlett's test of sphericity provides the statistical probability that the correlation matrix has significant correlations amongst the variables (Kaiser, 1970). If the test is not significant, one can reject the null hypothesis that the correlation matrix is an identity matrix (explained earlier in the previous chapter). Based on the results of the Bartlett's test, $\chi 2=11102.429$ with 1275 d.f, p<.01, the null hypothesis was rejected. Since the correlation matrix is not an identity matrix, the items are considered factorable.

Factor Analytic Procedure

Exploratory Factor Analysis identifies relevant factors within the data. The factors were set up as a reflector model (Kercher, 2005), to conduct the analysis. Principal Axis Factoring is the preferred method to use when the purpose is to evaluate the structure of a factor (Taylor, 2010). In order to identify the meaningful factors underlying the items of the instruments, Principal Axis Factoring with oblique rotation (Direct Oblimin method) was used to analyze the factor structure in this dataset.

Scree Plot

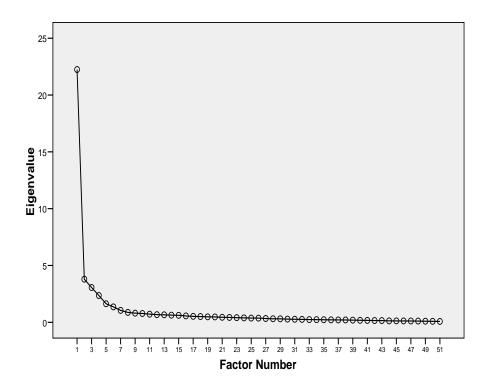


Figure 9. Scree plot for patient instrument

A Scree plot was obtained on running the EFA. To interpret the number of factors using a Scree plot, a determination is made by examining the data points of the Scree plot. Factors are determined by examination of the change in slope (vertical to horizontal), also referred to as 'elbow', of the plotted data points (Tabachnick & Fidell, 2001). The Scree plot in Figure 9 is not conclusive, as it is not clear where the elbow lies. Many variables in a model, as in this case, can produce artifacts, which complicate the determination of the Scree plot elbow. Scree plot, in any case is not an exact measure (Donnon & Hammond, 2007). It is also not the only basis for specification of the number of factors to be extracted.

Since only well-validated scales were being used in this study, there existed a prior notion about the possible number of factors present. Hence, nine factors were specified for extraction. The nine factor solution had a total explained variance of 73%. The average of the residuals of the reproduced correlation matrix was less than 0.05. The decision to retain items in the Exploratory Factor Analysis was made essentially in consideration of the strength of the factor loadings of items on the factor in the pattern matrix. All items in the instrument possessed a factor loading of more than 0.4 on the appropriate factor, and were therefore considered to relate significantly to their respective factors (Table 6). Two of the items from the empathy scale had a secondary loading of 0.32 on the PNEA overall-mood scale. This was however not particularly problematic (explained in the discussion section). As expected from prior empirical evidence and theory, nine latent structures emerged from the factor analysis procedure. Factor 1 was labeled Empathy and consists of 6 items; Factor 2 was labeled Diabetes knowledge and consists of 8 items; Factor 3 was labeled Shared decision-making and consists of 5 items; Factor 4 was labeled Social support and consist of 3 items; Factor 5 was labeled PNEA-Vision and consists of 7 items; Factor 6 was labeled Trust and consists of 6 items; Factor 7 was labeled Information exchange and consists of 5 items; Factor 8 was labeled PNEA-Overall mood and consists of 6 items and Factor 9 was labeled Rapport and consists of 5 items. Table 6 presents the factor loadings of all items on the factors.

	Fa1	Fa2	Fa3	Fa4	Fa5	Fa6	Fa7	Fa8	Fa9
PNEA-Vision									
pneaptvi28: pt doc healthy image		-			0.767				
pneaptvi29: pt doc possibilities	0.122	-			0.498		-0.163		
pneaptvi30: future better		-			0.680				
pneaptvi31: pt inspired by doc					0.632				
pneaptvi32 focused on positive image					0.691				
pneaptvi33: interaction healthy image					0.726				
pneaptvi34: pt doc positive qualities	0.119				0.691			-0.145	
Shared Decision-making									
sdm6: pt treatment advice			0.687					0.238	
sdm7: pt help treatment plan			0.709						
sdm8: pt suggest treatment			0.747						
sdm9: pt participate treatment plan			0.740		-0.144		-0.102	-0.164	
sdm10: pt treatment goal and option			0.723						0.117
Empathy									
em22: doc listens	0.416		0.119		0.236			0.251	
em23: doc understand reasons	0.415				0.216	-0.101		0.322	
em24: doc understand diff. people	0.442				0.204			0.240	
em25: doc understands point of view	0.425				0.215			0.272	
em26: doc puts himself in my shoes	0.444				0.217		-0.155	0.265	
em-r27: doc not understand feeling	0.421				0.223			0.325	
Diabetes Knowledge									
dk-r41: diabetes by kidney failure		0.766							
dk-r42: diabetes curable		0.703							
dk43: fbs 200 high		0.651							0.102
dk-r44: exercise increase insulin need	-0.182	0.527					-0.163		
dk45: diabetes cause poor circulation		0.653		-0.133		-0.122			
dk46: cut heal slowly		0.602	-0.136						0.120
dk47: diabetes damage kidney		0.607						0.125	
dk-r48: diabetes needs special food		0.751				0.116	-0.274		
Social Support									
ss49: family/friend help				0.840					
ss50: family/friend count on	0.113			0.554		-0.218			
ss51: family/friend concern				0.571					

Table 6. Factor loadings for patient instrument

Fa=Factor

	Fa1	Fa2	Fa3	Fa4	Fa5	Fa6	Fa7	Fa8	Fa9
Information Exchange									
ie1: pt share info					0.214	-0.192	-0.481	0.129	
ie2: pt excellent communication					0.102	-0.155	-0.556		0.156
ie3: pt answer questions					0.142	-0.212	-0.474	0.115	0.163
ie4: pt talk understand					0.165	-0.192	-0.522	0.139	
ie-r5: pt little communication						-0.160	-0.570		0.177
Trust									
tr-r16: pt not trusted						-0.707			0.117
tr17: pt trusted					0.106	-0.672			
tr18: pt care					0.110	-0.537			0.124
tr-r19: pt not trust						-0.560	-0.155		
tr-r20: pt not care	0.127					-0.704	-0.102		
tr21: pt trust	0.102				0.199	-0.638			
PNEA- Overall mood									
pneaptov35: pt good to come to office								0.698	
pneaptov36: pt comfortable to come						-0.139		0.649	
pneaptov-r37: pt not comfortable to come						-0.207		0.659	
pneaptov38: pt come feel good								0.767	
pneaptov-r39: pt choice other doc	0.140						-0.128	0.695	
pneaptov40: pt overall feel good	0.117							0.763	0.130
Rapport									
rap11: pt bond					0.197		-0.108	0.187	0.531
rap12: pt look forward doctor					0.177	-0.109	-0.147	0.189	0.480
rap13: pt care doctor					0.235	-0.108	-0.167	0.134	0.452
rap14: pt doc personal interest					0.140	-0.159	-0.139	0.142	0.522
rap15: pt close relationship			1		0.192		-0.180	0.182	0.448

Table 6. Factor loadings for patient instrument (contd.)

Fa=Factor

Displayed in Table 7 below is the factor correlation matrix for the nine factors of the patient instrument.

e /. Factor correlation matrix for patient instrument											
	1	2	3	4	5	6	7	8	9		
Empathy	1										
Diabetes Knowledge	0.080	1									
Shared Decision-Making	0.030	0.040	1								
Social Support	0.036	0.179	0.086	1							
PNEA – Vision	0.465	0.257	0.150	0.010	1						
Trust	-0.406	-0.192	-0.107	-0.212	-0.467	1					

-0.087

0.146

0.009

-0.553

0.479

0.527

0.430

-0.549

-0.458

1

-0.536

-0.389

1

0.428

1

lati Table 7. Fact

-0.230

0.400

0.423

-0.200

0.237

0.137

-0.194

0.120

0.069

1

2

3

4

5

6

7

8

9

Rapport

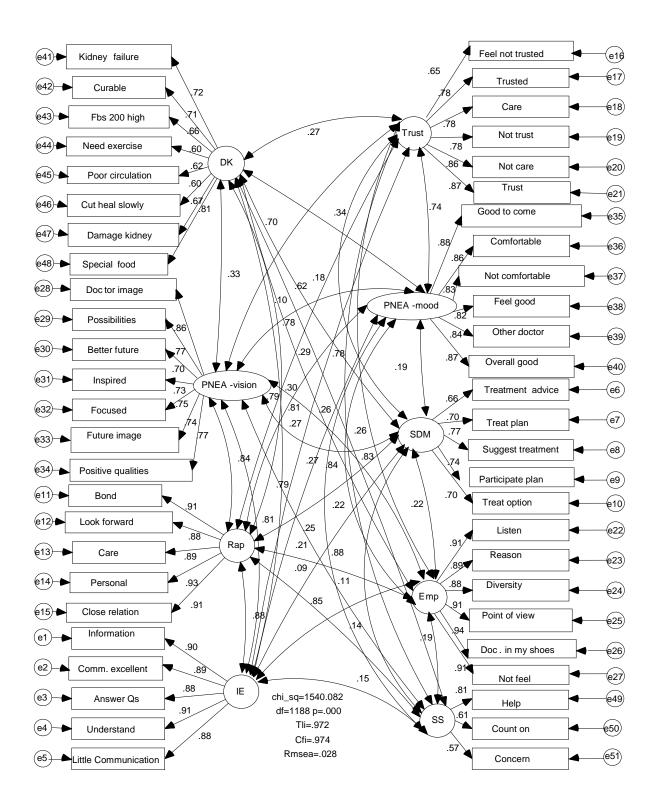
Information Exchange

PNEA - Overall Mood

Reliability coefficients for all the factors were determined. Standardized alpha was used as a measure of reliability to determine the internal consistency of the factors. All the items of each scale had positive correlations with each other. The "Alpha if item deleted" column represents alpha reliability co-efficient if the item is removed. It was observed in each case, that by removing any item from the scale, no substantial improvement (<0.05) was gained in alpha. This also gave validation to the decision of retaining all the items in the factors (Kercher, 2005). In any case, all of the items in the scales were theoretically important indicators. Alpha greater than 0.7, is generally considered to denote good internal consistency (Berard & Lacasse, 2008). The scales were found to be reliable as they all had a Standardized alpha above 0.7, with the exception of the Social support scale, which had a Standardized alpha of 0.69.

