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Relationship Between Health Literacy and End-Stage Renal Disease among Type II Diabetics

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Abstract

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MPH, Des Moines University, 2012

BA, Simpson College, 2007

Dissertation Submitted in Fulfillment

of the Requirements for the Degree of

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Abstract

The progression of End Stage Renal Disease (ESRD) among type II diabetics is preventable, yet complications continue to plague many. Reports show that 29.1 million people (9.3%) in the United States have diabetes, and 40% of those individuals develop ESRD. Four research questions explored the relationship between ESRD, health literacy, and healthcare. Data from 2010-2015 from the National Institute of Health (NIH) was quantitatively analyzed. The conceptual framework was the revised health service utilization theory. The target population included 3939 diverse males and females between the ages of 20-75 diagnosed with type II Diabetes. Results from Chi-square, cross-tabulation, binary, and multinomial logistic regression revealed that there is a statistically significant relationship between inadequate health literacy and ESRD ($p = <0.05$), inadequate health literacy and healthcare services ($p = <0.05$), and healthcare services and development of ESRD ($p = <.001$). Findings exposed significant demographic co-factor differences. Males developed ESRD more than females, and African American and Hispanic populations were almost 2 times more likely than Caucasians to develop ESRD. As participants age, odds for developing ESRD increase about 2-3 times. Both race and education were significant predictors of inadequate health literacy. African Americans and Hispanics were 3 times more likely to have inadequate health literacy than Caucasian participants. Lower education increased the odds of having inadequate health literacy approximately 7.6 times. Results show that Caucasian participants had higher education levels and private health insurance, whereas African Americans and Hispanics had lower education and no insurance or Medicaid. Implications from this research show that social determinants among vulnerable populations are impacting an individual's health literacy and ability to adequately manage their health. Evidence from this study generates social change through recognition that health literacy is fundamental when attempting to prevent chronic disease complications and promote positive health.

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Dedication

In dedication to my mother who passed away in 2014 due to ESRD complications associated with type II diabetes. Her joy of life, and ongoing dedication to continued learning instilled in me the motivation and dedication to strive for higher education. I would also like to recognize my best friend, my husband, and my three children for supporting me and sacrificing over the years as I have continued my education. Without your support, I could not have done this, and having you in my life has pushed me to want something better for all of us.

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Chapter 1: Introduction to the Study

Introduction

As the prevalence of diabetes continues to grow, so does the risk of associated complications relative to the disease (Diabetes Trends, 2010). For example, the incidence of end-stage renal disease (ESRD) in 2013 was more than 115,000 individuals and in 51,000 of those cases the primary cause was diabetes (United States Renal Data System, 2015). In past years, though ESRD was more commonly seen in cases of type I diabetics (Centers for Disease Control and Prevention [CDC], 2011), now more than 40% of individuals with ESRD have type II diabetes (United States Renal Data System, 2015). However, there are gaps in research on why diabetics continue to develop ESRD (Inzucchi et al., 2012). Despite prevention programs, interventions, multiple education approaches, and treatments, individuals with diabetes continue to experience complications (Kanwar et al., 2011). In this study, I examined if there is a relationship between low levels of understanding, associated risks, and unmanaged diabetes by measuring levels of health literacy among type II diabetes who develop ESRD. Routes of disease management and methods of delivery for medical information were researched to explore if there is a significant association between method of disease management and levels of health literacy.

The impact of potential positive social change offered by this research is that it can lead to a better understanding of how to effectively provide information to patients with diabetes, thereby supporting improved health literacy. This then could lead to improved disease management, improved diabetes educational programs, and reduced

prevalence of ESRD associated with diabetes, which can improve overall public health.

This chapter begins with background information on complications related to type II diabetes and the need to research this phenomenon. This chapter includes an outline of the gaps in the literature relative to health literacy and ESRD among type II diabetics. The problem, purpose of the research, nature of the study, and research questions are also described. Additionally, the theoretical framework is outlined, limitations and assumptions are acknowledged, and key terms and concepts are defined. Finally, the chapter includes a summary of the significance of this research.

Background

This study can contribute to public health by providing information that addresses gaps related to the impact that health literacy has on diabetic associated complications such as ESRD (Fox et al., 2012). Current information is limited regarding reasons why diabetes continues to progress to disorders such as ESRD even when treatment and medications are available (Fox et al., 2012). Additionally, there is controversy over why the prevalence of ESRD continues to remain prominent and why patient behaviors do not support healthy disease management (Collins et al., 2012). There are also debates among research, medical, and public health professionals as to what is the best method of effective disease management that supports health literacy (Bailey et al., 2014). Thus, I examined whether complications associated with diabetes are due to a lack of health literacy that limit healthy behaviors or if ESRD is related to other factors. This research can contribute to public health information by offering insight as to the best approach to reach diabetic patients to prevent ESRD.

Millions of individuals across the globe have been diagnosed with diabetes as well as a multitude of health complications related to diabetes (Inzucchi et al., 2012). Complications such as ESRD not only add a significant economic burden on the economy but also diminish an individual's quality and length of life. Improving health literacy and knowing the best method in which to effectively deliver medical information has the potential to prevent complications associated with diabetes.

Problem Statement

It has become increasingly recognized that diabetes is the primary cause of ESRD among type II diabetics (Chantrel et al., 1999). Diabetes is the single primary cause of ESRD in both the United States as well as across Europe (American Diabetes Association, 2014). Over the last decade, the number of type II diabetic patients with ESRD has doubled from approximately 6 million to 12 million in the United States alone (Kanwar, Sun, Xie, Liu, & Chen, 2011). The CDC (2011) reported that in 2010, 29.1 million people (9.3%) in the United States had diabetes, and 35-40% of those individuals had been afflicted with ESRD because of it. Though in the past complications such as diabetic nephropathy were more prevalent in type I diabetics, researchers claim that the statistics have changed (CDC, 2011). Experts emphasize that type II diabetes is preventable, and ESRD can be avoided (Inzucchi et al., 2012). With proper education, diet, and exercise, the disease and associated complications can be controlled and minimized (Kanwar et al., 2011). However, the occurrence of renal failure has amplified (Kanwar et al., 2011), though researchers are not sure if this is due to the number of individuals with type II diabetics tripling over the last two decades or because

medications allow diabetics to live longer even when the disease is not adequately controlled (Inzucchi et al., 2012). Concerns are that even though patients are treated, informed, and educated, long-term health outcomes with complications related to diabetes continue.

To understand and take control of personal health effectively, health literacy is essential (Tang, Pang, Chan, Yeung, & Yeung, 2008). However, research has shown that in the past more than 90 million Americans had literacy levels that were so low that they could not adequately function in today's health care settings (Rothman et al., 2004). Individuals with low literacy have had difficulty following medical advice correctly and did not understand their disease, leading to worse health outcomes (Rothman et al., 2004). Despite the significance of health literacy, there is a gap in research related to the effect health literacy has on long-term outcomes for diabetics (Al Sayah, Majumdar, Williams, Robertson, & Johnson, 2013). There is also controversy over which disease management method most effectively overcomes potential health literacy issues, and whether methods that better address health literacy can improve health outcomes and prevent diabetic complications such as ESRD. This study addressed these gaps through an exploration of the association between health literacy levels and type II diabetics who develop ESRD. The study can also provide insight as to whether the type of disease management diabetic patients receive has an impact on their level of health literacy. Diabetes is a costly condition that causes both morbidity and mortality, and ESRD extenuates both the economic burden as well as diminishes the quality of life for these individuals (Beulens, Grobbee, & Nealb, 2010). Associated complications related to

ESRD can add more than 35 billion dollars to the $245 billion dollars annually that burdens the U.S. economy (Beulens et al., 2010). Researchers have predicted that if effective solutions are not identified, the number of diabetics with kidney disease and ESRD will double over the next decade (Bailey et al., 2014).

Purpose of the Study

The purpose of this study was to use a quantitative approach to measure the relationship among type II diabetics who develop ESRD and their level of health literacy. There is limited research on the effects health literacy has on long-term health outcomes among type II diabetics. Few studies have included methods of disease management examining how medical information is delivered and the impact it has on health literacy and ESRD. The dependent variable in the study was ESRD among type II diabetics. The independent variables and covariates included health literacy and routes of delivery of medical information as methods of disease management. Additionally, variables such as age, race, education level, and gender were examined as covariates to measure statistical associations. I quantitatively measured different methods for providing health information within disease management and compare it to levels of health literacy and the outcome of ESRD. This research can offer insight as to which delivery methods of health information are the most appropriate based on education levels, supporting improved health literacy and reducing diabetes-related complications such as ESRD.

Research Questions and Hypothesis

Initially I investigated levels of health literacy among diabetic patients who developed ESRD and examined the routes of medical information delivery within disease

management. The initial research questions were as follows. Research Questions 2 and 3 however, had to be revised based on available data, which will be discussed in Chapter 4. The original research questions and hypotheses that were to guide this study include:

Research Question 1: Is there a relationship between inadequate levels health literacy and developing ESRD among type II diabetics, when controlling for confounding factors such as gender, education, race, and socioeconomic status?

$H_0$1: There is no relationship between inadequate levels of health literacy and developing ESRD among type II diabetics when controlling for confounding factors such as gender, education, race, and socioeconomic status.

H_a1: There is a relationship between inadequate levels of health literacy and developing ESRD among type II diabetics when controlling for confounding factors such as gender, education, race, and socioeconomic status.

Research Question 2: Is there an association between the method of disease management and an individuals' level of health literacy related to type II diabetes?

$H_0$2: There is no association between the method of disease management and an individuals' level of health literacy related to type II diabetes.

H_a2: There is an association between the method of disease management and an individuals' level of health literacy related to type II diabetes.

Research Question 3: Is there a relationship between the method of disease management and developing ESRD complications among diabetics?

$H_0$3: There is no relationship between the method of disease management and developing ESRD complications among diabetics.

H_a3: There is a relationship between the method of disease management and developing ESRD complications among diabetics.

Research Question 4: Are demographic cofactors such as gender, race, age, socioeconomic status, and education different when comparing outcomes of ESRD, inadequate health literacy, and health insurance status among diabetic participants?

H_04: There are no differences with demographic cofactors such as gender, race, age, socioeconomic status, and education when comparing outcomes of ESRD, inadequate health literacy and health insurance status among diabetic participants

H_a4: There are differences with demographic cofactors such as gender, race, age, socioeconomic status, and education when comparing outcomes of ESRD, inadequate health literacy and health insurance status among diabetic participants.

Conceptual Framework

The basis for this study was a modified version of Lee's (2004) health literacy, health status, and health service use conceptual framework. I also used Ishikawa and Yano's (2008) conceptual role of health literacy in improving patient participation pathway model. This revised framework is used to compare health literacy to health status, health service use, as well as additional pathways to health outcomes. This conceptual framework was founded on the idea that the four pathways in which results are affected include (a) disease and self-care knowledge, (b) health behaviors, (c) disease management and provider relationships, and (d) compliance with treatment. According to this framework, social support can help determine positive health outcomes (Lee, Arozullah, Cho, Crittenden, & Vicencio, 2009). Furthermore, with Ishikawa and Yano's

amended model, mechanisms in which an individual patient's health literacy affects behaviors, participation, and health outcomes are also considered. These individual variables include cognitive and social skills at three levels (functional, communicative, and critical) and include (a) ability and or motivation to gain access to information, (b) using information obtained, (c) understanding problems and seeking appropriate medical help when needed, and (d) making informed and quality self-management decisions regarding one's own health (Ishikawa & Yano, 2008). This framework offered a way to link previous studies in relation to health literacy, diabetes-related complications, and long-term health outcomes, as well as providing a foundation for future research.

Nature of the Study

This study was a correlational quantitative study to measure the level of health literacy among type II diabetic patients. I compared results from randomly selected males and females between the age of 20-75 from diverse backgrounds who have enrolled in the Chronic Renal Insufficiency Cohort (CRIC). The selected participants in the study had been diagnosed with type II diabetes, and I explored the relationship of health literacy with developing ESRD among them. A quantitative approach was used to answer research questions and examine association between health literacy and ESRD outcomes.

Secondary data collected from the CRIC over a period of 2 years from 2013-2015 was used. Survey and questionnaire data from CRIC were analyzed to explore the relationship between health literacy levels, methods of disease management, and ESRD outcomes. With descriptive, inferential, and correlational statistics, I quantified health literacy and disease management methods to outcomes of ESRD.

Over a period of 6 months, I explored which methods within disease management represent an effective use of the delivery of medical information and analyzed which methods result in higher levels of health literacy. I examined whether this reduces the incidence of ESRD in this cohort. The dependent variable in the study was ESRD among type II diabetics. Independent variables include (a) health literacy and (b) routes of delivery of medical information within disease management. Additionally, variables and covariates such as age, race, education level, and gender were examined for their statistical associations with ESRD, and health literacy and medical information delivery routes were analyzed.

Definitions of the Variables

Type II diabetes: Disease attributed to those who have been diagnosed by a provider with diabetes mellitus and labeled according to ICD-9-CM diagnosis codes 250.0, 250.00, 250.01, 250.02, or 250.03 (Center for Medicare and Medicaid Services, 2016). Patients labeled as having diabetes mellitus both insulin dependent and noninsulin dependent are included in this definition. This definition refers to all patients identified as having diabetes mellitus, whether the disease is controlled by diet and or exercise, oral medications, or insulin injections (Center for Medicare and Medicaid Services, 2016).

Diabetes-related end-stage renal disease (ESRD): When patients are diagnosed with type II diabetes prior to a diagnosis of ESRD (National Institute of Diabetes and Digestive and Kidney Diseases [NIDDK], 2016).

End-stage renal disease (ESRD): When diabetic patients have progressed from chronic kidney failure to an increased level of kidney dysfunction (NIDDK, 2016). The

Center for Medicare and Medicaid Services defines diabetic ESRD as diabetic patients whose medical records show one or more of the following (Center for Medicare and Medicaid Services, 2016):

1. Estimated Glomerular Filtration rates (eGFR) less than 15 mL/min per 1.73 m2
2. Creatinine levels > 10 mg\dl
3. Blood Urea Nitrogen (BUN) levels >80mg\dl
4. ICD-9-CM Diagnosis codes identifying diabetes with renal manifestations 250.4, 250.40, 250.41, 250.42, 250.43, or 585.6.
5. Currently undergoing or have undergone within 12 months of the examination of data, hemodialysis or peritoneal dialysis.
6. Patients that are on a waiting list for a kidney transplant or have undergone a kidney transplant.

Health literacy: The ability to show a level of understanding in which outcomes related to diabetes are positive (Al Sayah et al., 2013). For this research, health literacy is defined as the ability to be able to effectively communicate and comprehend medical instructions appropriately and to be able to effectively navigate and function within the health care system (Al Sayah et al., 2013). In this study, education level, communication ability, and compliance with medical treatments, appointments, and instructions are markers for health literacy. Data reported from the Unites States Renal Database identified patients as psychologically unfit as having low health literacy (United States Renal Data System, 2015).

Disease management: Categorized to six categories: (a) the patient/provider relationship and clinic visits, (b) emergency room or urgent care visits, (c) other medical facility such as nursing homes, (d) automated telephone self-management, (e) off-site group visits, and (f) no intervention received. These six categories for disease management are further divided into two broader categories provider/professional guided disease management and self-guided disease management (Rothman et al., 2004).

Assumptions

One of the assumptions of the study was that individuals with lower levels of health literacy will be more likely to develop complications related to diabetes such as ESRD. The assumption is that diabetics who have a having a higher level of health literacy have a better understanding of how to control their diseases and will not develop further complications. Additionally, further complications would not evolve if patients understand the necessity to follow instructions related to their disease management plan; diabetic individuals who have lower levels of health literacy may not understand or recognize the potential risks of complications, leading to mismanagement of their condition and diabetic complications such as ESRD. It was also assumed that current practices of disease management are adequately providing medical information and instructions to diabetic patients independent of their level of health literacy. The assumption that health literacy and the methods in which information is delivered impacts outcomes is critical. Before interventions can be effective, researchers need to first know how to adequately reach diabetic individuals and provide a level of understanding that allows them to manage their disease and improve health outcomes.

Scope and Delimitations

The scope of this research included type II diabetics who have developed ESRD and the relationship between developing ESRD and health literacy. The focus of the research was whether adequate health information related to managing diabetes is being effectively disseminated. The study was concentrated on type II diabetics' levels of health literacy and the relationship between levels of literacy, diabetic complications such as ESRD, and the methods in which medical information is being distributed. The issue of internal validity of this study was to look at the distribution of health literacy and examine the relationship between lower levels of health literacy, the method of dissemination, and whether these methods are preventing complications or falling short.

Populations that were included in the study were type II diabetics older than age 21 and younger than 74 who have been identified as being high risk for ESRD. Boundaries of the study are that type I diabetics were excluded whereas type II diabetics who have been diagnosed with chronic kidney insufficiency prior to a diagnosis of ESRD were included. To generalize to a larger population, populations and their levels of health literacy were quantitatively measured using descriptive statistics and correlation analysis. Data were organized by patients with type II diabetes, their level of health literacy, and the type of disease management received. ESRD was the dependent variable in this study.

As a foundation of the external validity of the study, I used a conceptual framework that links health literacy to health services and pathways to health outcomes (Nutbeam as cited in Ishikawa & Yano, 2008). Theoretical models that were considered but not used for this study include the process-knowledge model of health literacy, which

is focused on individuals' capacity to memorize information and their vocabulary knowledge (Chin et al., 2011). Chin et al. (2011) based this model on the fact that these two components are the most commonly used measures of health literacy. Another model considered for this study was the health belief model—an established conceptual framework to describe how a person's health behavior is an expression of health beliefs (Maiman & Becker, 1974). This model has been used in the past to predict health behavior, including the use of health services (Maiman & Becker, 1974). To consider this model, an assumption that beliefs rather than health literacy are influencing behaviors would be presumed, contradicting the hypothesis in this study. The theoretical model used for this study was a health service use conceptual framework—a model that includes health literacy, health status, health service use, and considers variables such as knowledge, behaviors, disease management, and social influences that may affect health outcomes (Lee et al., 2009). The health use model was selected because it encompasses a more inclusive theory to consider a variety of variables that can impact health outcomes.

Limitations

The limitations of this study include finding validated measures for levels of health literacy specific to populations with diabetic complications. The study includes data to measure and compare levels of health literacy. Due to the complex and multifaceted definition of health literacy, there is a threat to both external and internal validity, but by including a test/retest approach that includes both correlation and regression analysis, reliability can be substantiated (Allen, Zoellner, Motley, & Estabrooks, 2011). Health literacy is a concept that can challenge internal validity within

a research study, but by implementing controls (Baker, 2006), I was able to eliminate most confounding variables and propose a possible cause and effect. Past studies indicate that better tools to measure health literacy are needed (Baker, 2006).

The evidence strength was also a contributing limitation, which was addressed by grading evidence consistently, looking at effect size by including correlation analysis and linear regression within same groups. This method of grading has been supported by past research (see Berkman, Sheridan, Donahue, Halpern, & Crotty, 2011). Other limitations include the risk of bias such as verifying whether the complications were independently related to health literacy rather than to other medical complications, side effects to diabetic medications, or personal choice. There was a risk of bias in determining that unmanaged care is due to a lack of understanding rather than a deliberate choice to dismiss proper treatment. I included reliable data and statistical methods to compensate for evidence strength and address these limitations (see Berkman et al., 2011). Other methods to prevent bias included ensuring that the instruments and surveys used to collect and evaluate the data maintain a best practices protocol. A good practice includes careful structuring of the language used within the questionnaires (Berkman et al., 2011). It also means making sure that the appropriate questions are being asked within the surveys (Berkman et al., 2011). To reduce bias, I also attempted to incorporate questions applicable to the research and appropriate for the intended target population.

Significance

The significance of this study is the potential contribution of public health information that can address gaps in research related to health literacy and diabetic

complications such as ESRD. Current research has limited explanations on the phenomenon of why diabetic complications such as ESRD continue, when treatment, medications, and disease management are available (Fox et al., 2012). There is controversy over why the prevalence of ESRD continues to remain prominent and why patient behaviors do not support healthy disease management (Collins et al., 2012). I examined whether there is a relationship between ESRD complications among diabetics and a lack of health literacy. Additionally, there are debates among research, medical, and public health professionals as to what is the best method of effective health literacy (Bailey et al., 2014). Results from this research can offer insight as to the best approach to reach diabetic patients to support health literacy and reduce diabetic complications. The social change impact offered by this research is that it helps provide a better understanding of how to effectively provide information to patients with diabetes and support higher levels of health literacy. This can not only reduce ESRD and or other diabetic complications but guide public health intervention programs and improve overall health among diabetic populations.

Summary

Millions of individuals across the globe have been diagnosed with diabetes and diabetes-related complications (Inzucchi et al., 2012). Complications such as ESRD burden the economy and significantly diminish individuals' quality and length of life. Improving health literacy and knowing the best method in which to deliver the medical information has the potential to prevent complications associated with the disease, thereby improving disease management, diabetes educational programs, and reducing the

prevalence of ESRD or other health complications associated with diabetes.

This chapter started with a brief introduction of the problem, the problem statement, background information, and the purpose of the study. The research questions and hypothesis were outlined, and the theoretical framework that the study is founded on was described. The nature of the study, where the variables were defined, was included as well as the scope, delimitations, assumptions, and limitations that were addressed to support the both external and internal validity. Finally, this chapter ended with the significance of the study and the social change implications and positive public health contributions that can be made by this research.

In Chapter 2, a literature review is provided that begins by setting the stage on the impact that health literacy has on health outcomes. Chapter 2 then includes literature outlining complications with diabetes and more specifically ESRD associated with diabetes. The chapter ends with literature on the delivery of health information and health literacy models within different approaches of disease management. The literature review provided in Chapter 2 is intended to offer a foundational outline in which to support the research needs of this study.

Chapter 2: Literature Review

Introduction

Type II diabetes has in the last decades become recognized as the primary cause of ESRD (Chantrel et al., 1999). The American Diabetes Association (2014) even acknowledges that diabetes is the primary cause of ESRD in the United States. Though in the past, complications such as diabetic nephropathy were more prevalent in type I diabetics, researchers claim that the statistics have changed (CDC, 2011). Over the last decade the prevalence of ESRD has doubled, and approximately 12 million type II diabetics in the United States now have ESRD (Kanwar et al., 2011). The CDC also reported that in 2010, 29.1 million people (9.3%) in the United States had diabetes, and 35-40% of those individuals had ESRD related to diabetes (CDC, 2011). With the increase in individuals with type II diabetes, the occurrence of renal failure has increased (Kanwar et al., 2011). However, it is not clear whether the increase of ESRD is because the amount of type II diabetics has tripled over the last two decades or rather because medications allow diabetics to live longer lives. Researchers have examined whether ESRD is a consequence of diabetics deliberately not following their medical plan, side effects related to medications, or because type II diabetics do not understand the long-term risks of complications related to uncontrolled diabetes (Inzucchi et al., 2012).

Past research has shown that individuals with low literacy have difficulty following medical advice correctly, do not understand their disease, and have worse health outcomes (Rothman et al., 2004). Type II diabetes is preventable and ESRD can be avoided (Inzucchi et al., 2012), and with proper education, diet, and exercise, the disease

and associated complications can be controlled and minimized (Kanwar et al., 2011). Health literacy is essential to making these health changes (Tang et al., 2008); however, research in the past indicated that more than 90 million Americans had literacy levels that were so low that they could not adequately function in health care settings (Rothman et al., 2004). Additionally, health literacy has been acknowledged as a cause for unmanaged diabetic complications, though research on the impact of health literacy on long-term health outcomes such as ESRD had been limited (Al Sayah et al., 2013).

This study addressed whether unmanaged diabetes is a result of low literacy levels or a choice not to manage this health condition. This study also addressed gaps in research related to health literacy's effect on long-term outcomes such as ESRD among type II diabetics as well as the controversy over which methods deliver medical information effectively, supporting health literacy to achieve positive health outcomes and prevent diabetic complications (see Al Sayah et al., 2013). I used a correlational quantitative study to measure association between levels of health literacy, disease management methods, and ESRD complications associated with diabetes. The purpose of this study was to explore the relationship between healthy literacy and how medical information is being delivered and received among type II diabetic patients to create social change that improves public health services and reduces chronic disease complications.

This chapter provides a literature review of long-term complications associated with type II diabetes like ESRD. The chapter offers discussion on the prevalence of ESRD among type II and type I diabetics. Additionally, gaps in research regarding health

literacy will be addressed. The chapter will begin with a description of the literature related to complications associated with type II diabetes and the prevalence of ESRD. Next, the relationship between health literacy within disease management and different modes of delivery of medical information among diabetics' that develop ESRD will be reviewed. Finally, theoretical frameworks associated with health literacy and health outcomes will be explored, and a summary will conclude the chapter.

Literature Search Strategy

The primary databases used for this research were Ebsco, Pub Med, Academic Search Complete, as well as a multidatabase search using Thoreau through the Walden University Library. Over a duration of more than 2 years, seminal literature was collected and examined. The databases retrieved more than 10,000 articles when searching *type II diabetes and complications*; however, when narrowed to include *health literacy*, approximately 600 entries resulted. Investigating *ESRD and type II diabetes* resulted in 449 articles to select applicable literature. A comprehensive examination of full-text peer-reviewed articles selected from 2010 to present day was explored. Key words used in this literature review included *diabetes, health literacy, end-stage renal disease, diabetes-associated complications, type II diabetics and dialysis, disease management of diabetes, barriers to diabetes disease management, diabetic nephropathy*, and *theoretical frameworks related to health outcomes and health literacy*. Websites used to gather background information included the American Diabetes Association website, the NIDDK website, CDC website, and the National Kidney Foundation website.

Conceptual Foundation

The basis for this study was a modified version of Lee's (2004) health literacy, health status, and health service use conceptual framework. The revised conceptual model links health literacy to health status, health service use, and includes pathways to health outcomes (Nutbeam as cited in Ishikawa & Yano, 2008). The four pathways this framework is founded on include (a) disease and self-care knowledge, (b) health behaviors, (c) disease management and provider relationships, and (d) compliance with treatment. In this framework, social support is also considered as a determinant of positive health outcomes (Lee et al., 2009). Furthermore, with Ishikawa and Yano's (2008) amended model, mechanisms in which a patient's health literacy affects behaviors, participation, and health outcomes are also considered. These mechanisms include cognitive and social skills at three levels (functional, communicative, and critical) and involve having the ability and motivation to gain information, using information, understanding problems and seeking appropriate medical help when needed, and making informed decisions regarding health (Ishikawa & Yano, 2008).

The origin of the conceptual framework was generated after unexpected findings from a 1992 National Adult Literacy Survey that showed that more than 40 million Americans were functionally illiterate (Lee et al., 2009). The survey suggested that levels of education did not correlate with reading and comprehension of medical information and understanding, and this impacted health outcomes (Lee et al., 2009). The results of the survey brought awareness to the ability of the public to be able to function adequately in health care settings (Lee et al., 2009). These findings perpetuated the conceptual

framework as outlined by Lee et al. (2009) as well as by Ishikawa and Yano (2008), who expanded it and used this hypothesis as the foundation for describing the relationship between health literacy and health outcomes.

Previous research has shown the importance of integrating multiple conceptual theories into one concrete model, especially concerning a model that can improve disease prevention and promote health (Sorensen et al., 2012). Summarizing an integrated approach to conceptual frameworks enhances interventions, provides consistent tools to measure outcomes, and improves health care delivery and overall health. As a basis for this research, the integrated conceptual health literacy-health outcome model offered a method to link previous studies regarding health literacy, examine diabetes-related complications associated with literacy, and investigate health information delivery methods as well as provide a foundation for future research.

Literature Review

Prevalence and the Impact of Complications Associated with Type II Diabetes

The prevalence of type II diabetes has increased over the last 15 years, and experts claim that if preventative practices and or policies do not change the occurrence will continue to rise (Guariguata et al., 2014). Not only will the numbers of adults with type II diabetes increase but so will the number of individuals with complications related to diabetes (Guariguata et al., 2014). To emphasize the significance of the growing rate of diabetes, Guariguata et al. (2014) measured the prevalence of type II diabetes in 2013 and estimated what the prevalence would be in the year 2035 if conditions remain unchanged. They found that in 2013 among adults 20 to 79 across 219 countries and territories there

were approximately 38.8 million adults with type II diabetes, with a projection of 591.9 million adults in 2035 (Guariguata et al., 2014). The highest prevalence was seen in North America, but with age adjustments the Middle East and North Africa had higher numbers (Guariguata et al., 2014). The greatest number of adults with type II diabetes were ages 40-59, though adults between the ages of 60-79 were estimated to have the largest increase over time (Guariguata et al., 2014). Additionally, individuals at a lower income status and living in urbanized areas had a greater prevalence of diabetes, which would continue if conditions remain (Guariguata et al., 2014). Literature shows that current treatments, though not preventing the disease, increase life expectancy for type II diabetics. But with this comes additional challenges, such as a growing prevalence of type II diabetics that develop related complications that decrease the quality of life and place an added extensive economic burden on the health care system globally.