Confirmatory Factor Analysis of Patient Instrument

Confirmatory Factor Analysis (CFA) was conducted to confirm the factor structure and item fit of the patient instrument. CFA was performed on the complete patient dataset, as with the EFA explained earlier. Items were specified to load onto nine factors, as suggested by the hypothesized model. Figure 10 illustrates the measurement model of the patient instrument with standardized path coefficients. The standardized Beta weights in AMOS output are analogous to the factor loadings in EFA. CFA Factor loadings (Table 8) for the patient instrument ranged from 0.565 to 0.938, which indicated that the items are good indicators of the scales. As recommended by Burant (2008), the chi-square goodnessof-fit, Comparative Fit Index (CFI), Tucker-Lewis Index (TLI) and the Root Mean Square Error of Approximation (RMSEA), were examined to assess the fit of the CFA measurement model. Except for the chi-square, all the other statistics indicated a good fit between the proposed nine-factor model and the observed data: $\chi 2=1540.082(df = 1188)$, p<.001, CFI=0.972, TLI=0.974 and RMSEA=0.028.



DK= Diabetes knowledge, SDM=Shared decision making, Rap=Rapport, Emp=Empathy, IE=Information Exchange, SS=Social Support

Figure 10. CFA Measurement model of patient instrument

Construct	Items	Loading
	tr-r16: pt not trusted	0.650
	tr17: pt trusted	0.783
Trust	tr18: pt care	0.778
	tr-r19: pt not trust	0.775
	tr-r20: pt not care	0.863
	tr21: pt trust	0.874
	sdm6: pt treatment advice	0.655
Shared Decision-	sdm7: pt help treatment plan	0.700
making	sdm8: pt suggest treatment	0.775
Ū	sdm9: pt participate treatment plan	0.737
	sdm10: pt treatment goal and option	0.703
	ie-r5: pt little communication	0.884
Information	ie4: pt talk understand	0.908
Exchange	ie3: pt answer questions	0.884
	ie2: pt excellent communication	0.888
	ie1: pt share info	0.900
	em22: doc listens	0.915
	em23: doc understand reasons	0.888
Empathy	em24: doc understand diff. people	0.884
1 ,	em25: doc understands point of view	0.912
	em26: doc puts himself in my shoes	0.938
	em-r27: doc not understand feeling	0.914
	pneaptvi34: pt doc positive qualities	0.775
	pneaptvi33: interaction healthy image	0.745
	pneaptvi32 focused on positive image	0.749
PNEA - Vision	pneaptvi31: pt inspired by doc	0.727
	pneaptvi30: future better	0.700
	pneaptvi29: pt doc possibilities	0.769
	pneaptvi28: pt doc healthy image	0.857

Table 8. CFA Factor loadings for patient instrument

Construct	Items	Loading
	ss49: family/friend help	0.814
Social Support	ss50: family/friend count on	0.608
	ss51: family/friend concern	0.565
	pneaptov35: pt good to come to office	0.882
	pneaptov36: pt comfortable to come	0.862
PNEA – Overall	pneaptov-r37: pt not comfortable to come	0.831
mood	pneaptov38: pt come feel good	0.817
	pneaptov-r39: pt choice other doc	0.841
	pneaptov40: pt overall feel good	0.868
	rap15: pt close relationship	0.912
	rap14: pt doc personal interest	0.930
Rapport	rap13: pt care doctor	0.895
	rap12: pt look forward doctor	0.883
	rap11: pt bond	0.906
	dk-r48: diabetes needs special food	0.812
	dk47: diabetes damage kidney	0.665
	dk46: cut heal slowly	0.603
Diabetes	dk45: diabetes cause poor circulation	0.622
Knowledge	dk-r44: exercise increase insulin need	0.599
	dk43: fbs 200 high	0.656
	dk-r42: diabetes curable	0.708
	dk-r41: diabetes by kidney failure	0.723

Table 8. CFA Factor loadings for patient instrument (contd.)

Exploratory Factor Analysis of Physician Instrument

Preliminary procedures

Univariate statistics (Table 9) show that the variables were normally distributed (skewness<+/-3 and kurtosis<+/-8) and there was sufficient variability (SD>1) in the variables. The inter-item correlation item matrix (Table 11) showed that none of the items

was highly correlated (<0.9), thereby suggesting that there was no problem with multicollinearity (Tabachnick & Fidell, 2007). The tolerance statistic (Table 10) reveals that VIF and tolerance were within normal range (VIF<10, Tolerance >0.1). Also, analysis for influential outliers in the data showed that none were present (Cook's D<1).

Item	Mean	Std. Deviation	Skewness	Kurtosis	Minimum	Maximum
1	3.96	1.184	-0.942	-0.195	1	5
2	3.84	1.224	-0.615	-0.803	1	5
3	3.80	0.981	-0.102	-1.208	2	5
4	4.16	1.191	-1.315	0.498	1	5
5	3.84	1.407	-0.929	-0.515	1	5
6	3.68	1.192	-0.218	-1.486	2	5
7	3.96	1.184	-0.651	-1.151	2	5
8	3.64	1.093	-0.547	-0.393	1	5
9	3.64	1.055	-0.475	-0.228	1	5
10	3.52	1.139	-0.623	-0.198	1	5
11	3.56	1.237	-0.522	-0.682	1	5
12	3.56	1.102	-0.333	-0.600	1	5
13	3.84	1.009	-0.382	-0.600	2	5

Table 9. Descriptive statistics for physician instrument

N=375

Item	Tolerance	VIF
1	0.186	5.367
2	0.180	5.556
3	0.291	3.438
4	0.370	2.703
5	0.249	4.009
6	0.352	2.839
7	0.161	6.200
8	0.264	3.787
9	0.276	3.621
10	0.270	3.700
11	0.212	4.717
12	0.265	3.775
13	0.236	4.246

Table 10. Collinearity statistics for physician instrument

Suitability for Factor Analysis

The inter-item correlation matrix, Kaiser-Meyer-Olkin Measure of Sampling Adequacy and Bartlett's Test of Sphericity were examined to determine the suitability of factor analysis. The inter-item correlation matrix (Table 11) revealed that most of the variables were moderately correlated with each other.

Item	1	2	3	4	5	6	7	8	9	10	11	12	13
1	1												
2	.660**	1											
3	.511**	.608**	1										
4	.317**	.568**	.542**	1									
5	.478**	.544**	.413**	.422**	1								
6	.360**	.542**	.562**	.460**	.591**	1							
7	.771**	.660**	.753**	.431**	.405**	.502**	1						
8	.144**	.377**	.382**	.414**	.197**	.312**	.361**	1					
9	.598**	.452**	.356**	.237**	.231**	.323**	.598**	.583**	1				
10	.491**	.432**	.163**	0.082	0.097	.238**	.370**	.341**	.555**	1			
11	.481**	.351**	.357**	.211**	.466**	.394**	.426**	.417**	.431**	.645**	1		
12	.263**	.484**	.328**	0.089	-0.015	.262**	.296**	.604**	.486**	.466**	.359**	1	
13	.465**	.499**	.495**	.389**	.349**	.258**	.532**	.494**	.360**	.559**	.747**	.444**	1
**n< 01													

Table 11. Correlation matrix for physician instrument

**p<.01

The Kaiser-Meyer-Olkin Measure of Sampling Adequacy statistic for the correlation matrix was 0.698. The results of Bartlett test, $\chi 2=3764.555$ with 78 d.f, p<.01, rejected the null hypothesis that the correlation matrix is an identity matrix. Based on both these results, the items were considered factorable.

Factor Analytic Procedure

Principal Axis Factoring with oblique rotation (Direct Oblimin method) was used to analyze factor structure.

Scree Plot

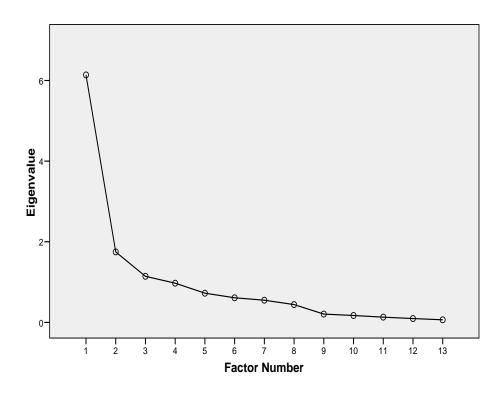


Figure 11. Scree plot for physician instrument

The change in the slope of plotted data points in the Scree plot (Tabachnick & Fidell, 2001) is one of the criteria for determining the number of factors to be extracted. The plot shown above (Figure 11) is suggestive of two factors. Two factors were specified for extraction based on the prior notion of the number of factors (which existed because only well-validated scales were being used in the study) and the Scree plot.

The two factor solution had a total explained variance of 60%. The average of the residuals of the reproduced correlation matrix was less than 0.05. The pattern matrix (Table 12) showed that all items loaded properly (>0.40) on the appropriate factors. One of the items from the PNEA - Vision scale, however, had a secondary loading of 0.33 on the

PNEA - Overall mood scale. All the items on both these scales held together remarkably well. Also, both the scales measured fairly different dimensions, as one assessed the physician's vision of the future, while the other measured the present overall mood of the physician. Therefore, the small secondary loading was not a concern and the item was retained. As expected from prior empirical evidence and theory, two latent structures emerged. Factor 1 was labeled PNEA - Vision and consists of 7 items, and Factor 2 was labeled PNEA - Overall mood and consists of 6 items. Table 12 displays items grouped by factor and ordered according to the strength of the factor loadings for the two scales.

	Factor 1	Factor 2
PNEA - Vision		
pneadvi3: ph future better	0.758	
pneadvi5: ph focused	0.733	-0.112
pneadvi4: ph inspired	0.691	
pneadvi6: ph healthy future image	0.679	
pneadvi2: ph possibilities	0.670	0.246
pneadvi7: ph pt positive qualities	0.664	0.261
pneadvi1: ph healthy image	0.509	0.326
PNEA – Overall mood		
pneadov-r10: ph not comfortable office	-0.168	0.874
pneadov-r12: ph choice elsewhere		0.710
pneadov9: ph comfortable office	0.141	0.640
pneadov11: ph office coming good	0.152	0.633
pneadov13: ph overall good	0.224	0.609
pneadov8: ph good office	0.115	0.555

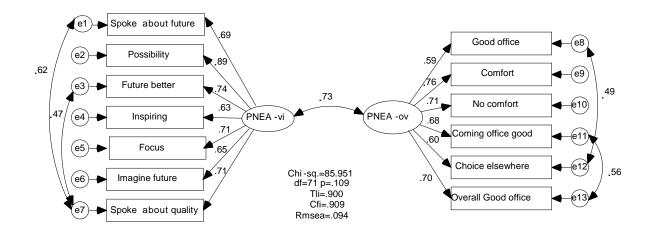
Table 12. Factor loadings for physician instrument

The correlation between the two factors was 0.505. Reliability estimates were determined by calculating Standardized alpha. All the items of each scale had positive correlations with each other. No substantial improvement (<0.05) in alpha was gained by

removing any item, thus validating the decision to retain all the items in the two scales. Both the scales had good internal consistency (Standardized α >0.7), which indicated that they were reliable.