Diabetes and End-Stage Renal Disease

The incidence rate of ESRD among the general population has consistently increased. Between the years of 1980 through 2010 there has been approximately a 600% (from 19,000 to 114,000) increase in the number of individuals with ESRD in the United States (United States Renal Data System, 2015). Though recent data shows that from 2010 to 2012 rates have begun to plateau, the number has still significantly increased over the last 30 years and continues to present a substantial burden on the U.S. health care system and economy. However, the incidence rate varies when adjusted for age, race and ethnicity, geographic location, and conditions such as diabetes (United States Renal Data System, 2015). Some researchers have claimed that since 1990 to 2010 diabetes

associated complications have decreased, but ESRD compared to cardiovascular disease, amputation, and hypertension is an exception dependent on the population affected (Gregg et al., 2014). There are gaps in research whether the reasons for these differences of ESRD are due to the growing number of diagnosed type II diabetics, the fact that diabetics are living longer, or limited health literacy. According to Fox et al. (2012), diabetes is the primary cause of ESRD; among the U.S. population, more than 30% of diabetics are diagnosed with ESRD.

With proper screening and diabetes management ESRD can be prevented, which includes screening for albumin levels once diagnosed with diabetes and after that testing annually for levels of albuminuria (microalbumin and or macroalbumin) and to monitor the glomerular filtration rate of the kidneys (American Diabetes Association, 2014). Evidence shows micro and macro albumin are early markers of identification of kidney damage. Other research reveals that to slow renal disease, it is critical for diabetics to maintain normal glycemic levels, track the albumin-to-creatinine ratio, and prevent hypertension (American Diabetes Association, 2014). Additionally, diabetics who struggle with other complications such as cardiovascular problems or systemic vascular problems and who are often prescribed ace inhibitors, diuretics, and or calcium channel blockers, may be at risk of consequential damage to their kidneys. The literature indicates that there is a need to explore whether intervention methods are adequately addressing health literacy needs to prevent diabetic complication such as ESRD in the future (Fox et al., 2012). Therefore, I examined health literacy among II diabetics diagnosed with ESRD and whether patients have sufficient knowledge of risk factors to allow for control of

ESRD.

Health Literacy within Disease Management for Patients with Chronic Diseases

According to the American Medical Association (2005) health literacy is defined as the ability to be able to read, write, and understand basic health care information. Research shows that more than 30 % of English-speaking patients have low health literacy and that those patients with the greatest need of health services are the ones with the lowest level (Tang et al., 2008).

Evidence outlines that there is a relationship between health literacy, disease management and health outcomes, including ones associated with diabetes (Tang et al., 2008). Though data shows low health literacy does, in fact, deter positive health outcomes for persons with chronic diseases such as diabetes, the debate is whether low literacy increases the risk of further complications such as end stage renal disease. Questions remain as to whether lower health literacy provokes a greater risk of further complications, questioning whether there is a parallel relationship between levels of literacy and diabetic complications.

In a study done by Tang et al. (2008) researchers found low health literacy is the greatest predictor of a person's health. Though studies have been inconsistent on the severity of outcomes related to low literacy, data did show that lower health literacy is associated with poorer diabetes knowledge (Tang et al. 2008). After reviewing more than 24 studies outlined in the literature, data showed that minority populations, persons with lower education, income, compromised health, elderly populations, and those for whom English is a second language, have more challenges functioning in the health care

environment (Tang et al., 2008). Vulnerable populations that were more likely to have lower health literacy had a tendency to struggle with reading, writing, and interpreting medical information including correct usage of medications (Tang et al., 2008). As outlined in the literature the complex chronic disease of diabetes requires individuals to be involved in their health and to demonstrate self-care management to result in better outcomes. Inconsistent past data waivers on whether the diabetic related end-stage renal disease is associated with low literacy.

One study showed lower literacy and an association with retinopathy and stroke, but not with nephropathy, heart disease, or amputations (Tang et al., 2008). Whereas a different study showed little association between low literacy and retinopathy, heart disease, and amputations, but showed an exception when considering end stage renal disease among certain diabetic populations (Beulens, Grobbee, & Nealb, 2010). The question remains then; do lower levels of health literacy increase the risk of end-stage renal disease among type II diabetics.

Modes of Delivery of Medical Information within Diabetes Disease Management Types

Gaps in research show that in addition to investigating whether lower health literacy is related to complications such as ESRD, it is imperative to examine disease management practices and how medical information is being delivered (Baily et al., 2014). There is minimal research that explores disease management and the impact it may have on levels of health literacy, and or complications such as ESRD (Baily et al., 2014). For the purpose of this research. I have organized disease management into five

categories outlined below and will use these categories to explore how medical information is being delivered, and the impact each has on health literacy and diabetes associated ESRD to examine if there is a relationship.

1. Diabetes Disease Management; The Patient\Provider Relationship

According to Bailey (2014), this method provides information through patient education. This includes methods such as one on one counseling where patients set goals and create an action plan with nurses, educators or physicians in a traditional clinical face to face setting. This method is founded on the patient\provider relationship, where direct communication, provider feedback, and materials with information and instructions are provided during individual counseling. This method requires physicians to adjust how they present information based on their professional assessment of the patient's health literacy levels.

2. Diabetes Disease Management; Patient/Pharmacist Relationship

This method is where pharmacists provide one on one counseling that discusses medications, risk complications, management of blood pressure and blood sugar

medications. With this method of management, pharmacists may also provide a care coordinator who talks with patients' and explains specific details related to medications and answers questions or concerns the patient may have related to their condition.

3. Diabetes Self-Management Education (DSME); Automated Telephone Self-Management (ATSM).

Automated telephone self-management, is a method of disease self- management

where after an initial patient\provider visit has established a plan of action, patients receive automated phone calls that prompt them weekly to report on their health status. Health status reports include regular blood glucose levels, A1C levels, diet information, weight, blood pressure, and physical activity levels. Follow-up is then provided by medical professionals after reviewing of reports.

4. Diabetes Self-Management Education (DSME); Group Medical Visits(GMV)

This type of disease self-management offers group counseling to individuals with a combination of medical professionals, and or psychologists. The group participates in educational activities, group question and answer discussions, medical evaluations, nutritional information, and or exercise events to build self–efficacy and essential disease self-management skills (Trotter, Hendricks, Scarsella, 2011).

5. No Intervention Received.

This category includes individuals who were screened and diagnosed in a clinical setting but did not undergo any official form of disease management.

Summary and Conclusions

In summary, chapter two provided literature that indicates that as the prevalence of diabetes increases so too does the risk and the number of individuals with complications associated with diabetes (Guariguata et al., 2014). Confidently the literature demonstrates evidence outlining that diabetes continues to be a growing concern, and that diabetes is the number one cause of ESRD. There are gaps and inconsistent research related to debates as to whether or not complications related to diabetes are increasing (Gregg et al., 2014). Gaps in research leave unanswered questions

as to which complications are most prevalent, and to what extent. One example highlighted by Beulens, Grobbee, and Nealb (2010) showed data that ESRD has increased among certain populations, but to what extent is limited, and researchers claim further research is needed to examine this hypothesis. One hypothesis for the increasing prevalence of diabetes and associated complications such as ESRD is that low health literacy affects individuals' ability to manage effectively their diabetes, leading to associated complications (Tang et al., 2008).

This hypothesis suggests that type 2 diabetics with lower levels of health literacy are most likely to have developed ESRD due to lack of understanding of medical information which limits their ability to manage and maintain control of their disease.

Other hypotheses suggest that certain methods of medical information delivery are more successful in reaching individuals and improving levels of health literacy than other routes (Bailey et al., 2014). What is known, is diabetes is prevalent, and this prevalence continues to grow (Guariguata et al., 2014). It is also known that diabetes is the number one cause of ESRD. What is not known is the relationship between levels of health literacy, the routes in which medical information is delivered, and the impact it has on associated complications. This study could fill in gaps where there is limited research related diabetes and the impact health literacy has on preventing further complications. Gaps in the research show there is a need also to examine best practices on how to successfully improve health literacy and best supply health information (Tang et al., 2008). This research can guide public health interventions thereby potentially improving health literacy, and health outcomes by reducing the risk of diabetic complications.

One significant gap in the current literature that chapter two presented is the relationship between levels of health literacy and ESRD as a complication to type II diabetes (Tang et.al. 2008). Current literature leaves unanswered questions as to why some diabetics develop ESRD and or other complications, where others do not. There are contradictions in the literature which do not explain or even clearly outline the significance of ESRD among diabetics and reasons for it. Though research definitively claims that diabetes is the number one cause of ESRD, questions remain as to which and why certain diabetic populations develop associated complications where others do not (Inzucchi et al., 2012). More research is needed to investigate possible explanations for this phenomenon. This study can provide insight as to whether there is a relationship between health literacy and associated complications. The study can provide information that examines whether there is a relationship between levels of health literacy, methods of diabetic disease management, and health outcomes. The research in this study can extend public health knowledge by providing insight as to best practices that can effectively provide disease management dependent on levels of health literacy among diabetic populations.

In Chapter three I provide the research design and rationale for the study reemphasizing the hypothesis and research questions. Chapter three describes the dependent variable, independent variables, and covariates that will be considered and measured. In this section, I will describe the target populations and the sampling procedures and include methods that support validity for the data analysis used in this research.

Chapter 3: Methodology

Introduction

The purpose of this study was to examine the relationship between levels of health literacy and ESRD developed as a complication from type II diabetes. Due to limited research on why some type II diabetic patients develop complications such as ESRD, I examined whether there is a correlation between type II diabetics who develop ESRD and lower levels of health literacy. To provide insight into future methods of disease management, I also compared the method of disease management with levels of health literacy. In this chapter, I will describe the definitions of the dependent variable, the independent variables, and covariates of this study. The chapter will then include the four research questions, and I will present the study design and how the variables were measured and operationalized in questionnaires. Once the design of the study has been provided, I will describe how the data were analyzed, including using chi-square analysis, Pearson *r* correlation, and binary and multinomial logistic regression. I will end this chapter by summarizing how the methodology chosen for this research can provide insight and information that can create change in the discipline of diabetic disease management.

Research Design and Rationale

The research design for this study was a quantitative cohort to look at group populations. I compared same subjects (individuals diagnosed with type II diabetes) across time with different disease management methods to determine the relationship between levels of health literacy and diabetic complications like ESRD. The dependent

variable in the study was ESRD among type II diabetics. The independent variables were the level of health literacy and the method of disease management. Covariates included age, gender, and race. Time and resource constraints were limited due to the use of secondary data that had been previously collected from 2013 through 2015. The use of existing cohort data for this correlational quantitative design allowed for streamlined analysis of the data within a 6-month period. The design choice selected for this study addressed gaps in research, offering comparison analysis to examine the relationship between health literacy and diabetic complications. This research design can advance public health knowledge on the impact health literacy has on chronic disease complications and be a guide for best approaches when implementing disease management interventions in the future.

Methodology

Population

According to the National Diabetes Report and the United States Renal Data System (2015), 44% of all new cases of ESRD in 2011 were due to diabetes, and more than 49,000 diabetics began receiving treatment and or therapy for kidney failure (American Diabetes Association, 2014). Additionally, in 2011 more than 225,000 people in the United States were living on dialysis or received a kidney transplant (American Diabetes Association, 2014). More than 9% of the U.S. population is affected diabetes, and more than 40% of these individuals are struggling with ESRD (United States Renal Data System, 2015). As with diabetes, ESRD affects populations of all ages, race, and genders, but with varying incidence. For this study the target population included racially

and ethnically diverse individuals who were diagnosed with type II diabetes (diabetes mellitus) and at high risk for chronic kidney disease. The target population included both males and females between the ages of 20-75. The population size, or estimated size, included approximately 2,000 participants enrolled in the CRIC from participating clinical centers across the United States.

The Chronic Renal Insufficiency Cohort (CRIC)

The CRIC is a study that was initiated by the NIDDK. The intent of this study was to increase understanding of chronic kidney and cardiovascular diseases (CRIC, 2016). The study originated in 2001 and data were collected from a baseline, throughout the study, and long-term follow up through the year 2015. Data collected from the cohort were used to examine risk factors associated with kidney and cardiovascular disease. The intent of the study was also to identify high risk populations and provide insight as to best treatment practices and intervention methods. More than 3,000 participants were recruited for the study from participating institutions (CIRC sites) both nationally and internationally. The original CRIC sites are outlined in Table 1 (CRIC, 2016).

Table 1

CIRC Study Cities

Clinical Research Center	Partnership Institutions	International Sites
Johns Hopkins Medicine	University of Utah	China
University of Pennsylvania	University of Miami	Japan
University Hospitals of Cleveland	University of North Carolina	Peru
Metro Health Medical center	George Washington University	Germany
Cleveland Clinic Foundation	University of Alabama	
University of Michigan		
Wayne State University		
Renaissance Renal Research Institute		
University of Illinois		
Tulane University		
Health Science Center California		
University of Kaiser Permanente		
University of Maryland		

Sampling Procedures for Recruitment, Participation, and Data Collection

For the purpose of this study, the data were used as secondary data and modified according to inclusion and exclusion criteria outlined in this chapter. The sampling strategy used in this study was collecting parts of secondary data from an established study that examined different variables yet measured similar outcomes. The sampling procedures involved collecting and organizing secondary data from the NIDDK CRIC. The sampling process included organizing the data set into two categories based on the strata needed for this study. The data set for this study includes data reflecting levels of literacy as well as development of complications like ESRD among a population of type II diabetics. A probability sampling procedure was used to collect comprehensive data, and in support of this theory-driven study, I included a stratified random sampling selection of the applicable data.

Narrowing down the data to participants with diabetes mellitus allowed inferential statistics to be used for frequency distributions and counts. Additionally, logistic regression was included to control for covariates and compare independent variables. The data for this study includes descriptive statistics using categorical data to measure and compare crosstabulations, chi-square analysis, frequency distributions, and counts between groups. The procedure for gaining access to this dataset required making a request to become a registered user of the database. Access allowed me to review a limited overview of the dataset prior to full access to the dataset. I then submitted in writing an official documented request that included an outline of the study and Institutional Review Board (IRB) approval to achieve full access to the dataset.

Sampling Frame

The sample was drawn from randomly selected secondary data and then further stratified by participants with diabetes mellitus. Using a stratified random sample allowed for an equal probability of selecting each unit within a group and enabled me to make statistical generalizations about the samples being studied (see Frankfort-Nachmias & Nachmias, 2008). Specific procedures allowed me to examine renal outcomes among type II diabetic populations and compare their levels of health literacy and methods of disease management using an applicable primary data set as an appropriate secondary dataset.

Inclusion Criteria

Data includes approximately 1,670 individuals diagnosed with diabetes mellitus who were willing to be enrolled in the chronic renal insufficiency cohort from July 2010 through August 2015 (NIKKD, 2016). Participants 21 to 74 who were diagnosed with diabetes mellitus with varying ranges of chronic renal insufficiency who had not yet progressed to ESRD based on age-adjusted glomerular filtration rates were included. Only participants living within the United States and who maintained follow up throughout the cohort were included. The CIRC sites used for this study are:

- University of Pennsylvania
- Johns Hopkins Medicine/University of Maryland
- University Hospitals of Cleveland /Metro Health Medical Center/Cleveland Clinic Foundation
- University of Michigan at Ann Arbor/Renaissance Renal Research

Institute / Wayne State University

- University of Illinois at Chicago
- Tulane University Health Science Center
- Kaiser Permanente of Northern California/University of California at San Francisco

The inclusion criteria allowed me to examine high-risk type II diabetics for clinical manifestations that could develop into ESRD and the relationship related to their level of health literacy. It also includes the received method of disease management throughout the cohort timeframe.

Exclusion Criteria

Data collected from participants outside the United States was excluded. As well as any participants indicating ESRD at baseline, such as individuals receiving renal replacement therapy, or a glomerular filtration rates of < 25 ml/min per 1.73 m2 at the onset of the study. Any participants at baseline and or within 12 months before to collection of data, who have received hemodialysis or peritoneal dialysis will not be included. Participants diagnosed with polycystic kidney disease or an active immunosuppression for glomerulonephritis were also excluded from the study.

Sample Size

As previously described the total overall sample was a random probability sample selection of 3339 participants who enrolled in the NIDDK CRIC. This sample was then further stratified by diagnosis of diabetes mellitus using a proportional stratification process that included using a simple random stratum selection based on two strata

(Bowling, 2014).

Approximately 50% of the original data set included participants with a diagnosis of diabetes mellitus and 50% without diabetes mellitus. The total number of units used for the study is (*N* = 1,670; population of type II diabetics). Using the stratified random probability equation outlined by Bowling (2014) the sample size needed based on proportionate stratification for the strata of diabetes mellitus for this study is (N=835). Assuming a confidence level of 95% and an α (alpha) level of 0.05, the proportionate stratification equation used (nh=([Nh/N])*n) (Bowling, 2014). Whereas nh is the sample size of stratum h, Nh is the population size of stratum h, N is the total population size, and n is total sample size (Bowling, 2014).

Effect Size, Power Analysis to Determine Sample Size

To calculate the effect size of this study, I included stratification of two groups to utilize the data collected from the population of type II diabetics. Both Chi Square Analysis and Correlation analysis were included to measure the effect size between two groups. Using multiple methods allowed comparison of outcomes among the population of type II diabetics for the dependent variable ESRD. It will allow comparisons of the outcome based on two factors, health literacy and Health Insurance Status (Sullivan & Feinn, 2012). This allows comparing two similar groups to measure the difference in outcomes allows for a controlled comparison that can provide quantified measurements of the effect size. To allow for a larger effect size and a margin of error (MOE) of ~ 2 % considering a normal distribution and a 95 % confidence interval (CI), with a critical value of (z-score)1.96 a larger sample size of (n=1670) units will be included.

After conducting a power analysis based on the statistical tests used in this study, the sample size of (n=1,670) units was determined to be adequate, providing both a larger effect size, as well as a lower MOE. The sample size (n=1,670) was determined adequate by performing a two-power analysis method, a traditional calculation, as well as using IBM SPSS Sample Power 3 software. The traditional calculation was based on the equation provided by Frankfort-Nachmias and Nachmias (2008). The equation outlined by Frankfort-Nachmias and Nachmias (2008) allows an estimated sample size to be drawn based on a simplistic calculation that uses Sampling error (SE), Population size (N), sample size (n), and optimal sample size (n'). This is the formula:

$$n' = \frac{n}{1+(n/N)} \quad = \quad n' = \frac{1{,}670}{1 + (1670/3339)} = 1{,}113 \text{ Estimated sample size needed.}$$

Additionally, I analyzed the sample size with a power analysis, using SPSS Power 3. For this analysis, a 95% (CI), and α (alpha) level of 0.05, with the inclusion of four levels of responses from ordinal data for the independent variable health literacy, was taken into consideration. With these factors included, the SPSS Sample Power 3 software suggested a sample size of (n=248) per group. This study included two groups 1) Diabetics with ESRD, and 2) Diabetics without ESRD, with this consideration the overall necessary sample size according to SPSS Sample Power 3 is (n=496) (SPSS, 2016).

Instrumentation

Recruitment procedures used to collect the quantitative data were done through partner collaborations with the Chronic Renal Insufficiency Cohort Coordinating Center

located at University of Pennsylvania along with other major medical organizations and facilities across the United States and also internationally (CRIC, 2016). Designated Chronic Renal Insufficiency Cohort (CRIC) clinical sites included: Johns Hopkins Medical School, University of Maryland, University Hospitals of Cleveland, Metro Health Medical Center, Cleveland Clinic Foundation, University of Michigan at Ann Arbor, Renaissance Renal Research Institute, Wayne State University, University of Illinois at Chicago, Tulane University Health Science Center, and Kaiser Permanente of University of California (CRIC, 2016). As well additional ancillary institutions such as the University of Utah, University of Miami, University of North Carolina, George Washington University, University of Alabama, and Hopkins University participated in recruiting participants (CRIC, 2016). Participants were recruited based on medical eligibility criteria and referred for screening and further assessment into the cohort.

Eligibility into cohort was based on health assessment that looked at age, and kidney function status to ensure participants were not at end stage renal failure at baseline (CRIC, 2016). Once eligibility was determined, participants completed a documented consent form outlining the details and requirements associated with being involved in the cohort (CRIC, 2016). Informed consent was obtained for participation throughout the study. Screening of participants was done at the clinical site, and data was collected through one-on-one interviews, where questionnaires were administered during the initial clinical exam. Demographic information was also collected at initial screening and included a date of birth, gender, marital status living arrangements, education level, ethnicity, race, employment status, income, and diagnosis of diabetes mellitus. There was

a complete medical history taken to account for any other pre- existing conditions, diet, smoking, alcohol use, any medications, exercise, and baseline methods of disease management.

According to the CRIC (2016) participants accepted into the study remained under the care of their primary care physicians, yet participants enrolled in the cohort were contacted by telephone six months after baseline screening, and annually after that for five years. Participants attended one of the clinical CRIC sites for follow-up assessments. Follow up visits monitored and tracked any new medical events, and or medications (CRIC, 2016). At the completion of the study, participants were provided a summary of their assessment, and a documented debriefing occurred, answering any questions and closing out the case.

A variety of instruments were used for collection of data to measure the variables for this study and are presented in the appendices section of this dissertation. The majority of which were in the form of a survey questionnaire. The data set selected for the study is a collection of information that appropriately fits the current study due to the variables examined. It includes looking at the outcome of ESRD among populations who have been diagnosed with diabetes mellitus. It also examines participants' levels of health literacy and the health care resources utilized.

Medical Event, General Health, and Health Care Utilization Questionnaire

Three different medical related questionnaires were used to collect participant data, such as demographics, medical history, and health care use. They included a Medical Event Questionnaire, a General Health Questionnaire and a Health Care

Utilization Survey. All of which were provided during the initial interview and completed by participants at baseline.

Medical Event Questionnaire

The Medical event questionnaire asked about personal health status including health conditions, history and or diagnosis of disease (specifically diabetes), current state of health (exercise, diet, smoking, alcohol or substance use, any medications), personal behaviors, and family history (CIRC, 2016).

General Health Questionnaire

The general health questionnaire collected demographic information, such as race, ethnicity, education level, income, age and gender. Specific questions included date of birth, gender, marital status, highest level of education completed and assessed participants' socioeconomic status (CIRC, 2016).

Health Care Utilization Survey

The health care utilization questions asked participants about their access to health care services. The types of services utilized, how often, and how and where they received their services if any. Questions asked participants about their type and frequency of current health care management (CRIC, 2016). Copies of the Medical Event Questionnaire outlined in Appendix A, the General Health Questionnaire, Appendix B, and the Health Care Utilization Survey, Appendix C, are included in the Appendices section of the dissertation.

Clinic Visits Status Questionnaire

Additionally, a Clinic Visits Status Questionnaire; Appendix D, was completed to

track the type of health care access utilized, such as whether it was through the use of an on-site medical visit with a physician, a telephone intervention, or other settings, such as offsite group services (CRIC, 2016). All the documented surveys were completed during the screening interview.

Self-Efficacy Questionnaire

The Self-Efficacy Questionnaire was a 10-question survey comprised of two sections. The first section was an observational survey based on the provider\patient visit. A copy of the Self-Efficacy Questionnaire is provided as Appendix E. This instrument provided scored observations of the patient based on a 1-5 scale, where 1 represented not being confident at all, and 5 represented being very confident. The second section was a self-reported survey using a 1- 10 scale. Where patients answered self-care, and self-management questions, grading themselves on their confidence levels, where 1 was not confident at all and 10 was totally confident.

Modified Mini Mental State Exam

The Modified Mini Mental State Exam (Appendix F) is a standard instrument used to score an individual's mental status, and level of dementia. The use of the instrument has extended to become a standard mechanism to test mental health status, cognitive ability, and memory associated with a variety of health conditions (Dong et al., 2013). According to Dong et al. (2013) the modified mini mental exam is an established validated, reliable, and sensitive cognitive screening that has over time increasingly assisted public health professionals in individuals' levels of cognitive ability through an administered exam that contained 30 questions. Individuals scoring below 20 were

identified as being cognitively impaired (CRIC, 2016).

Short Test of Functional Health Literacy (STOFHLA)

Health literacy data was collected using Short Test of Functional Health Literacy (STOFHLA) instrument, which is described below. The instrument was selected based on its ability to be able to provide data that evaluated and looked at how competent participants felt in their ability to manage health care issues, their mental status, education levels, and measuring their level of health literacy. The Short Test of Functional Health Literacy (STOFHLA) is a valid health literacy test. This instrument is presented as Appendix G. Kirk et al., (2012) points out

that the STOFHLA health literacy test is a reliable instrument that measures a person's ability to perform and understand health-related tasks. It is a credible widely used tool, known to be the standard in health literacy assessment (Kirk et al., 2012). For this study, the instrument measured both comprehension and numeracy of health-related material through a face-to-face administered, a 7- minute test that included 36 reading comprehension questions from 2 passages (CRIC, 2016).

The 36-point scale of the S-TOFHLA used a reliability coefficient of (0.97) using Chronbach's alpha. The scale was quantified by dividing questions into three categories of functional literacy; inadequate (0-16), adequate (17-22) and functional (23-36).

STOFHLA is a modified version of the Test of Functional Health Literacy in Adults (TOFHLA) which was developed in 1993 (Baker, Williams, Parker, Gazmararian, and Nurss (1999). The modified version allows professionals to reduce the time to administer the test to participants from 22 minutes to 12 minutes (Baker et al., 1999). The

shorter version of the functional health literacy test consists of the same content and criteria as the longer test but with less questions to allow for less time (Baker et al.,1999). Both versions of the functional health literacy exam are created with the same criteria of questions used to measure a patients' ability to read and understand things they commonly encounter in health care settings.

The specific changes from TOFHLA to STOFHLA include modifications from 17 numeracy items to 4, and from 3 comprehension passages to 2 within the test (Baker et al., 1999). All questions included in the STOFHLA were selected from the TOFHLA exam (Baker et al., 1999). The comprehension passages from the exam allows patients'' to select from a list of four words to select the best option to complete the sentence and fill in the blank (Baker et al., 1999).

The numerical section of the exam assesses quantitative literacy by determining a patients' ability to read and understand numerical information in the form of prescription bottles, appointment slips, or other health-related materials (Baker et al., 1999). The STOFHLA uses a tested scoring system to facilitate measurement of functional health literacy. The range of available scores for this study is 0 (0 correct) to 36 (all 36 correct) (NIKKD, 2017).

For this study adults who self-reported that he or she could not read, or who declined to take the assessment for any reason were given a missing value for the score (NIKKD, 2017). The health literacy variables were categorically coded into 3 categories as described above. Data analysis of the variables were measured using SPSS to ensure accuracy and validity for the statistical tests used for this study.

Renal Replacement Therapy Both Primary and Follow-Up Questionnaires

The renal replacement therapy questionnaires were used as instruments to collect the status of renal conditions. The primary survey is provided as Appendix H, and the follow up survey is under Appendix I. The primary survey was used for the determination of eligibility to examine whether individuals were currently receiving, or had ever received renal therapy, the status of kidney function, or whether they have ever had a kidney transplant (CRIC, 2016). The follow-up survey questionnaire was used to monitor renal function throughout the duration of the cohort to determine if at which stage ESRD developed.

Table 2

Data related to Dependent Variable of Type II Diabetics with ESRD

Instrument	Survey Questions	Responses to Question	Data type
General Health Questionnaire	Have you had any of the following tests or procedures since your last CRIC study contact Hemodialysis or peritoneal dialysis (treatment with an artificial kidney or blood cleaning treatment)?	Yes/No/Don't know	Nominal data
General Health Questionnaire	Since your last CRIC study contact, did you have surgery to create a dialysis shunt (also called a fistula or a graft)?	Yes/No/Don't know	Nominal data
General Health Questionnaire	Since your last CRIC study contact, have you undergone evaluation for a kidney transplant at a transplant center?	Yes/No/Don't know	Nominal data
General Health Questionnaire	Since your last CRIC study contact, were you on a waiting list to receive a kidney transplant?	Yes/No/Don't know	Nominal data
General Health Questionnaire	Since your last CRIC study contact have you had a kidney transplant?	Yes/No/Don't know	Nominal data
Renal Replacement Therapy Questionnaire	Are you currently on either hemodialysis or peritoneal dialysis	Yes/No/Don't know	Nominal data
Renal Replacement Therapy Questionnaire	If so when did dialysis start?_____ How long have you been on dialysis?	Within 6 months, 1 year, 2 years, 3 years, 4 years, 5 years, more than 5 years ago, don't know	Ordinal data
Renal Replacement Therapy Questionnaire	When were you told that your kidneys were not functioning and diagnosed with ESRD?	Within 6 months, 1 year, 2 years, 3 years, 4 years, 5 years, more than 5 years ago, don't know	Ordinal data
Medical Event Questionnaire	Within the last 5 years, where you were diagnosed or treated by a doctor or other health professional who told you (except during pregnancy) that you have diabetes or high blood sugar?	Yes/No/Don't know	Nominal data
Medical Event Questionnaire	How old were you when a doctor first told you that you had diabetes? _____ years old	Yes/No/Don't know	Ratio data/Nominal data

(table continues)

Instrument	Survey Questions	Responses to Question	Data type
Medical Event Questionnaire	Are you on a weight loss or exercise program to control your blood sugar?	Yes/No/Don't know	Nominal data
Medical Event Questionnaire	Are you currently taking insulin?	Yes/No/Don't know	Nominal data
Medical Event Questionnaire	Are you on a weight loss or exercise program to control your blood sugar?	Yes/No/Don't know	Nominal data
Medical Event Questionnaire	Are you currently taking injectable drugs, other than insulin, to manage your blood sugar?	Yes/No/Don't know	Nominal data
Medical Event Questionnaire	Do you currently take diabetes pills to lower your blood sugar? (These are sometimes called oral agents or oral hypoglycemic agents.)	Yes/No/Don't know	Nominal data
Medical Event Questionnaire	How many of the last 7 days did you test your blood sugar?	day 5 days days 6 days days 7 days days 9 None	Ratio Data
Medical Event Questionnaire	How old were you when you started taking diabetes medications?____years old	Don't know/Not Applicable	Nominal data
Medical Event Questionnaire	Of the days that you check your blood sugar, how many times a day do you usually test it? (check one response only)	1 Once a day 2 Twice a day 3 3 times a day 4 4 times a day 5 5 times a day 6 6 times a day or more-I do not test my blood sugar	Ratio data

Operationalization

The dependent variable, developing ESRD among type II diabetics, was measured based on the Medical Event Questionnaire, General Health Questionnaire, and Renal Replacement Therapy Questionnaire. These questionnaires asked participants specific questions related to the diagnosis of diabetes mellitus and kidney disease including end stage renal disease (ESRD). The data was then categorized into spreadsheets based on participants who were diabetic with ESRD and those who were not and compared to their levels of health literacy and the methods of disease management they received. The questions and data used from the above described questionnaires to determine the dependent variable of type II diabetics with ESRD is outlined in table 4.