Confirmatory Factor Analysis of Physician Instrument

Confirmatory Factor analysis was conducted to confirm the results of the Exploratory Factor Analysis. Items were specified to load onto two latent variables, as suggested by the results of the Exploratory Factor Analysis. In accordance with the recommendation of Burant (2008), Chi-square goodness-of-fit, Comparative Fit Index (CFI), Tucker-Lewis Index (TLI) and Root Mean Square Error of Approximation (RMSEA), were examined to assess the fit of the hypothesized model. Fit statistics for the initial model yielded the following indices: $\chi 2=111.81(df=75)$, p<.05, CFI=0.776, TLI=0.767 and RMSEA=0.143. Modification index suggested the addition of two paths on each of the two factors, which were also theoretically justified (described in the discussion chapter). The addition of the paths between the error terms of the items within each factor resulted in an improved and acceptable model fit: $\chi 2=85.951(df=71)$, p>.05, CFI=0.900, TLI=0.909 and RMSEA=0.094. CFA Factor loadings (Table 13) ranged from 0.595 to 0.886. These statistics indicate that the items are acceptable indicators of the scales.



PNEA-vi = PNEA vision, PNEA-ov = PNEA overall mood

Figure 12. CFA Measurement model of physician instrument

Construct	ltem	Loading
	pneadvi7: ph pt positive qualities	0.707
	pneadvi6: ph healthy future image	0.651
	pneadvi5: ph focused	0.709
PNEA - Vision	pneadvi4: ph inspired	0.629
	pneadvi3: ph future better	0.740
	pneadvi2: ph possibilities	0.886
	pneadvi1: ph healthy image	0.688
	pneadov8: ph good office	0.595
	pneadov9: ph comfortable office	0.756
	pneadov-r10: ph not comfortable office	0.707
PNEA – Overall mood	pneadov11: ph office coming good	0.681
	pneadov-r12: ph choice elsewhere	0.601
	pneadov13: ph overall good	0.701

Table 13. CFA Factor loadings for physician instrument

Exploratory Factor Analysis of Patient Companion Instrument

Preliminary Procedures

Descriptive statistics are displayed in Table 14. The variables were normally distributed (skewness<+/-3 and kurtosis<+/-8) and there was sufficient variability (SD>1). The inter-item correlation matrix for the patient companion instrument (Table 16) showed that none of the item were highly correlated (<0.9), suggesting that there was no problem with multicollinearity (Tabachnick & Fidell, 2007). Tolerance statistics (Table 15) confirmed the absence of multicollinearity (VIF<10, Tolerance >0.1). Furthermore, no influential outlier in the data was found (Cook's D<1).

Item	Ν	Mean	Std. Deviation	Skewness	Kurtosis	Minimum	Maximum
1	362	3.62	1.412	-0.579	-1.067	1	5
2	359	3.33	1.392	-0.265	-1.216	1	5
3	354	3.38	1.467	-0.323	-1.359	1	5
4	350	3.48	1.436	-0.439	-1.225	1	5
5	349	3.46	1.455	-0.432	-1.255	1	5
6	353	3.56	1.391	-0.550	-1.086	1	5

Table 14. Descriptive statistics for patient companion instrument

Item	Tolerance	VIF
1	.496	2.015
2	.567	1.764
3	.540	1.851
4	.611	1.636
5	.519	1.925
6	.557	1.796

Table 15. Collinearity statistics for patient companion instrument

Suitability for Factor Analysis

The inter-item correlation matrix, the Kaiser-Meyer-Olkin Measure of Sampling Adequacy, and Bartlett's Test of Sphericity were examined to determine if factor analysis was appropriate for this data set. The inter-item correlation table for the patient companion instrument (Table 16) shows that all of the items were moderately correlated with each other.

Item	1	2	3	4	5	6
1	1					
2	.534**	1				
3	.566**	.505**	1			
4	.520**	.495**	.405**	1		
5	.585**	.543**	.547**	.514**	1	
6	.546**	.506**	.559**	.481**	.493**	1

Table 16. Correlation matrix for patient companion instrument

The Kaiser-Meyer-Olkin Measure of Sampling Adequacy statistic for the correlation matrix of the patient instrument was 0.891 which is considered meritorious (Hair et al., 1998). Furthermore, based on the results of the Bartlett's test, $\chi 2=817.614$ with 15 d.f., p<.01, the null hypothesis that the correlation matrix is an identity matrix was rejected. This implied that the items were factorable.

Factor Analytic Procedure

The relevant factors within the instrument were identified by running Exploratory Factor Analysis.

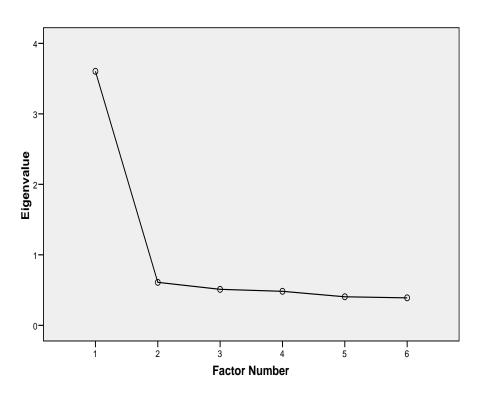




Figure 13. Scree plot for patient companion instrument

Scree plot was one of the methods used to determine the number of factors. The Scree plot shown above (Figure 13) suggests the presence of a single factor. Thus one factor was specified for factor extraction. The one factor solution had a total explained variance of 60%. The average of the residuals of the reproduced correlation matrix was less than 0.05. The Factor matrix showed that all items loaded satisfactorily (>0.40). As expected from prior empirical evidence and theory, one factor emerged. This factor was labeled Treatment Adherence. The factor loadings presented in the Table 17 are ordered according to the strength of the loadings.

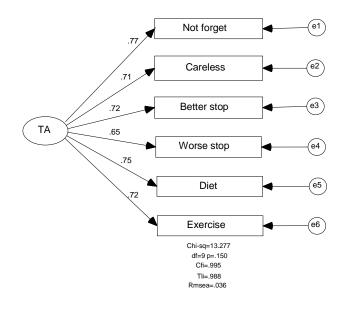
Factor/Item	Factor 1
Treatment Adherence	
ta1: never forget medication	0.774
ta5: pt adhere dietary advice	0.750
ta-r3: pt better stop medicine	0.717
ta6: pt adhere exercise regimen	0.715
ta-r2: careless taking medication	0.714
ta-r4: pt worse stop medicine	0.659

Table 17. Factor loadings for patient companion instrument

The reliability estimate for the single extracted factor was determined by calculating Standardized alpha. All six items of the scale had positive correlations with each other and item removal did not substantially improve the alpha statistic. The extracted factor had good internal consistency (Standardized α >0.7), which indicated that it was reliable.

Confirmatory Factor Analysis of Patient Companion Instrument

Confirmatory Factor Analysis (CFA) was conducted to confirm the results of the Exploratory Factor Analysis. The CFA was performed on the complete dataset collected from the patients' companions, as for EFA explained earlier. Items were specified to load onto a single factor, as suggested by the postulated model. Figure 14 illustrates the measurement model of the patient companion instrument with standardized path coefficients. The standardized beta weights in AMOS output are analogous to the factor loadings in EFA. Factor loadings for the patient companion instrument (Table 18) ranged from 0.650 to 0.774, which indicate that the items are good indicators of the latent variable. As recommended by Burant (2008), the chi-square goodness of fit, Comparative Fit Index (CFI), Tucker-Lewis Index (TLI) and the Root Mean Square Error of Approximation (RMSEA), were examined to assess the fit of the CFA measurement model. The fit statistics indicated adequate fit between the proposed one-factor model and the observed data: $\chi 2=13.277(df=9)$, p>.05, CFI=0.995, TLI=0.988 and RMSEA=0.036.



TA = Treatment Adherence

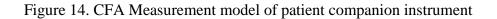


Table 18. CFA Factor loadings for patient companion instrument

Construct	Items	Loading
	ta1: never forget medication	0.774
	ta-r2: careless taking medication	0.711
Treatment	ta-r3: pt better stop medicine	0.724
Adherence	ta-r4: pt worse stop medicine	0.650
	ta5: pt adhere dietary advice	0.749
	ta6: pt adhere exercise regimen	0.715

Mediation analysis

Modified Baron and Kenny's method, as explained in the previous chapter, was used to analyze mediation analysis using HLM 6.0 software. The first section presents the results of the Intra-class Correlation. This is followed by tests of each of the hypotheses by Mediation analysis and Bootstrapping procedure.

Intra-class Correlation using HLM

This first set of analyses examined the variance in the outcome measure of treatment adherence across patients without regard to any predictor. Such a model is referred to as the unconditional model (Ruadenbush & Byrk, 2002). Intra-class Correlation (ICC) indicates the correlations between the observations of patients who belong to the same physician. Only if Intra-class Correlation is greater than 5% of the total variance in the outcome (ICC>0.05) does one need to model nesting on empirical grounds (Johnsrud & Rosser, 2002).

ICC was analyzed by running the unconditional model in HLM 6.0 software (Table 19).

The ICC was calculated as:

ICC = Level 2 variance/(Level1 variance+Level2 variance)

= 18.94/ (18.94+27.23)

$$=0.41$$

Table 19. Unconditional model statistics for Intra-class Correlation

Levels	Variance component	Chi-square	P value
Level 2	18.94	269.73	0.00
Level 1	27.23		

Thus the estimated correlation of observations within the same doctor (i.e., same doctor's patients) is 0.41. It is estimated from all data and applies to all physicians.

Intra-class Correlation using SPSS Mixed Model Function

Intra-class Correlation (ICC) was also analyzed using SPSS to verify the results obtained from HLM 6.0 software. For this purpose, the Mixed model function of SPSS was utilized. Presented below is the calculation and result for Intra-class Correlation obtained from SPSS.

Let the variance component estimate for the random factor DOCT ID = 18.94.

Let the variance component estimate for Residual = 27.23.

18.94 + 27.23 = 46.17

18.94/46.17 = 0.41

Thus, in this model, the doctor variance component is 41% of the total of both variance components. We can, therefore, say that treatment adherence clusters by doctors; meaning that two patients randomly selected from the same doctor are more likely to have similar treatment adherence than a pair of randomly selected patients representing different doctors.

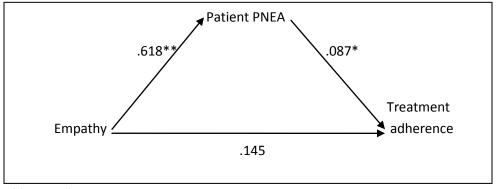
Hypothesis Testing: Mediation Analysis and Bootstrap Procedure

Hypotheses for the study were tested by conducting Modified Baron and Kenny mediation analysis, as described in the data analysis section, using HLM 6.0 software and Bootstrap procedure. Each hypothesis was tested while controlling for all the other predictors simultaneously.

Tests for Hypothesis 1a and 1b

Modified Baron and Kenny mediation analysis showed that the predictor variable of Empathy was positively and significantly related to the mediator variable of Patient PNEA (path a in Figure 5), Unstandardized Coeff.=0.618, SE=0.142, t(24)=4.349, p<0.01. Also, the mediator variable of Patient PNEA was positively and significantly related to the outcome variable of Treatment Adherence (path b in Figure 5), Unstd. Coeff.=0.087, SE=0.376, t(24)=2.333, p<0.05. This establishes a relationship between Empathy and Treatment Adherence, such that an increase in patient Empathy is related to an increase in Treatment Adherence. Thus, hypothesis 1a is supported.