The independent variables of health literacy and method of disease management will then be examined for each participant. The independent variable of health literacy was based on measurements collected from the STOFHLA scale, the general health questions (where education level was documented), and the modified mini mental state exam. All were given a numeric value, and coded. Participants received scores as listed; STOFHLA Scale inadequate (1), adequate (2) and functional (3), for education; <high school degree, (0), graduated high school or GED (1), some college (2), graduated with 2-year degree (3), graduated with 4-year degree (4), master's degree or greater (5). For the modified mini mental state exam participants received (1) for cognitively impaired (<20), or (2) for not cognitively impaired (>20). The values were then further analyzed to determine health literacy levels based on four levels of overall health literacy; below basic (0-2.5), basic (2.6-5.0), intermediate (5.1-7.5), or proficient (7.6-10). To measure

the statistical relationship and strength of linearity, the dependent variable and the independent variables were compared using Pearson r correlation, and linear regression to examine the significance.

The independent variable; method of disease management was based on the health care utilization and clinic visit status questionnaires. Using the health care utilization data, and clinic visit status data, disease management was based on six categories: 1) the patient\provider relationship, clinic visits, 2) Emergency room or Urgent care visits, 3) other medical facility; nursing homes, 4) automated telephone self-management 5) off-site group visits, 6) no intervention received. The independent variable of method of disease management was then compared to participants' levels of health literacy, and the outcome of ESRD.

Data Analysis Plan

The dataset used in the study originated from the Chronic Renal Insufficiency Cohort Study (CRICS) and is stored within the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) central repository. Once full permission to the dataset is granted, a multivariate analysis using secondary data will be conducted to investigate the relationship between levels of health literacy, disease management methods, and developing ESRD among diabetics. Data was analyzed using SPSS version 23. The initial research questions were as follows, though as discussed later in Chapter 4 I revised Research Questions 2 and 3 based on the available data.

Research Question 1: Is there a relationship between inadequate levels health literacy and developing ESRD among type II diabetics, when controlling for confounding

factors such as gender, education, race, and socioeconomic status?

$H_0$1: There is no relationship between inadequate levels of health literacy and developing ESRD among type II diabetics when controlling for confounding factors such as gender, education, race, and socioeconomic status.

H_a1: There is a relationship between inadequate levels of health literacy and developing ESRD among type II diabetics when controlling for confounding factors such as gender, education, race, and socioeconomic status.

Research Question 2: Is there an association between the method of disease management and an individuals' level of health literacy related to type II diabetes?

$H_0$2: There is no association between the method of disease management and an individuals' level of health literacy related to type II diabetes.

H_a2: There is an association between the method of disease management and an individuals' level of health literacy related to type II diabetes.

Research Question 3: Is there a relationship between the method of disease management and developing ESRD complications among diabetics?

$H_0$3: There is no relationship between the method of disease management and developing ESRD complications among diabetics.

H_a3: There is a relationship between the method of disease management and developing ESRD complications among diabetics.

Research Question 4: Are demographic cofactors such as gender, race, age, socioeconomic status, and education different when comparing outcomes of ESRD, inadequate health literacy, and health insurance status among diabetic participants?

$H_0$4: There are no differences with demographic cofactors such as gender, race, age, socioeconomic status, and education when comparing outcomes of ESRD, inadequate health literacy and health insurance status among diabetic participants

H_a4: There are differences with demographic cofactors such as gender, race, age, socioeconomic status, and education when comparing outcomes of ESRD, inadequate health literacy and health insurance status among diabetic participants.

Descriptive statistics and frequency distributions were used to measure the demographic data categorizing diabetic status, outcome status of ESRD, health literacy levels, and disease management. Frequency distributions, Chi Square analysis and binary logistic regression will be used to display any relationship between diabetics' with ESRD and their level of health literacy. Chi Square analysis and multinomial logistic regression will be used to explore any significant relationship among health literacy and ESRD while controlling for confounding variables.

Additionally, categorical data will be used to perform Chi Square analysis and correlation methods between the population outcome status data (ESRD or no ESRD) relative to their level of health literacy and the method of disease management received. Logistic regression and correlation analyses will be used to explore any significant relationship between levels of heath literacy, and certain types of disease management methods. This will allow comparisons to be demonstrated between participants who developed ESRD and those who did not. Pearson R correlation will be completed to measure the strength of the associations of each hypothesis.

Assuming all data is parametric, inferential statistics using logistic regression, Chi

Square analysis and correlation methods will be performed to account for confounding variables and covariates. Counts and frequency distributions will be used to quantitatively measure demographic data such as age, gender, and race.

To determine significance, when performing logistic regression and correlation analysis, common assumptions include that there is no relationship between the X and Y axis within the population (Illowsky, 2016). The alpha level of 0.05 will be the parameter used to determine significance when performing correlation comparisons, logistic regression, and Chi Square analysis statistics. If the p-value is < 0.5 the null hypothesis will be rejected. Conversely, a greater p-value suggests that I cannot reject the null hypothesis and indicating there is no effect, and the relationship between the variables is not significant.

Threats to Validity

Sample selection bias may exist in this study due to the secondary dataset being collected from a chronic renal insufficiency cohort, which included participants predisposed for some type of renal dysfunction. The data set selection may also be considered a convenience sample, due to the applicable nature of the data collected from the primary study. This could be considered a threat to external validity due to the limitation of generalization to the general public. These threats however, were addressed by including a larger sample size, larger effect size, smaller MOE, Z-score of 1.96, and a 95% CI for a randomly selected population of renal cohort participants (CRIC, 2016). Other methods addressing threats to validity included performing multiple statistical methods. Multiple methods (ANCOVA, linear regression, and Pearson R Correlation)

compared results among both diabetics and non-diabetics with and without ESRD incorporating a control group comparison and offering reliability through replication. As outlined by Sullivan, and Feinn (2012) allowing for a larger effect size and a smaller margin of error (MOE), while maintaining a 95 % confidence internal (CI), strengthens both internal and external validity of a study.

Ethical Procedures

Ethical standards and conduct will be followed according to Walden University's Institutional Review Board (IRB) and according to the code of conduct for research involving human participants. Secondary data will be used for this study. Ethical standards will be applied when requesting data from the registrar and throughout the process of gaining access to the dataset. IRB guidelines have been maintained throughout the initial data collection and will be maintained during the secondary data collection (CRIC, 2016). The secondary dataset is anonymous and participant information is not identifiable but instead data will be assigned a unique number for the purpose of this study. Protection of all data and records will be implemented to allow access to only essential individuals involved in the study of this data.

Ethical practices will be followed to protect and store data so that its integrity can be maintained for a minimum of five years within secured locations both electronically and hard copy in a locked filing system. Ethical judgment will be followed when analyzing the data, with consideration to contractual obligations made between both the participants and the primary researchers.

Summary

Using secondary data from the Chronic Renal Insufficiency Cohort (CRIC), the relationship between levels of health literacy and developing ESRD among type II diabetics will be examined; correlation between levels of health literacy with the methods of disease management will be determined. Inferential statistics will be used with categorical data to perform Chi Square analysis, and correlation methods such as Pearson R Correlation, and logistic regression. Descriptive statistics and frequency distributions will be used to measure the data categorizing diabetic status and outcome status, as well as demographic data. Multiple statistical analysis methods will be conducted using a larger sample size to increase effect size and reduce MOE to minimize threats to validity.

Instruments used to measure the dependent variable; type II diabetics with ESRD included the Medical Event Questionnaire, General Health Questionnaire, Clinic Visits Status questionnaire, Health Care Utilization Survey, and Renal Replacement Questionnaire. Instruments used to measure the independent variables of health literacy, and method of disease management, were the STOFHLA scale, the general health questionnaire, the Self-Efficacy Questionnaire, and the modified Mini Mental Exam.

In Chapter 4, I will describe in detail the data collection process, participants' responses, recruitment outcomes, and results with response rates. I will also discuss the revision of Research Questions 2 and 3 based on the available data. This chapter of the study will outline descriptive, inferential, and demographic data, incorporating tables and graphs as applicable. Statistical results demonstrating the response to the hypotheses and research questions posed in the study will be reported. Finally, I will describe how the

sample results are representative of a larger population and outline how the research provided in the study can offer insightful research to the practice of public health.

Chapter 4: Results

Introduction

The purpose of this study was to investigate if there is a relationship between inadequate levels of health literacy and ESRD complications among type II diabetics. I conducted the study to test the hypotheses that there is a relationship between methods of diabetes disease management, health literacy levels, and patients who develop ESRD. My intent was to examine whether current medical services are adequately reaching patients at their literacy level, enabling them to better manage their disease and prevent diabetic complications. To explore this phenomenon, I originally formulated the following research questions. Due to data discrepancies discussed later in this chapter. Original Research questions 2 and 3 presented below, are later revised. This will be discussed in more detail later in this chapter.

Research Question 1: Is there a relationship between inadequate levels health literacy and developing ESRD among type II diabetics, when controlling for confounding factors such as gender, education, race, and socioeconomic status?

Research Question 2: Is there an association between the method of disease management and an individuals' level of health literacy related to type II diabetes?

Research Question 3: Is there a relationship between the method of disease management and developing ESRD complications among diabetics?

Research Question 4: Are demographic cofactors such as gender, race, age, socioeconomic status, and education different when comparing outcomes of ESRD, inadequate health literacy, and health insurance status among diabetic participants?

To answer the research questions, I explored the relationship between developing ESRD and participants' level of health literacy. I also looked at whether health literacy levels differed depending on participants' service of healthcare and the type of health insurance they possessed. I examined whether there was any relationship between the type of health insurance a participant had and the outcome of developing ESRD. I also examined and controlled for relationships between health literacy and ESRD outcomes and covariates of gender, age, income, education, and race.

In this chapter, I will describe the data collection process, the variables, and the timeframe of the process. I will also describe discrepancies that transpired from the original plan presented in Chapter 3 and discuss the change to the independent variable, method of disease management. I will present demographic characteristics of the sample population and describe the sample process used and include the statistical validity of the sample population. Finally, I will present the analysis of the results measured in the study.

Data Collection

To conduct this study, secondary data was acquired after an agreement was made with the National Institute of Health, CRIC. Once the agreement was in place, IRB approval was verified, and required security documents were officially signed, access to a secured link within the National Institute of Health data repository was received. A secure login and password was required to access the link within the data repository. The data link provided access to a zip file that included 20 different data sets with more than 40,000 data bits. The data file also included a data dictionary, variable code book,

publications, protocols, and a manual of operations. The timeframe for the data collection process outlined was approximately 4 weeks.

Data for this study was secondary data collected by the CRIC from voluntary participants who experienced related symptoms of cardiovascular disease and renal insufficiency disorders from 2001 to 2015.The secondary data used for this study was comprised from all seven participating clinical sites across the United States as outlined in Chapter 3 (NIDDK, 2016). For this study, data from 430-500 participants from each clinical site were included. To achieve a confidence interval of 95%, the number of participants required for this study was a minimum of N =8 35. There were 3,939 ethnically diverse participants from whom data was collected over a 5-year period. Data collected during visits numbered 1 and 2 were prescreening interviews, where information was provided, lab samples collected, and eligibility and assessments were conducted (NIKKD, 2016). Baseline data were collected during visit number 3. Tracking and follow-up data on participants was collected through visit number 13 over a 5-year period (NIKKD, 2016). Data collected included 2,802 participants who completed the cohort through all 13 visits; whereas 1,137 original participants in the cohort either dropped out or expired at some stage during the cohort visits.

Discrepancies in Data Collection

The dependent variable measured for this study was the development of ESRD. The independent variables that were used include both health literacy and health care service based on participants' type of health insurance. Originally, the independent variables were to include health literacy and the method of disease management a

participant received (relating to Research Questions 2 and 3). After receiving and reviewing the dataset, however, the dataset did not include any data related to the disease management that participants received. The most relevant variables in the dataset included participants' type of health care service dependent on their type and status of health insurance coverage. The discrepancies related to the lack of available data as described led me to readjust the original Research Questions 2 and 3 as presented earlier. Research Questions 2 and 3 were modified with consideration to the available data. The intent to research an association between health care services, health literacy, and diabetic complications like ESRD remained despite these changes. The revised research questions are:

Research Question 2: Is there an association between types of healthcare services and inadequate levels of health literacy among type II diabetics?

Research Question 3: Is there a relationship between developing ESRD among type II diabetic populations, and healthcare services?

New Independent Variables

The independent variable of healthcare services was measured based on the newly identified data of health insurance. Health insurance status and type of health insurance was derived from data collected during enrollment interviews and documented on a Health Data Review form (NIKKD, 2017). Responses were categorized into six levels:

1. None (no health insurance or coverage),
2. Medicaid\public aid,
3. any Medicare,

4. VA/military/champus,
5. private/commercial,
6. unknown/incomplete info

As evidence to support the use of the new data of health insurance to determine healthcare services, research shows that there is an association between types of health careservices, health care use, and health outcomes (Harris, 2001). In fact, according to Sommers, Gunja, Finegold, and Musco (2015), healthcare services vary dependent on the type of health insurance received. The second independent variable measured in the study was health literacy using the instrument Short Test of Functional Health Literacy in Adults (STOFHLA). This independent variable remained the same as outlined in Chapter 3.

Demographic Characteristics of Participants

Analytical results for this study were derived from 3,939 participants from racially and ethnically diverse backgrounds, aged 21-74, who were predisposed to develop some form of mild-renal insufficiency (NIKKD, 2017). The data were stratified by participants with type II diabetes (n = 1,908, 48%) and those without (n = 2,031, 52%) and examined in further detail. A stratified randomized sample was used for CRIC to provide a representative sample of the population of interest. The application of a randomized stratified sampling provided a strong external validity and a credible generalization to be made from the CRIC sample to the population at large (Bowling, 2014). See Tables 3 and 4 for details.

Table 3

Demographic Characteristics of Participants

Demographics	*n*	%
Sex		
Male	2,161	54.9
Female	1,778	45.1
Race\Ethnicity		
White	1,638	41.6
African American	1,650	41.9
Hispanic	497	12.6
Other *	154	3.9
Age		
<30	65	1.7
30-40	252	6.4
41-50	493	12.5
51-60	1,169	29.7
61-70	1,433	36.4
>70	527	13.4
Income		
20,000 or <	1,240	31.5
20,000-50,000	958	24.3
50,000-100,000)	734	18.6
more than 100,000	392	10.0
didn’t wish to answer	615	15.6

(table continues)

Demographics	*n*	%
Education		
6th <	212	5.4
7-12th	616	15.6
Ged\HS Diploma	741	18.8
Tech or Voc college	191	4.8
Some college no degree	955	24.2
College grad	709	18.0
Prof or grad degree	514	13.0
Missing	1	0
Diabetes at Baseline		
No	2,031	51.6
Yes	1,908	48.4

Table 4

Demographic Characteristics of Participants with Diabetes

Demographics	*n*	%
Sex		
Male	1,064	55.8
Female	844	44.2
Race\Ethnicity		
White	649	34.0
African American	848	44.4
Hispanic	335	17.6
Other *	76	4.0
Age		
<30	14	.7
30-40	83	4.4
41-50	197	10.3
51-60	618	32.4
61-70	724	37.9
Income		
20,000 or <	735	38.5
20,000-50,000	455	23.8
50,000-100,000)	286	15.0
more than 100,000	138	7.2
didn’t wish to answer	294	15.4

(table continues)

Demographics	n	%
Education		
6th <	158	8.3
7-12th	365	19.1
Ged\HS Diploma	368	19.3
Tech or Voc. college	100	5.2
Some college no degree	460	24.1
College grad	288	15.1
Prof or grad degree	169	8.9

Note. N = 3,939; after data stratified by variable of type II diabetes N = 1,908

*Other = Asian, American Indian, Pacific Islander or Hawaiian

To further explore demographic variables and distribution differences based on the stratified data, frequency distributions and counts were analyzed based on the dependent variable of ESRD and the independent variables of health literary and health insurance. Furthermore, these variables were analyzed within the data analysis section of this chapter using chi-square analysis and logistic regression to determine if the relationships are significant.

Demographic Distribution: ESRD

Diabetic participants. Frequency distributions dependent of the diagnosis of ESRD were tabulated into Tables 5 and 6 and organized by the diagnosis of diabetes or not. Tabulations were used to explore the demographic distributions based on the diagnoses of ESRD. When analyzing demographic characteristics of individuals with type II diabetes based on the dependent variable of ESRD diagnoses, 539 (28%) of the individuals developed ESRD and 1,369 (72%) individuals did not. Of the 539 participants who developed ESRD, 317 (59 %) were male and 222 (41%) were female; of the 1369 who did not develop ESRD, 747 (55%) were male and 622 (45%) were female. Out of the overall population of diabetics (1,908), 16.6% of males and 11.6 % of females developed ESRD. Demographic data also showed that African Americans developed ESRD more often than other participants. Further, individuals between the age of 51-60 and 61-70 were the most affected by ESRD. When examining income, the highest percentage of individuals who developed ESRD had an income level of < 20,000 dollars annually. Though numbers were close, the greatest percentage of individuals who developed ESRD had some college but no degree followed by individuals who only had a

seventh-12th grade education without a high school diploma. Please see Table 5 for more detail.

Nondiabetic participants. In comparison, of the 2,031 participants who did not have type II diabetes, data showed that 288 (14%) of the individuals developed ESRD and 1,743 (86%) of individuals did not. Of the 288 participants who developed ESRD, 176 (61 %) were male and 122 (39%) were female; out of the 1,743 who did not develop ESRD 921 (52%) were male and 822 (47%) were female. Out of the overall population of nondiabetics (2,031), 8.7 % of males and 5.5 % of females developed ESRD. When comparing participants who did not have type II diabetes, data also showed that African Americans developed ESRD more often than other participants. Age was equitable across all categories, but 61-70 had the highest percentage with 51-60-year-olds close behind. Income levels for nondiabetics who developed ESRD showed the highest percentage of individuals who developed ESRD like with diabetics had an income level of < 20,000 dollars annually. Education levels again were equal across categories, but the greatest percentage of individuals who developed ESRD had some college, but no degree followed by participants with only a GED or high school diploma or those with a seventh-12th grade education. Please see Table 6 for more detail.

Table 5

Demographic Characteristics by Diagnoses of ESRD

Demographics	ESRD	No ESRD	% that Developed ESRD
Sex	539	1,369	
Male	317	747	16.6%
Female	222	622	11.6%
Race\Ethnicity	485	1,242	
White	118	509	6.8%
African American	245	527	14.2%
Hispanic	104	162	6.0%
Other *	18	44	1.0%
Missing	54	127	181
Age	539	1,369	
<30	6	8	0.31%
30-40	34	49	1.8%
41-50	77	120	4.0%
51-60	202	41	10.6%
61-70	170	554	8.9%
>70	50	222	2.6%
Income	539	1,369	
20,000 or <	252	483	13.2%
20,000-50,000	115	340	6.0%
50,000-100,000	70	216	3.7%
more than 100,000	26	112	1.4%
didn’t wish to answer	76	218	4.0%

(table continues)

Demographics	ESRD	No ESRD	% that Developed ESRD
Education	539	1369	
6th <	64	94	3.4%
7-12th	115	250	6.0%
Ged\HS Diploma	99	269	5.2%
Tech or Voc college	24	76	1.3%
Some college no degree	132	328	6.9%
College grad	71	217	3.7%
Prof or grad degree	34	135	1.8%

Note. Data are stratified by participants with diabetes (*N* = 1,908) and those without (*N* = 2,030)

Table 6

Demographic Characteristics by Diagnoses of ESRD (Participants Without Diabetes)

Demographics	ESRD	No ESRD	% that developed ESRD
Sex	288	1,743	
Male	176	921	8.7%
Female	112	822	5.5%
Race\Ethnicity	288	1,743	
White	81	908	4.0%
African American	158	644	7.8%
Hispanic	33	129	1.6%
Other *	16	62	0.8%
Age	288	1,743	
<30	16	35	0.8%
30-40	43	126	2.1%
41-50	57	239	2.8%
51-60	65	486	3.2%
61-70	79	630	3.9%
>70	28	227	1.4%
Income	288	1,743	
20,000 or <	92	413	4.5%
20,000-50,000	72	431	3.5%
50,000-100,000)	52	396	2.6%
more than 100,000	18	236	0.9%
didn’t wish to answer	54	267	2.7%

(table continues)

Demographics	ESRD	No ESRD	% that developed ESRD
Education	288	1742	
6th <	13	41	0.6%
7-12th	50	201	2.5%
Ged\HS Diploma	59	314	2.9%
Tech or Voc. college	17	74	0.8%
Some College no degree	72	423	3.5%
College grad	43	378	2.1%
Prof or grad degree	34	311	1.7%
Missing	0	1	

Note. Data are stratified by participants with diabetes (*N* = 1,908) and those without (*N* = 2,030)

Demographic Distribution: Heath Literacy

Diabetic participants. When analyzing demographic characteristics of individuals with type II diabetes based on the independent variable of health literacy, data showed that overall most diabetics had adequate levels of health literacy. However, when looking at levels of health literacy based on gender males had inadequate levels more often than females. When comparing health literacy levels based on the demographic characteristics of race African Americans had the highest percentage of inadequate levels, whereas Caucasians had the highest percentage of adequate levels. The majority of individuals with inadequate levels were between the age of 61-70, and most had incomes less than $20,000 annually. Where participants higher incomes more often had adequate levels of health literacy. Regarding education, most participants with inadequate levels had an education of less than sixth grade, where those participants with adequate levels of literacy had at least some college 270 (30%). Please see Table 7.

Table 7

Demographic Characteristics Related to Health Literacy of Diabetic Participants

Demographics	Inadequate	Marginal	Adequate	Missing or invalid
Sex	172 (14.7%)	99 (8.4%)	903 (76.9%)	734
Male	97 (56.4%)	63 (63.6%)	492 (54.5%)	412
Female	75 (43.6%)	36 (36.4%)	411 (45.5%)	322
Race\Ethnicity	172 (14.7%)	99 (8.4%)	903 (76.9%)	734
White	15 (8.7%)	15 (15.2%)	408 (45.2%)	211
African American	86 (50%)	56 (56.6%)	357 (39.5%)	349
Hispanic	68(39.5%)	26 (26.3%)	100 (11.1%)	141
Other *	3 (1.7%)	2 (2.0%)	38 (4.2%)	33
Age	172 (14.7%)	99 (8.4%)	903 (76.9%)	73 4
<30	0 (0%)	0 0	7 (.8%)	7
30-40	2 (1.2%)	2 (2.0%)	54 (6.0%)	25
41-50	10 (5.8%)	7 (7.1%)	110 (12.2%)	70
51-60	57 (33.1%)	39 (39.4%)	300 (33.2%)	222
61-70	77 (44.8%)	31 (31.3%)	325 (36.0%)	291
>70	26 (15.1%)	20 (20.2%)	107 (11.8%)	119

(table continues)

Demographics	Inadequate	Marginal	Adequate	Missing or invalid
Income	172 (14.7%)	99 (8.4%)	903 (76.9%)	734
20,000 or <	107(62.2%)	51 (51.5%)	235 (26.0%)	342
20,000-50,000	25(14.5%)	19 (19.2%)	250 (27.7%)	161
50,000-100,000	6 (3.5%)	9 (9.1%)	197 (21.8%)	74
>100,000	4 (2.3%)	4 (4.0%)	98 (10.9%)	32
didn't wish to answer	30 (17.4%)	16 (16.2%)	123 (13.6%)	125
Education	172 (14.7%)	99 (8.4%)	903 (76.9%)	734
6th <	51 (29.7%)	5 (5.1%)	15 (1.7%)	87
7-12th	50 (29.1%)	39 (39.4%)	99 (11.0%)	177
Ged\HS	33(19.2%)	22 (22.2%)	171 (18.9%)	142
Tech -Voc. Coll	6 (3.5%)	2 (2.0%)	54 (6.0%)	38
Some College	23 (13.4%)	15 (15.2%)	270 (29.9%)	152
College grad	5 (2.9%)	13 (13.1%)	183 (20.3%)	87
Prof or grad Degree	4 (2.3%)	3 (3.0%)	111 (12.3%)	51

Note. Data are stratified by participants with diabetes (N = 1,174) and those without (N = 1,541).

Nondiabetic participants. When analyzing demographic characteristics based on the independent variable of health literacy for non-diabetics, data once again showed that overall most non-diabetics also had adequate levels of health literacy. However, once again there were differences depending on demographics. When looking at levels of health literacy based on gender among non-diabetic participants, males again had inadequate levels more often than females. Health literacy levels based on the demographic of race for non-diabetic participants showed similar results as that of diabetic participants where African Americans had the highest percentage of inadequate levels and Caucasians had the highest percentage of adequate levels. The majority of non-diabetic individuals with inadequate levels were all between the age of 61-70. Most non-diabetic participants with inadequate health literacy had incomes less than $20,000 annually, and participants who had adequate levels were once again more likely to have higher salaries. When analyzing education, most participants with inadequate levels had an education of 7-12th with no high school diploma and participants with adequate levels of literacy had at least some college education. Please see Table 8.

Table 8

Demographic Characteristics Related to Health Literacy of Nondiabetic Participants

Demographics	Inadequate	Marginal	Adequate	Missing or invalid
Sex	83 (5.4%)	74 (4.8%)	1,384 (89.8%)	490
Male	56 (67.5%)	47 (63.5%)	726 (52.5%)	268
Female	27 (32.5%)	27 (36.5%)	658 (47.5%)	222
Race\Ethnicity	83 (5.4%)	74 (4.8%)	1,384 (89.8%)	490
White	10 (12.0%)	15 (20.3%)	768 (55.5%)	196
African American	51 (61.4%)	46 (62.2%)	466 (33.7%)	239
Hispanic	19 (22.9%)	11 (14.9%)	98 (7.1%)	34
Other *	3 (3.6%)	2 (2.7%)	52 (3.8%)	21
Age	83 (5.4%)	74 (4.8%)	1,384 (89.8%)	490
<30	0 (0)	0 (0)	34 (2.5%)	17
30-40	2 (2.4%)	2 (2.7%)	127 (9.2%)	38
41-50	7 (8.4%)	4 (5.4%)	225 (16.3%)	60
51-60	23 (27.7%)	25 (33.8%)	389 (28.1%)	114
61-70	37 (44.6%)	31 (41.9%)	474 (34.2%)	167
>70	14 (16.9%)	12 (16.2%)	135 (9.8%)	94
Income	83 (5.4%)	74 (4.8%)	1,384 (89.8%)	490
20,000 or <	47 (56.6%)	33 (44.6%)	239 (17.3%)	186
20,000-50,000	15 (18.1%)	19 (25.7%)	357 (25.8%)	112
50,000-100,000	5 (6.0%)	5 (6.8%)	369 (26.7%)	69
>100,000	0 (0)	1 (1.4%)	219 (15.8%)	34
didn’t wish to answer	16 (19.3%)	16 (21.6%)	200 (14.5%)	89

(table continues)

Demographics	Inadequate	Marginal	Adequate	Missing or invalid
Education	83 (5.4%)	74 (4.8%)	1384 (89.8%)	490
6th <	12 (14.5%)	6 (8.1%)	10 (.7%)	26
7-12th	40 (48.2%)	23 (31.1%)	87 (6.3%)	101
Ged\HS Diploma	14 (16.9%)	22 (29.7%)	224 (16.2%)	113
Tech-Voc coll.	5 (6.0%)	7 (9.5%)	64 (4.6%)	15
Some College no Degree	10 (12.0%)	12 (16.2%)	361 (26.1%)	112
College grad	1 (1.2%)	3 (4.1%)	335 (24.2%)	82
Prof or grad	1 (1.2%)	1 (1.4%)	302 (21.8%)	41

Note. Data are stratified by participants with diabetes (N = 1,174) and those without (N = 1,541).