Furthermore, there was an insignificant relationship (path c' in Figure 5) between the independent variable of Empathy and the dependent variable of Treatment Adherence, when the mediator variable was controlled, Unstd. Coeff =0.145, SE=0.097, t(24)=1.489, p>0.05. This implies that the relationship between Empathy and Treatment Adherence is completely mediated by Patient PNEA. Thus hypothesis 1b is supported. The path of the mediation is diagrammed in Figure 15.



P**<.01, P*<.05

Figure 15. Completely mediated model for empathy and treatment adherence

The results of the bootstrap test (Table 20) showed that a bootstrapped 95% Confidence Interval (CI) for the mediated or indirect effect was significant, as the 95% CI excluded zero (0.467; CI: 0.316 to 0.613 with 5000 resamples).

Tests for Hypothesis 2a and 2b

Modified Baron and Kenny mediation analysis results show that the predictor variable of Trust was positively and significantly related to the mediator variable of Patient PNEA (path a in Figure 5), Unstd. Coeff.=0.214, SE=0.079, t(24)=2.691, p<0.05. Also, the mediator variable of Patient PNEA was positively and significantly related to the outcome variable of Treatment Adherence (path b in Figure 5), Unstd. Coeff.=0.087, SE=0.376, t(24)=2.333, p<0.05. This substantiates a relationship between Trust and Treatment Adherence, such that an increase in patient Trust is related to an increase in Treatment Adherence. The results support hypothesis 2a.

Additionally, there was an insignificant relationship (path c' in Figure 5) between the independent variable of Trust and the dependent variable of Treatment Adherence, when the mediator variable was controlled, Unstd. Coeff.=0.134, SE=0.079, t(24)=1.697, p>0.05. This implies that the relationship between Trust and Treatment Adherence is completely mediated by Patient PNEA. Thus hypothesis 1b is supported. Figure 16 presents the mediation paths.

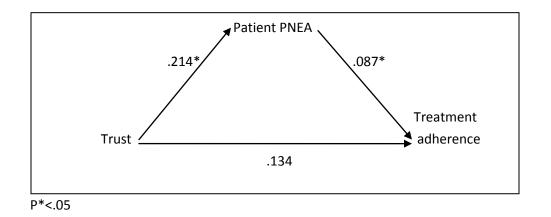


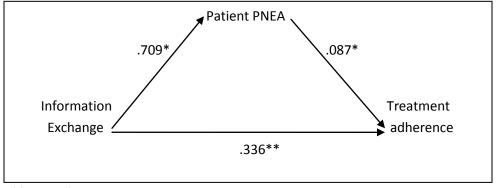
Figure 16. Completely mediated model for trust and treatment adherence

Table 20 delineates the results of the bootstrap procedure. The Indirect effect was found significant at 95% bootstrapped Confidence Interval level (0.476; CI: 0.377 to 0.554 with 5000 resamples).

Tests for Hypothesis 3a and 3b

Results of Modified Baron and Kenny mediation analysis show that the predictor variable of Information Exchange was positively and significantly related to the mediator variable of Patient PNEA (path a in Figure 5), Unstd. Coeff.=0.709, SE=0.254, t(24)=2.789, p<0.05. Also, the mediator variable of Patient PNEA was positively and significantly related to the outcome variable of Treatment Adherence (path b in Figure 5), Unstd. Coeff.=0.087, SE=0.376, t(24)=2.333, p<0.05. This establishes a relationship between Information Exchange and Treatment Adherence, such that an increase in patient Information Exchange is related to an increase in Treatment Adherence. Thus hypothesis 3a is supported.

However, there was a significant relationship (path c' in Figure 5) between the independent variable of Information Exchange and the dependent variable of Treatment Adherence, when the mediator variable was controlled, Unstd. Coeff.=0.336, SE=0.106, t(24)=3.160, p<0.01. This implies that the relationship between Information Exchange and Treatment Adherence is partially mediated by Patient PNEA. Hypothesis 1b is thereby supported. The path of the mediation is diagrammed in Figure 17.



P**<.01, P*<.05

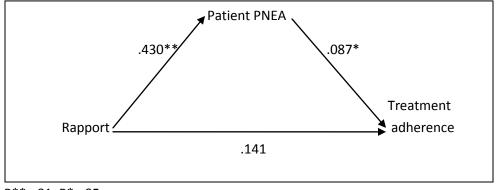
Figure 17. Partially mediated model for information exchange and treatment adherence

The results of the bootstrap test (Table 20) showed that a bootstrapped 95% Confidence Interval (CI) for the Indirect effect was significant as the 95% CI excluded zero (0.300; CI: 0.142 to 0.469 with 5000 resamples).

Tests for Hypothesis 4a and 4b

Modified Baron and Kenny mediation analysis results show that the predictor variable of Rapport was positively and significantly related to the mediator variable of Patient PNEA (path a in Figure 5), Unstd. Coeff.=0.430, SE=0.129, t(24)=3.319, p<0.01. Also the mediator variable of Patient PNEA was positively and significantly related to the outcome variable of Treatment Adherence (path b in Figure 5), Unstd. Coeff.=0.087, SE=0.376, t(24)=2.333, p<0.05. This substantiates a relationship between Rapport and Treatment Adherence, such that an increase in patient Rapport is related to an increase in Treatment Adherence. The results support hypothesis 4a.

Additionally, there was an insignificant relationship (path c' in Figure 5) between the independent variable of Rapport and the dependent variable of Treatment Adherence, when the mediator variable was controlled, Unstd. Coeff.=0.141, SE=0.133, t(24)=1.060, p>0.05. This implies that the relationship between Rapport and Treatment Adherence was completely mediated by Patient PNEA. Thus hypothesis 4b is supported. Figure 18 represents the mediation path.



P**<.01, P*<.05

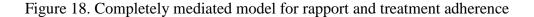


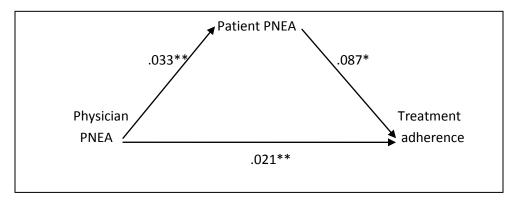
Table 20 delineates the results of the bootstrap procedure. The mediated or indirect effect was found significant at 95% bootstrapped Confidence Interval level (0.535; CI: 0.361 to 0.708 with 5000 resamples).

Tests for Hypothesis 5a and 5b

Modified Baron and Kenny mediation analysis results show that the relationship between the predictor variable of Shared decision-making and the mediator variable of Patient PNEA was insignificant (path a in Figure 5), Unstandardized Coeff.=0.086, SE=0.061, t(24)=1.416, p>0.05. The mediator variable of Patient PNEA was, however, significantly related to the outcome variable of Treatment Adherence (path b in Figure 5), Unstd. Coeff.=0.087, SE=0.376, t(24)=2.333, p<0.05. Since the relationship between the predictor variable of Shared decision-making and the mediator variable of Patient PNEA (path a) was insignificant, therefore, based on Modified Baron and Kenny analysis, no mediation exists (Kenny, Kashy, & Bolger, 1998). In addition, to test the possibility of a direct relationship between Shared-decision making and Treatment Adherence, step 1 of the Classical Baron and Kenny mediation analysis (1986) was run. The results showed that no relationship existed between Shared decision-making and Treatment Adherence (Unstd. Coeff.=0.067, SE=0.055, t(24)=1.224, p>0.05). The findings, therefore, do not support hypothesis 5a or 5b.

Tests for Hypothesis 6

Modified Baron and Kenny mediation analysis results show that the predictor variable of Physician PNEA was significantly related to the mediator variable of Patient PNEA, Unstd. Coeff.=0.127, SE=0.033, t(23)=3.842, p<0.01 and the mediator variable of Patient PNEA was significantly related to the outcome variable of Treatment Adherence, Unstd. Coeff.=0.087, SE=0.376, p<0.05. The relationship between Physician PNEA and the dependent variable of Treatment Adherence, when the mediator variable was controlled, was also found to be significant, Unstd. Coeff.=0.080, SE=0.021, t(23)=3.782, p<0.01. This implies that the relationship between Physician PNEA and Treatment Adherence was partially mediated by Patient PNEA. Hypothesis 6 is thereby supported.



P**<.01, P*<.05

Figure 19. Partially mediated model for physician PNEA and treatment adherence

The results of the bootstrap test (Table 20) showed that a bootstrapped 95% Confidence Interval (CI) for the Indirect effect was significant, as the 95% CI excluded zero (0.273; CI: 0.217 to 0.329 with 5000 resamples).

Tests for Hypothesis 7a and 7b

Modified Baron and Kenny mediation analysis results show that the relationship between the predictor variable of Co-morbid Depression and the mediator variable of Patient PNEA was insignificant (path a in Figure 5), Unstd. Coeff.=-0.708, SE=0.874, t(24)=-0.810, p>0.05. The mediator variable of Patient PNEA was significantly related to the outcome variable of Treatment Adherence (path b in Figure 5), Unstd. Coeff.=0.087, SE=0.376, t(24)=2.333, p<0.05. However, since the relationship between the predictor variable of Co-morbid Depression and the mediator variable of Patient PNEA was insignificant, therefore, no mediation exists (Kenny, Kashy, & Bolger, 1998). Moreover, step 1 of the Classical Baron and Kenny mediation analysis (1986) was run, and it was found that no direct relationship existed between Co-morbid Depression and Treatment Adherence (Unstd. Coeff.=-1.046, SE=0.506, t(24)=-2.066, p>0.05). The results, therefore, do not support hypothesis 7a or 7b.

Tests for Hypothesis 8a and 8b

Results of Modified Baron and Kenny mediation analysis show that the predictor variable of Social Support was insignificantly related to the mediator variable of Patient PNEA (path a in Figure 5), Unstd. Coeff.=0.139, SE=0.196, t(24)=0.709, p>0.05. The mediator variable of Patient PNEA was significantly related to the outcome variable of Treatment Adherence (path b in Figure 5), Unstd. Coeff.=0.087, SE=0.376, t(24)=2.333, p<0.05. Since the relationship between the predictor variable of Social Support and the mediator variable of Patient PNEA was insignificant, therefore no mediation exists (Kenny, Kashy, & Bolger, 1998). Additionally, step 1 of the Classical Baron & Kenny's mediation analysis (1986) was run, and it was found that no direct relationship existed between Social support and Treatment Adherence (Unstd. Coeff.=0.040, SE=0.143, t(24)=0.285, p>0.05). The results, therefore, do not support hypothesis 8a or 8b.

Tests for Hypothesis 9a and 9b

Modified Baron and Kenny mediation analysis results show that the predictor variable of Diabetes Knowledge was positively and significantly related to the mediator variable of Patient PNEA, (path a in Figure 5), Unstd. Coeff.=0.182, SE=0.107, t(24)=1.699, p<0.1. Moreover, the mediator variable of Patient PNEA was positively and significantly related to the outcome variable of Treatment Adherence (path b in Figure 5), Unstd. Coeff.=0.087, SE=0.376, t(24)=2.333, p<0.05. This establishes a relationship between Diabetes Knowledge and Treatment Adherence, such that an increase in patient

Diabetes knowledge is related to an increase in Treatment Adherence. Thus, hypothesis 9a is supported.