Demographic Distribution: Heath Care Access/Health Insurance

Diabetic participants. Frequency distributions were also done on demographic characteristics based on the second independent variable of health care service. Health care service was determined by the type and or whether participants had health care insurance. When analyzing the overall study population, the greatest percentage of individuals has some type of Medicare insurance. When examining health care access based on gender specific, males more often than females did not know their health insurance status and or were more often receiving military health care. Females on the other hand when compared to males more often were receiving some type of Medicaid or public aid source of health care. It was also notable that men more often than females reported as not having any health insurance. When comparing health care by race, Hispanic populations had the highest frequency of not having any health insurance,

whereas African Americans more often has some type of Medicaid or public aid, and Caucasians most often did not know their type of health care insurance, but when they did they more often had private health insurance. Regarding age the majority of people with no health insurance were between the ages of 51-60, and the majority of participants receiving Medicaid were between the ages of 61-70. As expected the majority of those receiving Medicare were between the ages of 61-70, and or >70. Those participants receiving military, private and or didn't know their insurance type were more often between the ages of 51-60. When looking at the demographic of income participants who either had no insurance, Medicaid or public aid, or received some type of Medicare all reported as earning less than $20,000 dollars annually. Participants with military insurance claimed to earn $20,000-50,000 dollars annually. The highest percentage of individuals who either received private health insurance or didn't know their health insurance reported as earning $50,000-100,000 dollars a year. Finally, when looking at the diabetic population and comparing education levels to health insurance status, participants who reported as having no health insurance most often had an education of less than a 6th grade level. Individuals who received Medicaid or public aid reported most often as having a 7th 12th grade with no diploma education. Participants receiving Military insurance also more often reported as having a 7th 12th grade with no diploma education, and those with Medicare, private insurance, or didn't know reported as having some college education. Please see Table 9 for more detail.

Table 9

Demographic Characteristics Regarding Health Insurance for Participants with Diabetes

Demographics	None	Medicaid	Medicare	Military	Private	Don't know	Missing
Total	142 (8.5%)	306 (18.4%)	644 (38.8%)	85 (5.1%)	209 (12.6%)	275 (16.6%)	247
Sex							
Male	77 (54.2%)	123 (40.2%)	385 (59.8%)	83 (97.6%)	100 (47.8%)	166 (60.4%)	130
Female	65 (45.8%)	183 (59.8%)	259 (40.2%)	2 (2.4%)	109 (52.2%)	109 (39.6%)	117
Race\Ethnicity							
White	23 (16.2%)	50 (16.3%)	246 (38.2%)	31 (36.5%)	80 (38.3%)	150 (54.5%)	69
African American	35 (24.6%)	182 (59.5%)	285 (44.3%)	48 (56.5%)	82 (39.2%)	93 (33.8%)	123
Hispanic	74 (52.1%)	62 (20.3%)	93 (14.4%)	5 (5.9%)	31 (14.8%)	25 (9.1%)	45
Other *	10 (7.0%)	12 (3.9%)	20 (3.1%)	1 (1.2%)	16 (7.7%)	7 (2.5%)	10
Age							
<30	1 (.7%)	4 (1.3%)	2 (.3%)	0 (0)	2 (1.0%)	2 (.7%)	3
30-40	6 (4.2%)	20 (6.5%)	14 (2.2%)	0 (0)	12 (5.7%)	22 (8.0%)	9
41-50	20 (14.1%)	44 (14.4%)	33 (5.1%)	6 (7.1%)	23 (11.0%)	51 (18.5%)	20
51-60	75 (52.8%)	99 (32.4%)	112 (17.4%)	35 (41.2%)	96 (45.9%)	110 (40.0%)	91
61-70	33 (23.2%)	100 (32.7%)	329 (51.1%)	34 (40.0%)	57 (27.3%)	77 (28.0%)	94
>70	7 (4.9%)	39 (12.7%)	154 (23.9%)	10 (11.8%)	19 (9.1%)	13 (4.7%)	30
Income							
20,000 <	92 (64.8%)	212 (69.3%)	229 (35.6%)	27 (31.8%)	31 (14.8%)	34 (12.4%)	110
20,000-50,000	25 (17.6%)	36 (11.8%)	186 (28.9%)	28 (32.9%)	58 (27.8%)	68 (24.7%)	54
50,000-100,000	3 (2.1%)	8 (2.6%)	88 (13.7%)	11 (12.9%)	61 (29.2%)	85 (30.9%)	30
>100,000	1 (.7%)	2 (.7%)	37 (5.7%)	1 (1.2%)	38 (18.2%)	49 (17.8%)	10
didn't answer	21 (14.8%)	48 (15.7%)	104 (16.1%)	18 (21.2%)	21 (10.0%)	39 (14.2%)	43

(table continues)

Demographics	None	Medicaid	Medicare	Military	Private	Don't know	Missing
Education							
6th <	35 (24.6%)	33 (10.8%)	46 (7.1%)	12 (14.1%)	12 (5.7%)	9 (3.3%)	23
7-12th	26 (18.3%)	100 (32.7%)	121 (18.8%)	28 (32.9%)	18 (8.6%)	20 (7.3%)	68
Ged\HS	3 (22.5%)	54 (17.6%)	140 (21.7%)	7 (8.2%)	20 (9.6%)	42 (15.3%)	52
Tech-Voc. Coll	4 (2.8%)	21 (6.9%)	34 (5.3%)	23 (27.1%)	11 (5.3%)	11 (4.0%)	12
College no degree	24 (16.9%)	70 (22.9%)	148 (23.0%)	11 (12.9%)	67 (32.1%)	79 (28.7%)	49
College Grad	17 (12.0%)	22 (7.2%)	90 (14.0%)	4 (4.7%)	53 (25.4%)	69 (25.1%)	26
Prof. Degree	4 (2.8%)	6 (2.0%)	65 (10.1%)	12 (14.1%)	28 (13.4%)	45 (16.4%)	17

Note. Data are stratified by participants with diabetes (*N* = 1,174) and those without (*N* = 1,541)

Nondiabetic participants. Similar to the diabetic population, non-diabetics in this study most often had Medicare health insurance. However, males once again, when comparing to females more often did not know their health insurance status and or were more often receiving military health care. Whereas females were receiving some type of Medicaid or public aid source of health care, and like the diabetic population men more often reported as not having any health insurance. When comparing race among non-diabetic populations however African Americans more often had no insurance, compared to Hispanic participants who had diabetes, and also more often had Medicaid and or some type of public aid. Caucasians once again more often reported as having Medicare and or private health insurance. Age remained consistent across all categories of health insurance, where the age range of 51-60 had the highest percentages. The only exception was Medicare where the greatest percentage of age was seen in the age range of 61-70. Regarding income results were similar to those of the diabetic population, where participants who either had no insurance, Medicaid or public aid, reported as earning less

than $20,000 dollars annually. Those however, receiving some type of Medicare reported as earning a bit higher wage than the diabetic population, and reported more often as earning $20,000-50,000 dollars annually. Participants with military insurance remained similar claiming to earn $20,000-50,000 dollars annually. Individuals who either received private health insurance or didn't know once again reported as earning $50,000-100,000 dollars a year. Education levels differed when compared to diabetic populations where overall the levels of educations seemed to be a bit higher. Those participants who reported as having no health insurance or Medicaid most often had either a GED, some high school, or a high school diploma, while those participants with private insurance reported as being a college graduate or having graduate or professional levels of education. Please see Table 10 for more detail.

Table 10

Demographic Characteristics Regarding Health Insurance for Participants without Diabetes

Demographics	None	Medicaid	Medicare	Military	Private	Don't know	Missing
Total	130 (7.0%)	217 (11.7%)	568 (30.7%)	111 (6.0%)	369 (20.0%)	453 (24.5%)	183
Sex							
Male	72 (55.4%)	95 (43.8%)	293 (51.6%)	98 (88.3%)	170 (46.1%)	269 (59.4%)	100
Female	58 (44.6%)	122 (56.2%)	275 (48.4%)	13 (11.7%)	199 (53.9%)	184 (40.6%)	83
Race\Ethnicity							
White	25 (19.2%)	46 (21.2%)	318 (56.0%)	42 (37.8%)	204 (55.3%)	279 (61.6%)	75
African American	61 (46.9%)	145 (66.8%)	209 (36.8%)	62 (55.9%)	108 (29.3%)	126 (27.8%)	91
Hispanic	39 (30.0%)	22 (10.1%)	27 (4.8%)	4 (3.6%)	37 (10.0%)	22 (4.9%)	11
Other *	5 (3.8%)	4 (1.8%)	14 (2.5%)	3 (2.7%)	20 (5.4%)	26 (5.7%)	6
Age							
<30	11 (8.5%)	4 (1.8%)	4 (.7%)	7 (6.3%)	4 (1.1%)	18 (4.0%)	10
30-40	9 (6.9%)	22 (10.1%)	7 (1.2%)	9 (8.1%)	41 (11.1%)	71 (15.7%)	12
41-50	35 (26.9%)	33 (15.2%)	33 (5.8%)	41 (36.9%)	73 (19.8%)	90 (19.9%)	23
51-60	49 (37.7%)	67 (30.9%)	59 (10.4%)	45 (40.5%)	143 (38.8%)	152 (33.6%)	40
61-70	20 (15.4%)	64 (29.5%)	313 (55.1%)	9 (8.1%)	92 (24.9%)	112 (24.7%)	63
>70	6 (4.6%)	27 (12.4%)	152 (26.8%)	7 (6.3%)	16 (4.3%)	10 (2.2%)	35
Income							
20,000 <	69 (53.1%)	136 (62.7%)	143 (25.2%)	32 (28.8%)	29 (7.9%)	29 (6.4%)	67
20,000-50,000	28 (21.5%)	21 (9.7%)	182 (32.0%)	42 (37.8%)	91 (24.7%)	92 (20.3%)	47
50,000-100,000	9 (6.9%)	15 (6.9%)	105 (18.5%)	17 (15.3%)	122 (33.1%)	160 (35.3%)	20
>100,000	1 (.8%)	4 (1.8%)	42 (7.4%)	6 (5.4%)	80 (21.7%)	110 (24.3%)	11
didn't answer	23 (17.7%)	41 (18.9%)	96 (16.9%)	14 (12.6%)	47 (12.7%)	62 (13.7%)	38

(table continues)

Demographics	None	Medicaid	Medicare	Military	Private	Don't know	Missing
Education							
6th <	16 (12.3%)	5 (2.3%)	14 (2.5%)	1 (.9%)	5 (1.4%)	5 (1.1%)	8
7-12th	26 (20.0%)	65 (30.0%)	70 (12.3%)	10 (9.0%)	23 (6.2%)	14 (3.1%)	43
Ged\HS	35 (26.9%)	51 (23.5%)	122 (21.5%)	28 (25.2%)	43 (11.7%)	51 (11.3%)	43
Tech-Voc. Coll	8 (6.2%)	11 (5.1%)	23 (4.0%)	8 (7.2%)	16 (4.3%)	18 (4.0%)	7
College no degree	24 (18.5%)	57 (26.3%)	139 (24.5%)	40 (36.0%)	93 (25.2%)	103 (22.7%)	39
College Grad	18 (13.8%)	23 (10.6%)	104 (18.3%)	18 (16.2%)	101 (27.4%)	124 (27.4%)	33
Prof. Degree	3 (2.3%)	5 (2.3%)	96 (16.9%)	6 (5.4%)	87 (23.6%)	138 (30.5%)	10

Note. Data are stratified by participants with diabetes (*N* = 1,174) and those without (*N* = 1,541).

Results

Secondary data analysis focused on three main variables, health literacy, health care services based upon status of health insurance, and the dependent variable of developing ESRD. The variable of healthcare services was revised to measure the participants' healthcare services based upon health insurance status rather than the type of disease management received. Health literacy was measured using the STOFHLA instrument, healthcare services was based on health insurance status from self- reported

baseline data, and the variable of ESRD was based on medical evaluations from the primary data. Multiple datasets were provided and prior to analysis were sorted, combined, and duplicates removed. The data was entered in SPSS version 23 where descriptive statistics, frequency distributions, and correlation tests were performed. Chi-square, binary, and multinomial logistic regression was used for statistical analysis on the population of study participants. The data analysis includes a comparison of demographic variables based on the independent and dependent variables providing a descriptive overview of the results. Relationships between variables were examined among participants.

Overview of Statistical Tests Used

To explore the phenomenon presented in research questions Research Question 1, Research Question 2, and Research Question 3, bivariable associations were analyzed among participants with diabetes (N=1908). Chi Square analysis, Crosstabulation, and Correlation tests were performed for research questions one thru three. Statistical tests were used to determine if relationships are significant between Research Question 1) ESRD and inadequate healthy literacy; Research Question 2) inadequate health literacy and healthcare services based on health insurance status; and Research Question 3) ESRD and Healthcare services based on health insurance status. Research question four (Research Question 4) however, is analyzed using three individual analysis for each of the outcomes (Inadequate health literacy, ESRD, and health insurance status) and examined based on the covariates of gender, race\ethnicity, socioeconomic status, education and age. A Chi square analysis and binary logistic regression were used on the

outcome of inadequate health literacy and ESRD and the covariates. A Chi square analysis and multinomial logistic regression was used to explore the relationship between the six categories of health insurance status and the described demographic covariates.

Research Question 1

Research Question 1: Is there a relationship between inadequate levels of health literacy and developing ESRD among type II diabetics, when controlling for confounding factors such as gender, age, education, income, and race?

$H_0$1: There is no relationship between inadequate levels of health literacy and developing ESRD among type II diabetics when controlling for confounding factors such as gender, education, race, and socioeconomic status.

H_a1: There is a relationship between inadequate levels of health literacy and developing ESRD among type II diabetics when controlling for confounding factors such as gender, education, race, and socioeconomic status.

For this research question I performed a Chi square analysis. Both the dependent variable of ESRD and the independent variable of inadequate health literacy were nominal variables. The dependent variable of ESRD is a dichotomas categorical variable where 0=No development of ESRD and 1= Yes, participants developed ESRD. The independent variable for this analysis was inadequate health literacy. Where a dummy variable was created, making the independent variable a binary categorical variable. Inadequate levels of health literacy =1, and other=2, which included marginal and adequate levels. Cross-tabulation counts showed that when controlling for confounding factors among diabetic participants, participants who developed ESRD had a higher

percentage of inadequate (12.4%) levels of health literacy compared to those participants who did not develop ESRD (7.7%). Overall most participants in both categories (those who developed ESRD and those who did not) had marginal and or adequate levels of health literacy (91%). The cross tabulations show that not only did those who developed ESRD have a higher percentage of inadequate levels, but they also had a lower percentage of participants who had marginal and adequate levels (87.6% compared to 92.3%) than those who did not develop ESRD. Of the 1908 diabetic participants, 539 (28.2%) developed ESRD and 1369 (71.8%) did not (see Table 11).

Table 11

Cross-tabulation: Inadequate Health Literacy and ESRD

		Level of Health Literacy		
ESRD Status		Other	Inadequate	Total
No ESRD	Count	1,264	105	1,369
	% within developed	92.5%	7.7%	100%
	% within level of HL	72.8%	61%	71.8%
	% of total	66.2%	5.5%	71.8%
ESRD	Count	472	67	539
	% within developed	87.6%	12.4%	100%
	% within level of HL	27.2%	39%	28.2%
	% of total	24.7%	3.5%	28.2%
	Total count	1,736	172	1,908
	% within developed ESRD	91%	9%	100%
	% within level of HL	100%	100%	100%
	% of total	91%	9%	100%

To further explore the relationship between the dependent variable of ESRD and

the independent variable of inadequate health literacy, a chi square analysis was performed on the diabetic participants (N=1908). When analyzing the relationship between inadequate health literacy and ESRD, the Chi Square analysis revealed that the relationship is significant (X2 (1, N=1908) =10.686, p value= <0.001). The results showed that no assumptions had been violated and that there is a significant relationship between developing ESRD and inadequate levels of health literacy (see Table 12).