Furthermore, there was an insignificant relationship (path c' in Figure 5) between the independent variable of Diabetes Knowledge and the dependent variable of Treatment Adherence, when the mediator variable was controlled, Unstd. Coeff.=0.018, SE=0.035, t(24)=0.514, p>0.05. This implies that the relationship between Diabetes Knowledge and Treatment Adherence was completely mediated by Patient PNEA. Thus, hypothesis 9b is supported.

The results of the bootstrap test (Table 20) showed that a bootstrapped 95% Confidence Interval (CI) for the Mediated or Indirect effect was significant, as the 95% CI excluded zero (0.419; CI: 0.217 to 0.329 with 5000 resamples).

Predictor	Estimate	S.E	95% CI	
			LL	UL
Empathy	.4671	.0756	.3166	.6136
Trust	.4768	.0451	.3776	.5546
Information Exchange	.3006	.0829	.1424	.4692
Rapport	.5355	.0891	.3613	.7080
Physician PNEA	.2739	.0276	.2176	.3290
Diabetes Knowledge	.4199	.0634	3023	.5522

Table 20. Bootstrap results for mediated effects

The figure below with all the variables in the model summarizes indirect path results, which are considered by Kenny, Kashy, and Bolger (1998) as "essential" (p. 260) in establishing mediation.

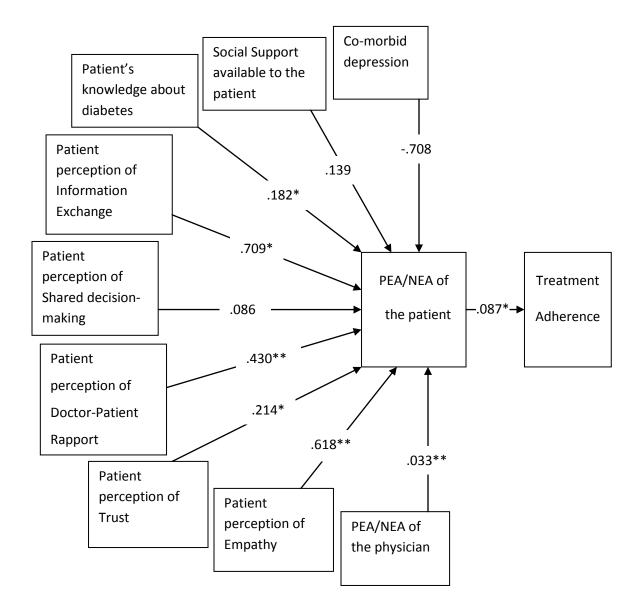


Figure 20. Summary of indirect mediation paths with all variables in the model

Table 21. Hypotheses and Results summary

	Hypothesis	Result
H1a	Empathy increases Treatment adherence	Supported
H1b	Patient PNEA mediates the relationship between Empathy and Treatment adherence	Completely mediated
H2a	Trust increases Treatment adherence	Supported
H2b	Patient PNEA mediates the relationship between Trust and Treatment adherence	Completely mediated
H3a	Information exchange increases Treatment adherence	Supported
H3b	Patient PNEA mediates the relationship between Information exchange and Treatment adherence	Partially mediated
H4a	Rapport increases Treatment adherence	Supported
H4b	Patient PNEA mediates the relationship between Rapport and Treatment adherence	Completely mediated
H5a	Shared decision-making increases Treatment adherence	Not Supported
H5b	Patient PNEA mediates the relationship between Shared decision-making and Treatment adherence	Not mediated
H6	Patient PNEA mediates the relationship between Physician PNEA and Treatment adherence	Partially mediated
H7a	Co-morbid depression decreases Treatment adherence	Not Supported
H7b	Patient PNEA mediates the relationship between Co- morbid depression and Treatment adherence	Not mediated
H8a	Social Support increases Treatment adherence	Not Supported
H8b	Patient PNEA mediates the relationship between Social Support and Treatment adherence	Not mediated
H9a	Diabetes knowledge increases Treatment adherence	Supported
H9b	Patient PNEA mediates the relationship between Diabetes knowledge and Treatment adherence	Completely mediated

CHAPTER V: DISCUSSION

This chapter begins with a discussion of the study findings. Subsequently, implications of the research findings, and the limitations of the study are discussed. Finally some suggestions for future research are outlined.

Discussion of Findings from Sample Characteristics

The descriptive statistics suggest that many of the characteristics of the sample population in this study are similar to that reported in other epidemiological studies on type 2 diabetes patients. Diabetes type 2 was more common among men (54%) than women (46%). Similar gender distributions of diabetes type 2 patients have been reported recently in diabetic epidemiological research studies from other parts of the world (e.g., Grant et al., 2009). The sample had a mean age of 55 years for the diabetic patients, which is also similar that to that found in other epidemiological studies (Grant et al., 2009).

Also of interest is the patient's average monthly household income of US \$262 in the sample. Recent studies have reported a figure of US \$90 as the average monthly household income in the rural areas of Pakistan (Lloyd, Mete, & Grant, 2009). However, since the average urban area income (the study was conducted in an urban setting) is almost three times that of rural areas (Langidrik, et al., 2007), a patient's household income in the sample is about the same as the expected average household income for an urban area dwelling in Pakistan. This gives credence to the notion that type 2 diabetes is not a disease afflicting only the affluent anymore, but is affecting average households. The demographic statistic of about three previous visits by the patient to the physician's clinic indicated that although these were follow-up visits, they were not long-term patients of these physicians. This is what was desired in this study, since long-term visitations could have potentially positively biased the patient's perception about the doctor.

The average age of the physicians in this study was 44 years, which is similar to the average age of all the physicians in the United States who are active in patient care (HRSA, 2008). The gender distribution of physicians with about 25% of female doctors in the study roughly corresponds to the gender distribution of physicians in the United States (HRSA, 2008).

However, some of the descriptive statistics in this study were different from those reported from Western samples in the literature. The average number of adults reported per household in the United States is 2.11 (Abegunde & Stanciole, 2008) while the average number of adults in the household of the patients in this study was 7.06. This is due to the fact that people usually live in joint family systems in Pakistan. This statistic, likely had an impact on the variable of Social support, which was assessed in the study. Not surprisingly, the high mean values for Social support items in the study, presumably indicated that the greater family size helped in the availability of support to the patient. Additionally, the prevalence of co-morbid depression in diabetic patients in the study was about 24%. This is much less than the recently reported figure of 35% in a study conducted in a Western European country (Pouwer et al., 2010).

Discussion of Findings from Exploratory Factor Analysis

A large quantity of missing data on an item may reflect that the item is not clear or that the item is not applicable to the study population. A number of cases had no response to item 40, "Overall it feels good to be here". Given the context that the survey is being administered to patients in a clinical setting, the item may be confusing. Very few, if anyone, feel "good" about visiting a doctor's clinic, even though it may be in their own interest. With hardly any concept of regular medical check-up in Pakistan, a clinic or hospital visits tend to stigmatize the person to some extent as a "sick" person. In this context, the term "feeling good" to come to a clinic, may have made the item ambiguous.

The descriptive analysis also showed that the items related to Social support had high means (>4). Thus the respondents perceived that they had a high level of Social support from their family and friends. Furthermore, relatively higher means for Diabetes knowledge items indicated correct responses. The high means for Diabetes knowledge items and low dispersion (standard deviation) shows that the patients were generally well informed about the basic etiology, pathophysiology and management of diabetes, to which the items related. This is not surprising, since the government in Pakistan constantly makes an effort to disseminate knowledge about diabetes through state-run television channels and radio, newspapers and other media outlets. In addition, diabetes health education programs are conducted in all hospitals and most large clinics across cities.

The patient instrument was found appropriate for factor analysis. The most positive indicators for a successful factor analysis are Bartlett's test of sphericity and the Kaiser-Meyer-Olkin Measure of Sampling Adequacy. Visual inspection of the correlation matrix had raised some initial questions regarding the suitability of factor analysis since a few

variables were not correlated. However, the strength of the Kaiser-Meyer-Olkin measure of Sampling Adequacy and Bartlett's test suggested that there was a high probability that the correlation matrix had significant correlations among the variables, which made factor analysis an appropriate method of analysis for this study. Nine latent factors emerged from Exploratory Factor Analysis (EFA) of the patient instrument. These factors were labeled Empathy, Diabetes knowledge, Shared decision-making, Social support, PNEA-Vision, Trust, Information exchange, PNEA-Overall mood and Rapport. These EFA results were not a surprise since only well-validated scales were used in this study. All of the items possessed adequate primary factor loadings on the appropriate factors, based on a cut-off point of 0.4, which was chosen as the threshold. Two items of the empathy scale had a secondary loading of 0.32 on the PNEA overall-mood scale. However, all the items on both these scales held together well. Furthermore, both the scales assessed very different concepts, with one measuring the patient's perception of empathy in a clinical encounter, and the other measuring the overall mood of the patient. A secondary loading of 0.32 is not very high, and in fact some investigators consider a higher threshold of >0.40 for secondary loading (Meyer, 2009; Ng et al., 2009). Deletion of none of the items would have substantially increased the alpha coefficient for the scales; therefore, all the items were retained as part of the measures. Eight of the nine scales had adequate internal reliability (Standardized α >0.7) except Social support scale, which had a Standardized alpha of 0.69. The reason for the relatively low alpha for Social support could be attributed to the small number of items constituting the scale (only 3 items). Similarly, the physician and the patient companion instruments revealed a bi-dimensional (labeled PNEA-Vision and PNEA-Overall mood) and a uni-dimensional (labeled Treatment adherence) structure

respectively, and showed adequate internal consistency (Standardized α >0.7) for the subscales.

Discussion of Findings from Confirmatory Factor Analysis

As expected, the Confirmatory Factor Analysis substantiated the results of the Exploratory Factor Analysis. However, minor modification was required for the two factors of the physician instrument. The modification process was assisted by the AMOS output, which generates modification indices to help assess what paths may be added or removed to improve the empirical fit of the proposed model to the data (Burant, 2008). The modification indices suggested addition of two paths amongst the measurement error terms of the factors, to help improve the goodness-of-fit. Model re-specification was carried out not solely on the basis of modification indices, but also based on logic and theory. Theoretically, the correlated errors maybe a result of method effect (Brown, 2006). Method effect may stem from similarly worded assessment items, social desirability or acquiescence (Podsakoff, Mackenzie, Lee, & Podsakoff, 2003). The item "coming to this office makes me feel good" and item "overall it feels good to come to my office" are similarly worded and have almost the same meaning. Related wordings are also present amongst items "the patients and I spoke of a healthy image of their future" and "our future will be better than the past". Thus, it is likely that the error covariance amongst the items is not based on substantively important elements, but associated with item wordings (Marsh, 1996). Other reasons for the items on the factors to be closely related and have correlated error terms, could be because of social desirability issues (Brown, 2006), which one could expect in a communal society like Pakistan where the survey was conducted.

Discussion of Findings from Mediation Analysis

While the extant literature indicates that a number of psychosocial variables of doctor-patient relationship are related to treatment adherence, the process linking them has remained elusive. This dissertation proposes a mediating process to explain that mechanism. By doing so, it brings to center-stage, the role of Positive Emotional Attractor and Negative Emotional Attractors (PEA/NEA) in the realm of doctor-patient interaction, with its consequent research and clinical implications.

The main purpose of the study was to study the mediating role of PEA/NEA between the psychosocial variables of doctor-patient interactive relationship and that of Treatment adherence. This study was guided by nine hypotheses. Six of these were related to psychological aspects of the relationship. The other three assessed the social support, impact of co-morbid depression and the patient's knowledge about diabetes.

All the hypotheses were tested using multilevel modeling software (HLM 6.0). HLM analysis helps to account for the nested nature of data involved in patient-physician studies, which have been previously ignored in many research designs. The analysis of some of those previous studies involving treatment adherence and other outcomes may be misleading, since consequences of group membership were usually not evaluated. The use of HLM techniques for this study controls for the influence of clustered data.

It is appropriate to conduct Mixed model analysis (HLM) if the Intra-class Correlation (ICC) is greater than 0.05 (Johnsrud & Rosser, 2002). The calculation of ICC is the initial component of HLM analysis, and the point of departure of multilevel models from OLS regression. Since an ICC of 0.41 was obtained for this study through HLM analysis, therefore, it indicated that in this dataset, treatment adherence was clustered by doctors.

Mediation analysis showed that a patient's perception of empathy, trust, information exchange, rapport, and patient's knowledge of diabetes, was positively and significantly related to treatment adherence (H1a, H2a, H3a, H4a and H9a supported). These findings are in keeping with many of the earlier research studies reported in the literature (Gilbert and Hayes, 2009; Gordon, Street, Sharf, & Souchek, 2006; Hopfield, Linden & Tevelow, 2006; Chew, Bradley, Flum, Corina, & Koepsell, 2004; Dimatteo, 2004; Kim, Kaplowitz, & Johnston, 2004; Davies & Rundall, 2000).

The results also revealed that the relationships of empathy, trust, rapport and diabetes knowledge with that of treatment adherence were completely mediated by patient PNEA (H1b, H2b, H4b, and H9b supported); whereas the relationships of information exchange and physician PNEA with treatment adherence were only partially mediated by patient PNEA (H3b and H6). According to Kenny, Kashy, and Bolger (1998), complete mediation entails that the mediator is the key variable that accounts for the relationship between the independent and the dependent variable; whereas partial mediation denotes that there are variables other than the mediator that also explain the relationship. The findings of complete mediation in this study are of vital importance. They imply that the mediation by patient PNEA is the primary mechanism that accounts for the relationship between the antecedent(s) of empathy, trust, rapport and diabetes knowledge, and the outcome of treatment adherence. These are crucial empirical findings as they highlight the pivotal role of a patient's emotional state. These findings are also important since this is the first known study in which the mechanism by which psychosocial variables of the doctor-

patient relationship and treatment adherence relate to each other has been explored, using patient PNEA as a mediator. By helping to understand the mechanism, this research study adds to existing literature.

Figure 21 below obtained from HLM, depicts the relationship between patient PNEA scale and Treatment adherence per doctor.

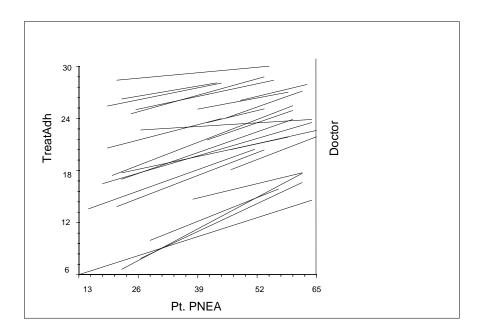


Figure 21. Relationship between patient PNEA and treatment adherence per doctor

High scores on the PNEA scale indicate a positive emotional state whereas lower scores represent a negative emotional state. Treatment adherence scores range from 6 to 30, and the patient PNEA scores range from 13 to 65. The graph above shows high variance in adherence at any level of patient PNEA. Notably, Figure 21 illustrates that positive emotional state in the patient is related to greater treatment adherence, whereas a negative emotional state is related to lower levels of treatment adherence, across doctors. This

pattern holds true for the patients of each doctor as well. These findings make sense because positive emotions, represented in this study by the Positive Emotional Attractor, help a person to focus on future possibilities and instill hope in that person. Positive Emotional Attractor can also help make a person more creative and flexible in approaching a problem. Thus, in the light of the above findings, a diabetic patient who is in a positive emotional will be more flexible and amenable to change. Such a patient would remain appropriately focused on what he/she needs to do to recuperate. As a result, such individuals would be more likely to adhere to the treatment regimen that has been prescribed. As opposed to this, a diabetic patient who is in a negative emotional state is less hopeful about the future and not amenable to change. Consequently, such a patient is not willing to alter his/her behavior and adhere to the lifestyle change that a diabetic treatment regimen entails. A closer examination of the figure also suggests the presence of two or three treatment adherence clusters. Although not very clear, the lower cluster (i.e. the lower five lines in the graph) seems to have comparatively steeper slopes. This would imply that there is more variance in patient treatment adherence for doctors who also have poorly compliant patients. Conversely for the upper cluster, there is comparatively less variance in patient treatment adherence for doctors who do not have poorly compliant patients. The latter could possibly be due to ceiling effect. In large datasets, the suggestive clustering could be inquired into by splitting the data. However, since the current sample is at the lower threshold of the required sample size for HLM analysis, therefore splitting the data is not feasible for this study. The pattern could perhaps be investigated in future studies with larger sample size, and richer data, which include detailed characteristics of the medical centers, physicians etc.

The results of the mediation analysis did not support any relationship between a diabetic patient's perception of Shared decision-making, Social support or presence of Comorbid depression with treatment adherence (H5a, H5b, H7a, H7b, H8a and 8Hb not supported). These findings contradict earlier studies which have reported a relationship between these variables (Cames et al., 2008; Whitney et al., 2008; Chlebowy & Garvin, 2006; Goldring et al., 2002). The variable of Shared decision-making was chosen as one of the predictors in this research, based on several previous studies which found a relationship between Shared decision-making and Treatment adherence in diseases in general, but not specifically diabetes. Shared decision-making entails reaching a consensus between the doctor and the patient about issues such as dosage and time of medication intake, size of pill, etc. However, an analysis of the pharmacotherapeutics of diabetes makes it clear why Shared decision-making does not have a role in the management of diabetes. While in many diseases such as bacterial infections, patients might have the option to choose a oncea-day or twice-a-day antibiotic pill, and those of different potencies; the medications for diabetes have to be taken usually at an exact time, and in specific dosages in order for the blood sugar levels to be regulated optimally. Furthermore, with regards to exercise for diabetes management, the current security situation in that region of the world is such that it is difficult to chart out exercise plans. Whenever there is an incident which disrupts the law and order and situation, which unfortunately is becoming more frequent, people avoid venturing out of their homes to gymnasiums for workout, or going to parks for walk. Furthermore, cultural issues might also be involved. It is possible that Pakistanis have a lower expectation of having a say or partaking in the decision-making, as "power distance" is higher in Pakistan, as compared to the United States. Thus, there may not be much room

for Shared decision-making to take place. This was also evident from the relatively low mean values reported for items related to the Shared decision-making variable, by diabetic patients in this study.

It may also seem counter-intuitive at first that Social support would not be a predictor of patient PNEA as reported in the study findings. However, if we analyze the society of Pakistan, where the study was conducted, we can make sense of this result. Pakistan, like a number of other developing Asian countries, is communal in nature, where people live in joint family systems. This is evidenced by the demographic statistics in this dataset (Table 2), which shows that a majority of the household have an average of more than 7 adult persons living in it. The Social support available is ubiquitous. This was also borne out in this research by the fact that almost every patient who came for the outpatient clinic visit had a household companion to assist him/her in the clinic. The descriptive analysis also showed a high level of Social support (as discussed earlier), as the mean for the Social support items were high. This implies that most of the patients believed that they had high levels of Social support. However, this Social support did not elicit an Emotional state in the patient, as evidenced from results of mediation analysis. Although this might sound foreign in societies like that of the United States and many countries in Western Europe, the ubiquity of Social support available in Pakistan may be responsible for it being less appreciated in that society. Thus, a plausible explanation for the study findings could be that the patients take Social support for granted and therefore it does not arouse a significant emotional state in them.

This study also did not find co-morbid depression in diabetics to be significantly related to treatment adherence, as opposed to some previous studies conducted in Western countries (Ciechanowski, Katon, & Russo, 2000). While there could be many possible reasons, it was found that the percentage of co-morbid depression in diabetes in this study was less than those in recent epidemiological investigations conducted in some Western countries (Pouwer et al., 2010). Furthermore, when depression symptoms reach a certain threshold, it is termed as clinical depression (Heiby, 1986), and that is when it is more likely to negatively affect emotions and lifestyle behaviors. Clinical depression could therefore affect treatment adherence but non-clinical depression would probably have little or no affect. In this study diabetic patients with both clinical and non-clinical depression were present. Thus, it is possible that many of those in this study were not clinically depressed, and consequently had no negative impact on treatment adherence.

Implications for Research

This study contributes new findings and provides an empirical design to explain the mechanism for the relationship between psychosocial variables of doctor-patient relationship and treatment adherence. The study also lends support to the Intentional Change Theory (ICT) (Boyatzis, 2006). In doing so, it brings to center-stage, the role of Positive and Negative Emotional Attractors within the framework of Boyatzis' ICT model (Figure 1).

The first stage of the ICT model is the Ideal self. In this stage, PEA can help produce an image to emerge from a person's aspirations. This instills hope in that person. A diabetic patient who has a high level of PEA will be hopeful, as studies have consistently shown that an inextricable link exists between positive emotions and hopefulness (Magaletta & Oliver, 1999; Cramer & Drykacz, 1998; Snyder, Hoza, Pelham et al., 1997). Thus, positive emotions instill hope for a better and healthy future for the diabetic patient (Stage 1 of ICT). Treatment adherence involves change in behavior, and positive emotions can lead to behavior modification in the diabetic patient, which relates to the Experimentation stage (Stage 4) of the ICT model. This so happens because positive emotions have been shown to lead to openness, greater degree of flexibility and willingness to change (explained in detail earlier). Hence, PEA may give confidence to overcome the uncertainty of engaging in new behaviors. Thus, a diabetic patient who has a high level of PEA is more willing to experiment with the prescribed treatment regimens, which in most cases involve life-changing behaviors. This then supports the notion that PEA helps sustain desired change (Boyatzis, 2006).

This study also sought to establish methodological improvement over previous literature related to physician-patient relationship. Prior studies on doctor-patient relationship in clinical settings have mostly ignored multilevel issues. The research recognized the nested nature of physician-patient interactions and therefore appropriately used multilevel modeling to test the hypotheses.

Lastly, this study helps extend the research base beyond the United States and Western Europe. Most of the published research in the arena of physician-patient relationship is confined to sample populations from Western countries, which have been systematically studied. This study is, therefore, a useful addition to literature providing insight into the complex doctor-patient relationship in a communal Eastern culture.

Implications for Practice

There are practical implications that emerge based on this research. There could potentially be huge implications of this study on the management of diabetes. One of the biggest practical implications is in the realm of diabetic education, provided by counselors and clinicians. Identification of patient PNEA as a mediator will improve the effectiveness of intervention programs. It could also reduce costs, as resources can be appropriately focused on elements that enhance treatment adherence, in light of the study findings. Presently, in many countries a newly diagnosed diabetic patient goes through an educational and instructional program, in which the main focus is on informing the patients about the complications related to long-term diabetes. The programs frequently include shocking pictures of diabetic foot or amputations, presented to instill fear in such patients, in hopes of getting treatment compliance. The approach is obviously not working, as suggested by the low levels of treatment adherence. However, despite the fact that this approach does not work, it is still the default style. A recent study in Ireland (Lambe & Collins, 2010), documented the use of fear appeal as a "common approach" (p. 221) for lifestyle counseling in general medical practice. Similarly, Bonnar-Kidd, Black, Mattson, and Coster (2009) have recently acknowledged the "use of fear appeals in health promotion and health communication campaigns" (p.167).

This study suggests that it could be much more beneficial for diabetic educational programs, if the educators concentrate on the arousal of positive emotions in the patient and instill them with hope for a healthy future and a willingness to change their lifestyle. This could lead to much better treatment adherence with consequent health benefits. Thus,

this research provides insights into development of effective educational interventions which are designed to encourage behavior change.

Findings from the present study suggest that clinicians would benefit from better understanding the importance of tapping into a diabetic patient's emotional state. These could inform teaching strategies in medical schools. This includes training of medical professionals to conduct interviews in ways to evoke positive emotions during clinical encounters. Activation of a patient's Positive Emotional Attractor during the medical interview process would lead to willingness to change and consequent better treatment adherence, especially with the lifestyle changes required in diabetic patients. Awareness of how the physician can positively influence the patient may motivate clinicians to re-assess their medical interviewing skills.

Better treatment adherence by diabetics can result in a healthier future life, and potentially help avoid severe complications associated with the illness. This would prove to be physiologically, psychologically and financially helpful to the patient.

Limitations

In a convenience sample the researcher does not exercise control over the representativeness of the sample (Gravetter & Forzano, 2009). Since convenience sampling method was used in this study, it is possible that those diabetics agreed to participate who felt strongly about the issue being investigated (Sousa, Zauszniewski, & Musil, 2004). If that was the case, then the sample may not be representative of the population. This could

potentially affect the replicability and generalizability of the study (Rubin & Winrob, 2010).

A limitation of this study is that the items were not randomized in the surveys. This to some extent can result in self-consistent responses, which can potentially inflate internal reliability and make the results biased (Eiser, Eiser, & Havermans, 1995). Another limitation is the nature in which the survey data was collected. It was primarily self-reports from the patients. Self-reports are known to have in-built bias and have been criticized for over-estimating measures (Osterberg & Blaschke, 2005).

Given the sensitive nature of the data, it is possible that participants may have provided socially desirable responses to the survey. This could especially hold true in complex societies with high power distance, like Pakistan. In other words, respondents may have provided more positive response to questions to give the impression of better relationship with their caregivers.

It is possible that if the study had been conducted in another type of healthcare unit, then the results would have been different. Thus, for example, if diabetic patients were assessed in the emergency room, instead of obtaining data in the out-patient clinic, the adherence outcome might have been different. Furthermore, the presence of severe comorbidities such as diabetic encephalopathy can negatively influence cognitive functions (Manschot, et al., 2006). It is possible that these could have affected the responses of some participants who were suffering from such complications.

Since the study was conducted in an underdeveloped Asian country, a question remains as to the extent to which cross-cultural generalizability of this study to the developed countries of the West is possible. For example, due to cultural differences, perceived empathy and social support in a South Asian society may be different from the results of such a study in a large, inner-city medical clinic in the US. The research was conducted in a society which is more collectivist in nature as compared to the West. Therefore, the study findings may also have been influenced by patterns of relationships which are different as compared to more individualistic Western cultures.

No data regarding the centers in which the research was carried out were collected. This was a missed opportunity, since such information could have created the possibility of conducting a three-level HLM analysis.

Future Studies

This study is the first to examine the role of patient PNEA in a mediational model of treatment adherence. Therefore, while the results are interesting, they should be considered as preliminary findings, upon which future studies could build. Clearly, more research is needed in this area. There are several opportunities for future research based on this study. An obvious next step could be to assess treatment adherence with direct physiological measures as evidence of clinical outcomes, such as blood sugar levels in diabetic patients. This approach would increase the objectivity of the outcome variable.

Longitudinal studies are needed to gain better insight into the mechanisms and relationships associating medical interviews and treatment compliance over time. Such studies would involve medical interviews at one point of time and assessments of treatment adherence later on. Since diabetes is a chronic condition, such longitudinal studies would help give a more holistic assessment of compliance to treatment, over a period of time. Lastly, to overcome the generalizability issue, it would be desirable to test the study model in another culture by replicating the present study in a Western country. Since psychosocial variables are involved, different cultural settings could possibly lead to varied results. Therein, it would be interesting to compare any difference in findings on the basis of cultural distinctions.

Conclusion

In conclusion, this study provides an empirical design for a mediational model of treatment adherence in type 2 diabetes. This is the first study, to my knowledge, to investigate in an Eastern culture, the role of a patient's emotional state in the doctor-patient relationship, and how it affects adherence to treatment. Specifically, this research tested the proposition that a patient's positive and negative emotional states, represented by Positive and Negative Emotional Attractors (PNEA), mediate the relationship between the psychosocial variables of the doctor-patient relationship, and treatment adherence. Results show that patients' PNEA completely mediates the relationship of empathy, trust, rapport and diabetes knowledge with treatment adherence. In other words, a patient's perceived level of empathy, trust, rapport and diabetes knowledge is associated with improved treatment adherence, when the patient experiences positive emotions. Also, according to the results, higher levels of a patient's positive emotional state are related to higher levels of treatment adherence. Techniques related to arousing a positive emotional state in patients should therefore be employed in patient education, and taught in medical curriculum.

Adherence to diabetes treatment in the case of type 2 diabetes, requires behavior or life-style change. This study suggests that Positive and Negative Emotional Attractors may play an important role in bringing about a sustained, desired behavioral change, to help increase treatment adherence. In this way, the study findings also help validate Boyatzis' Intentional Change Theory. APPENDICES

Appendix - I

Information Exchange Scale (Patient survey)

My doctor is willing to share all relevant information with me

Communication between my doctor and me is excellent

My doctor is willing to answer all my questions

My doctor talked to me in words that I could understand

There is little communication between my doctor and myself

Appendix - II

Shared Decision-making Scale (Patient survey)

My doctor asks my advice regarding treatment options

I helped the doctor in planning my treatment

My doctor encourages suggestions about appropriate treatment of my illness

Both the doctor and I participated greatly in planning treatment of my illness

Together, my doctor and I set goals and discuss treatment options

Appendix - III

Rapport Scale (Patient survey)

I feel that there is bond between me and my doctor

I look forward to seeing my doctor when I visit the clinic/hospital

I strongly care about my doctor

My doctor takes personal interest in me

I have a close relationship with my doctor

Appendix - IV

Trust Scale (Patient survey)

I do not feel trusted by my doctor

I feel trusted by my doctor

I care about my doctor

I do not trust my doctor

I do not care about my doctor

I trust my doctor

Appendix - V

Empathy Scale (Patient survey)

My doctor understands me by listening attentively to me

My doctor understands the reasons for my actions

My doctor understands people even who are from different backgrounds

My doctor understands my point of view even when it is different from his own

My doctor tries to understand me by putting himself in my shoes

My doctor does not understand my inner feelings

Appendix - VI

PNEA Scale (shown here for patient survey; a modified version was used for physician survey)

My doctor gave me a healthy image of the futureMy doctor and I discussed possibilities for my futureOur future will be better than the pastI feel inspired by my doctor's positive future imageWe are focused on a healthy and positive future imageOur interaction created a healthy image of the futureThe doctor spoke about some of my positive qualitiesIt is good for me to come to this doctor's officeI am comfortable coming to this doctorI am not comfortable coming to this doctorComing here makes me feel goodIf I had a choice I would go somewhere elseOverall it feels good to be here

Appendix - VII

Diabetes Knowledge (Patient survey)

Diabetes is caused by failure of the kidneys to keep sugar out of the urine.

Diabetes can be cured

A fasting blood sugar level of 210 mg/dl is too high

Regular exercise will increase the need for insulin or other diabetic medication

Diabetes often causes poor circulation

Cuts and abrasions on diabetes heal more slowly

Diabetes can damage my kidneys

A diabetic diet consist mostly of special foods

Appendix - VIII

Social Support (Patient survey)

I can easily get help from family/friends if I need

I have close family/friends who I can count on if I have a serious problem

My family/friends show concern about me

Appendix - IX

Treatment Adherence Scale (Patient companion survey)

I never forget to take my medication

I am careless at times about taking my medicine

When I feel better I sometimes stop taking my medicine

If I feel worse by taking my medicine, then I stop taking it

I know the long-term benefits of taking medicine as told by my doctor

Sometimes I forget to refill/repurchase my prescription medicine on time

I adhere to the dietary advice given by my doctor

I adhere to the exercise regimen advised by my doctor

APPENDIX - X



TO BE FILLED BY THE PATIENT'S ATTENDANT

NOTE: This survey takes approximately 1 minute to complete.

Gender: Male / Female

Age: _____

Below you will find a series of statements about your doctor office visit. Using the scale on the

right, please encircle to indicate how much you agree or disagree with each statement. Please think

of the habits of the patient you are accompanying and answer the questions below.

1=Strongly Disagree, 2=Disagree, 3=Neutral, 4=Agree, 5=Strongly Agree					
1. The patient never forgets to take medication	1	2	3	4	5
2. The patient is careless at times about taking medicine	1	2	3	4	5
3. When the patient feels better he/she sometimes stop taking medicine	1	2	3	4	5
4. If the patient feels worse by taking the medicine, then he/she stops taking it	1	2	3	4	5
5. The patient adheres to the dietary advice of the doctor	1	2	3	4	5
6. The patient adheres to the exercise regimen advised by the doctor	1	2	3	4	5

APPENDIX – XI



TO BE FILLED BY THE PATIENT

NOTE: This survey takes approximately 12 minutes to complete.

Gender: Male/Female Age ____ Household Income _____ No. of adults in household: _____

No. of previous visits to this doctor: ____ Associated depression (diagnosed): Yes/No

Below you will find a series of statements about your doctor office visit. Using the scale on the right, please encircle to indicate how much you agree or disagree with each statement. **Please think** of your most recent outpatient visit to this doctor and answer the questions below.

1=Strongly Disagree, 2=Disagree, 3=Neutral, 4=Agree, 5=Strongly Agree					
1. My doctor is willing to share all relevant information with me	1	2	3	4	5
2. Communication between my doctor and me is excellent	1	2	3	4	5
3. My doctor is willing to answer all my questions	1	2	3	4	5
4. My doctor talks to me in words that I can understand	1	2	3	4	5
5. There is little communication between my doctor and myself	1	2	3	4	5
6. My doctor asks my advice regarding treatment options	1	2	3	4	5
7. I helped the doctor in planning my treatment	1	2	3	4	5
8. My doctor encourages suggestions about appropriate treatment of my illness	1	2	3	4	5
9. Both the doctor and I participated greatly in planning treatment of my illness	1	2	3	4	5
10. Together, my doctor and I set goals and discuss treatment options	1	2	3	4	5
11. I feel that there is a bond between me and my doctor	1	2	3	4	5

1=Strongly Disagree, 2=Disagree, 3=Neutral, 4=Agree, 5=Strongly Agree					
12. I look forward to seeing my doctor when I visit the clinic/hospital	1	2	3	4	5
13. I strongly care about my doctor	1	2	3	4	5
14. My doctor takes personal interest in me	1	2	3	4	5
15. I have a close relationship with my doctor	1	2	3	4	5
16. I do not feel trusted by my doctor	1	2	3	4	5
17. I feel trusted by my doctor	1	2	3	4	5
18. I care about my doctor	1	2	3	4	5
19. I do not trust my doctor	1	2	3	4	5
20. I do not care about my doctor	1	2	3	4	5
21. I trust my doctor	1	2	3	4	5
22. My doctor understands me by listening attentively to me	1	2	3	4	5
23. My doctor understands the reasons for my actions	1	2	3	4	5
24. My doctor understands people even if they are from diverse backgrounds	1	2	3	4	5
25. My doctor understands my point of view if it is different from his own	1	2	3	4	5
26. My doctor tries to understand me by putting himself in my shoes	1	2	3	4	5
27. My doctor does not understand my inner feelings	1	2	3	4	5
28. My doctor gave me a healthy image of the future	1	2	3	4	5
29. My doctor and I discussed possibilities for my future	1	2	3	4	5
30. Our future will be better than the past	1	2	3	4	5
31. I feel inspired by my doctor's positive future image	1	2	3	4	5
32. We are focused on a healthy and positive future image	1	2	3	4	5
33. Our interaction created a healthy image of the future	1	2	3	4	5

1=Strongly Disagree, 2=Disagree, 3=Neutral, 4=Agree, 5=Strongly Agree					
34. The doctor spoke about some of my positive qualities	1	2	3	4	5
35. It is good for me to come to this doctor's office	1	2	3	4	5
36. I am comfortable coming to this doctor	1	2	3	4	5
37. I am not comfortable coming to this doctor	1	2	3	4	5
38. Coming here makes me feel good	1	2	3	4	5
39. If I had a choice I would go to some other doctor	1	2	3	4	5
40. Overall it feels good to be here	1	2	3	4	5
41. Diabetes is caused by failure of the kidneys to keep sugar out of the urine	1	2	3	4	5
42. Diabetes can be cured	1	2	3	4	5
43. A fasting blood sugar level of 210 mg/dl is too high	1	2	3	4	5
44.Regular exercise will increase the need for insulin or other diabetic medication	1	2	3	4	5
45. Diabetes often causes poor circulation	1	2	3	4	5
46. Cuts and abrasions in diabetes heal more slowly	1	2	3	4	5
47. Diabetes can damage my kidneys	1	2	3	4	5
48. A diabetic diet consist mostly of special foods	1	2	3	4	5
49. I can easily get help from family/friends if I need	1	2	3	4	5
50. I have close family/friends who I can count on if I have a serious problem	1	2	3	4	5
51. My family/friends show concern about me	1	2	3	4	5

APPENDIX - XII



TO BE FILLED BY THE PHYSICIAN

NOTE: This survey takes approximately 2 minutes to complete.

Gender: Male / Female

Age: _____

Below you will find a series of general statements about patients who visit your office. Using the scale on the right, please encircle to indicate how much you agree or disagree with each statement. **Please think of**

your recent outpatient interaction with patients in general and answer the questions below.

1=Strongly Disagree, 2=Disagree, 3=Neutral, 4=Agree, 5=Strongly Agree					
1. The patients and I spoke of a healthy image of their future	1	2	3	4	5
2. The patients and I discussed possibilities for their future	1	2	3	4	5
3. Our future will be better than the past	1	2	3	4	5
4. I feel inspired by the patients' positive image	1	2	3	4	5
5. The patients and I are focused on a healthy future image	1	2	3	4	5
6. Our interaction produced a healthy image of the future	1	2	3	4	5
7. We spoke about some of the patients' positive qualities	1	2	3	4	5
8. It is good for me to come to my office	1	2	3	4	5
9. I am comfortable coming to my office	1	2	3	4	5
10. I am not comfortable coming to my office	1	2	3	4	5
11. Coming to this office makes me feel good	1	2	3	4	5
12. If I had a choice I would go somewhere else	1	2	3	4	5
13. Overall it feels good to come to my office	1	2	3	4	5

APPENDIX - XIII CASE WESTERN RESERVE UNIVERSITY EST. 1826

INFORMATION SHEET FOR THE PATIENT'S ATTENDANT

You are being asked to take part in a research study to help us get information about complying with physician's recommendations, regarding the patient whom you are accompanying today. Participation is voluntary and anonymous. Neither the researcher nor anybody else will be able to link as to who agreed to participate and who did not. Please read this and ask any questions that you may have before agreeing to be in the study.

The aim of this study is to increase our understanding of medical interview styles and the effect that they have on treatment adherence as recommended by the doctor for diabetes patients (Type 2). The findings of the study may contribute to the design of more effective medical interview techniques. If you agree to be in this study, we are asking you to complete the attached survey. You may fill out the survey form marked, To be filled by the patient's attendant, and return it to the researcher.

Filling the survey form will likely take not more than 1 minute. By completing the survey and returning you are indicating that you consent to participate. If you do not wish to participate, please do not return the survey. The study has no known or foreseeable risks. The benefits of participation are that the data you provide will contribute to the study described above and its potential benefits. These benefits are indirect. Therefore, there are no direct benefits to you.

<u>Confidentiality</u>: We will analyze the data we are collecting in aggregate (by combining all data collected and looking at them as a whole). None of the data we are collecting, or the reports of this study that we may publish in the future, will make it possible to identify a participant. In addition, all completed surveys will be kept in a locked cabinet and only the researcher named below will have access to them.

<u>Contacts and Questions</u>: The researcher for this study is Masud Khawaja. You may ask any questions you have now. If you have any questions later, you may contact the researcher by e-mail at <u>msk35@case.edu</u> or phone 92-3343518255 (Pakistan phone number)/ 1-732-371-8293 (USA phone number). If you would like to talk to someone other than the researcher about: (1) concerns regarding this study, (2) research participant rights, (3) research-related injuries, or (4) other human subjects issues, please contact University Hospitals Institutional Review Board at 1-216-844-1529 or write to Lakeside 1400, 11100 Euclid Avenue Cleveland, OH 44106, USA.

Please keep this information sheet for your records.



INFORMATION SHEET FOR THE PATIENT

You are being asked to take part in a research study based on your recent experience of doctor-patient interview in this consultant physician's office. Participation is voluntary and anonymous. There is no change in medical care whether you are or are not involved in the study. Neither the researcher nor anybody else will be able to link as to who agreed to participate and who did not. Please read this and ask any questions that you may have before agreeing to be in the study.

The aim of this study is to increase our understanding of medical interview styles and the effect that they have on treatment adherence as recommended by the doctor for diabetes patients (Type 2). The findings of the study may contribute to the design of more effective medical interview techniques. If you agree to be in this study, we are asking you to complete the attached survey. You may fill out the survey form marked, To be filled by the patient, and return it to the researcher.

Filling the survey form will likely take not more than 10 minutes. By completing the survey and returning in a sealed envelope, you are indicating that you consent to participate. If you do not wish to participate, please do not return the survey. The study has no known or foreseeable risks. The benefits of participation are that the data you provide will contribute to the study described above and its potential benefits. These benefits are indirect. Therefore, there are no direct benefits to you.

<u>Confidentiality</u>: We will analyze the data we are collecting in aggregate (by combining all data collected and looking at them as a whole). None of the data we are collecting, or the reports of this study that we may publish in the future, will make it possible to identify a participant. In addition, all completed surveys will be kept in a locked cabinet and only the researcher named below will have access to them.

<u>Contacts and Questions</u>: The researcher for this study is Masud Khawaja. You may ask any questions you have now. If you have any questions later, you may contact the researcher by e-mail at <u>msk35@case.edu</u> or phone 92-3343518255 (Pakistan phone number)/ 1-732-371-8293 (USA phone number). If you would like to talk to someone other than the researcher about: (1) concerns regarding this study, (2) research participant rights, (3) research-related injuries, or (4) other human subjects issues, please contact University Hospitals Institutional Review Board at 1-216-844-1529 or write to Lakeside 1400, 11100 Euclid Avenue Cleveland, OH 44106, USA.

Please keep this information sheet for your records.

APPENDIX - XV



INFORMATION SHEET FOR THE PHYSICIAN

You are being asked to take part in a research study based on your recent experiences of patient interviews. Participation is voluntary and anonymous. Neither the researcher nor anybody else will be able to link as to who agreed to participate and who did not. Please read this and ask any questions that you may have before agreeing to be in the study.

The aim of this study is to increase our understanding of medical interview styles and the effect that they have on treatment adherence as recommended by the physician for diabetic patients (Type 2). The findings of the study may contribute to the design of more effective medical interview techniques. If you agree to be in this study, we are asking you to complete the attached survey. You may fill out the survey form marked, To be filled by the physician, and return it to the researcher.

Filling the survey will likely take not more than 2 minutes. By completing the survey and returning it in a sealed envelope, you are indicating that you consent to participate. If you do not wish to participate, please do not return the survey form. The study has no known or foreseeable risks. The benefits of participation are that the data you provide will contribute to the study described above and its potential benefits. These benefits are indirect. Therefore, there are no direct benefits to you.

<u>Confidentiality</u>: We will analyze the data we are collecting in aggregate (by combining all data collected and looking at them as a whole). None of the data we are collecting, or the reports of this study that we may publish in the future, will make it possible to identify a participant. In addition, all completed surveys will be kept in a locked cabinet and only the researcher named below will have access to them.

<u>Contacts and Questions</u>: The researcher for this study is Masud Khawaja. You may ask any questions you have now. If you have any questions later, you may contact the researcher by e-mail at <u>msk35@case.edu</u> or phone 92-3343518255 (Pakistan phone number)/ 1-732-371-8293 (USA phone number). If you would like to talk to someone other than the researcher about: (1) concerns regarding this study, (2) research participant rights, (3) research-related injuries, or (4) other human subjects issues, please contact University Hospitals Institutional Review Board at 1-216-844-1529 or write to Lakeside 1400, 11100 Euclid Avenue Cleveland, OH 44106, USA.

Please keep this information sheet for your records.

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