Table 12

Chi-Square Test Results for Inadequate Health Literacy and ESRD

	Value	df	Asymptotic Sig (2-sided) p-value	Exact Sig. (2- sided)	Exact Sig. (1- sided)
Pearson chi-square	10.686[a]	1	.001		
Continuity Correction[b]	10.113	1	.001		
Likelihood ratio	10.097	1	.001		
Fisher's exact test				.002	.001
Linear-by-linear Association	10.680	1	.001		
N of valid cases	1908				

Note. a = 0 cells (0.0%) have expected count less than 5. The minimum expected count is 48.59. b = Computed only for a 2x2 table

Correlation analysis supported this by also presenting a significant (p value =< .001). The Phi and Cramer V was also significant (p=<.001) with an effect size of (.075). According to Cramer and Howitt (2004) this effect size is categorized as a small effect. These results indicate that though significant, inadequate health literacy has a small effect

on the development of ESRD (see Table 13). Based on these findings however, the null hypothesis for research question one (Research Question 1) can be rejected.

Table 13

Correlation Test Results for Health Literacy and ESRD

		Value	Asymptotic Standardized Error[a]	Approximate T[b]	Sig.
Nominal by Nominal	Phi	.075			.001
	Cramer's V	.075			.001
Interval by Interval	Pearson's R	.075	.025	3.276	.001[c]
Ordinal by Ordinal	Spearman Correlation	.075	.025	3.276	.001[c]
N of Valid Cases		1908			

Note. a = Not assuming the null hypothesis. b = Using standard error c = Based on normal approximation

Research Question 2

Research Question 2: Is there an association between types of healthcare services and inadequate levels of health literacy among type II diabetics?

$H_0$2- There is no association between types of healthcare services and an individuals' level of health literacy related to type II diabetes.

H_a2 -There is an association between types of healthcare services and an individuals' level of health literacy related to type II diabetes.

I explored research question two (Research Question 2), by specifically looking at the relationship between inadequate health literacy and health insurance types. For this research question I performed cross tabulations and a chi square analysis. The dependent variable for this analysis is the binary categorical variable of inadequate health literacy, and the independent variable of six categories of health insurance; (1) none, 2) Medicaid or public aid, 3) Medicare, 4) Military insurance, 5) private health insurance, and 6) participant did not know if they had health insurance or if they did, what they had). Of the 1908 diabetic participants, 163 had inadequate missing data and did not complete the health insurance status survey (see Tables 14 and 15).

When analyzing the relationship between inadequate levels of health literacy among diabetic participants and healthcare services based on health insurance, cross-tabulation counts showed that overall most participants in the study had Medicare as their health insurance. However, when comparing inadequate levels of health literacy to marginal and adequate levels (other), participates with inadequate levels more often had no health insurance (14.7%), or Medicaid/public aid (23.9%), compared to (7.9%) and (17.8%) respectively. Whereas participants with marginal and adequate levels more often had private (5.5%) and or military health insurance (13.0%) compared to (1.2%) and (8.6%) respectively (see Table 14 and Figures 1 and 2).

Table 14

Cross-tabulation of Health Insurance Status and Inadequate Health Literacy

	None	Medicaid	Medicare	Military	Private	unknown	Total
Other Levels (marginal- adequate)	118	267	573	83	195	262	1498
% within Inadequate	7.9%	17.8%	38.3%	5.5%	13.0%	17.5%	100.0%
% within Health Insurance Status (6 levels, first available visit)	83.1%	87.3%	89.0%	97.6%	93.3%	95.3%	90.2%
% of Total	7.1%	16.1%	34.5%	5.0%	11.7%	15.8%	90.2%
Inadequate Levels	24	39	71	2	14	13	163
% within Inadequate	14.7%	23.9%	43.6%	1.2%	8.6%	8.0%	100.0%
% within Health Insurance Status (6 levels, first available visit)	16.9%	12.7%	11.0%	2.4%	6.7%	4.7%	9.8%
% of Total	1.4%	2.3%	4.3%	0.1%	0.8%	0.8%	9.8%
Total Counts	142	306	644	85	209	275	1661
% within Inadequate	8.5%	18.4%	38.8%	5.1%	12.6%	16.6%	100.0%
% within Health Insurance Status (6 levels, first available visit)	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%
% of Total	8.5%	18.4%	38.8%	5.1%	12.6%	16.6%	100.0%

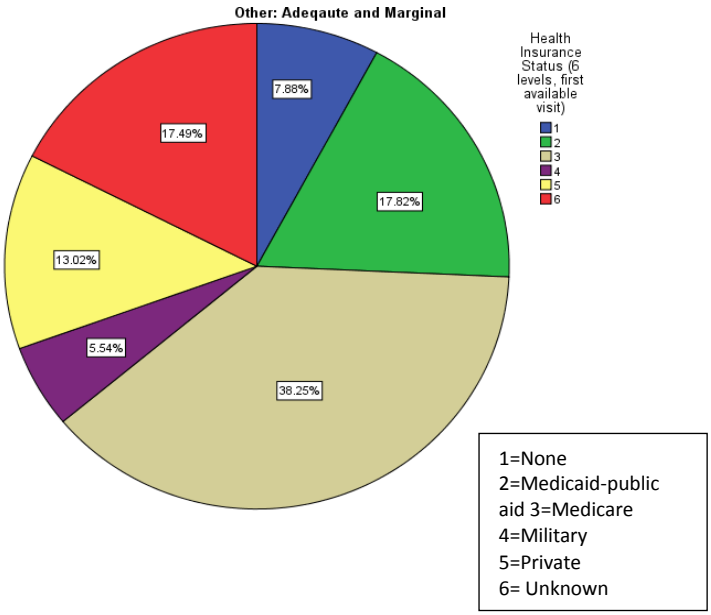

Figure 1. Health insurance status by other health literacy.

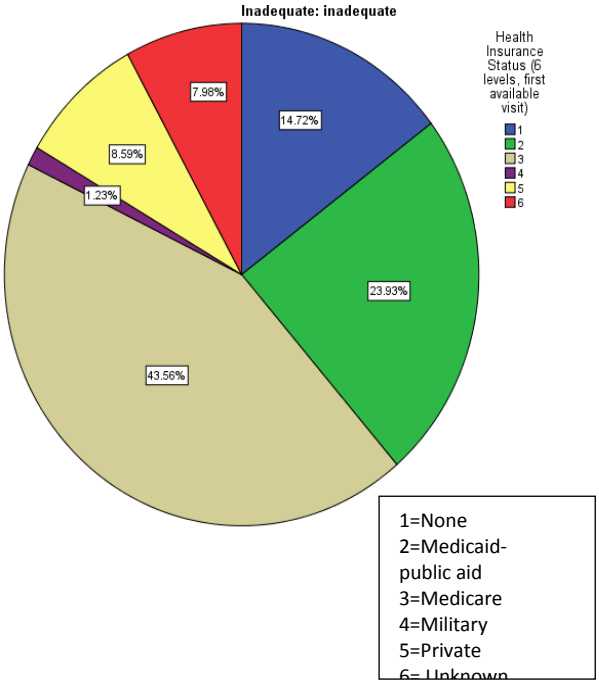

Figure 2. Health insurance status by inadequate health literacy.

Furthermore, when exploring the relationship between inadequate health literacy and health insurance status, a chi square analysis was performed. The Chi Square analysis revealed that the relationship between inadequate levels of health literacy and health insurance is significant (X2 (5, N=1661) =27.775, p value= <0.001). The results showed that no assumptions had been violated and that there is a significant relationship between inadequate levels of health literacy and having no health insurance and or any health insurance (see Table 15).

Table 15

Chi-Square Test Results for Health Insurance Status and Inadequate Health Literacy

	Value	df	Asymptotic Significance (2-sided)
Pearson chi-square	27.775[a]	5	.000
Likelihood ratio	30.340	5	.000
Linear-by-linear Association	23.421	1	.000
N of Valid Cases	1661		

Note. a = 0 cells (0.0%) have expected count less than 5. The minimum expected count is 8.34.

The correlation tests also showed that the Phi and Cramer V was significant (*p*=<.001), with a small to moderate effect size of (.129) indicating that the relationship between inadequate health literacy levels plays a small to moderate effect related to a participants' health insurance status (Cramer and Howitt,2004). Though the results show that there is a significant relationship between inadequate levels of health literacy and a participant's health insurance and or lack thereof, the analysis does not differentiate

between having health insurance, nor the type of health insurance a participant holds. Nonetheless, based on these results the null hypothesis for research question two (Research Question 2) can be rejected (see Table 16).

Table 16

Correlation Test Results for Health Insurance Status and Inadequate Health Literacy

		Value	Asymptotic Standardized Error[a]	Approximate T[b]	Sig
Nominal by Nominal	Phi	.129			.000
	Cramer's V	.129			.000
Interval by Interval	Pearson's r	-.119	.022	-4.873	.000[c]
Ordinal by Ordinal	Spearman correlation	-.120	.023	-4.939	.000[c]
N of Valid Cases		1661			

Note. a = Not assuming the null hypothesis. b = Using the asymptotic standard error assuming the null hypothesis. c = Based on normal approximation.

Research Question 3

Research Question 3: Is there a relationship between developing ESRD among Type II diabetic populations, and healthcare services?

$H_0$3- There is no relationship between healthcare services and developing ESRD complications among diabetics.

H_a3-There is a relationship between healthcare services and developing ESRD complications among diabetics.

When exploring healthcare services based on health insurance type, and the development of ESRD data included 1661 participants with 247 missing results, and no assumptions had been violated. Cross-tabulation counts again showed (as presented in Research Question 2) that overall the majority of diabetic participants primarily had Medicare as their health care insurance. When including the dependent variable of ESRD however, participants who developed ESRD had no health insurance (10.1%) or were receiving some type of Medicaid and or public aid (23.2%) more often than those participants who did not develop ESRD (7.9% and 16.3%) respectively (see Figures 3 and 4).

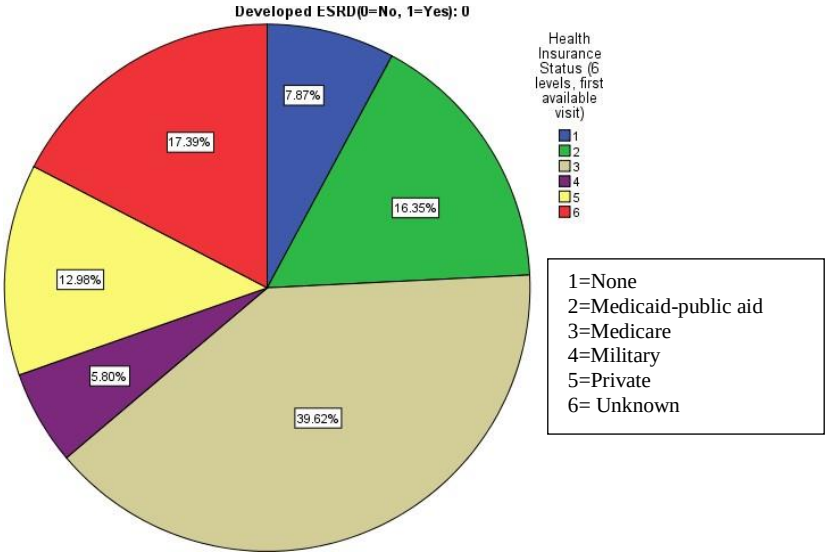

Figure 3. Health insurance status by no ESRD.

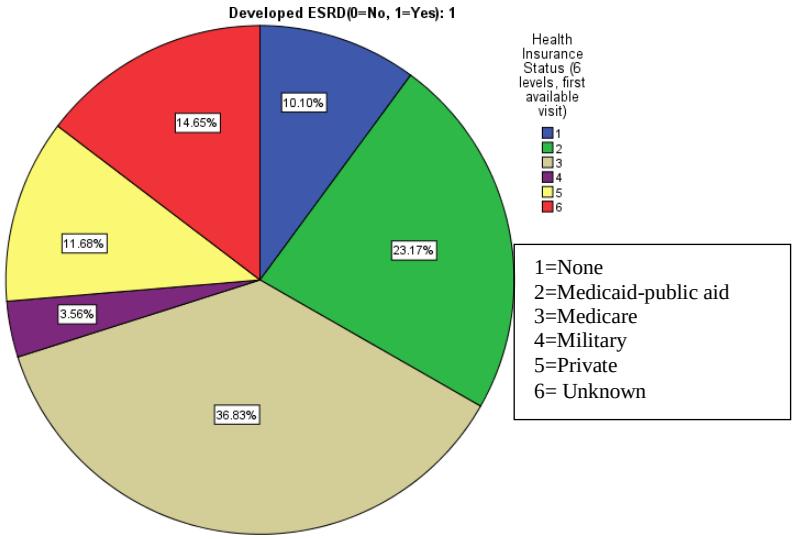

Figure 4. Health insurance status by ESRD.

Those participants who did not develop ESRD instead, had a greater percentage of Medicare (39.6%) military care (5.8%), private insurance (13%), or didn't know their health insurance (17.4%) compared to (36.8%, 3.6%, 11.7% and 14.7%) respectively among those with ESRD (see Table 17).

Table 17

Cross-tabulation of Health Insurance Status and ESRD

		Health Insurance Status (6 levels, available visit)						
		None	Medicaid	Medicare	Military	Private	Unknown	Total
0	Count NO ESRD	91	189	458	67	150	201	1156
	% within Developed ESRD (0=No ESRD)	7.9%	16.3%	39.6%	5.8%	13.0%	17.4%	100.0%
	% within Health Insurance Status (6 levels)	64.1%	61.8%	71.1%	78.8%	71.8%	73.1%	69.6%
	% of Total	5.5%	11.4%	27.6%	4.0%	9.0%	12.1%	69.6%
1	Count ESRD	51	117	186	18	59	74	505
	% within Developed ESRD (1=Yes ESRD)	10.1%	23.2%	36.8%	3.6%	11.7%	14.7%	100.0%
	% within Health Insurance Status (6 levels)	35.9%	38.2%	28.9%	21.2%	28.2%	26.9%	30.4%
	% of Total	3.1%	7.0%	11.2%	1.1%	3.6%	4.5%	30.4%
	Total Count	142	306	644	85	209	275	1661

Chi Square analysis, was performed to examine the relationship between the dependent variable of ESRD and the independent variable of health insurance status. Chi Square analysis results revealed that the relationship between health insurance status and ESRD is significant (X2 (5, N=1661) =17.087, p value= <0.05). The results showed that no assumptions had been violated and that there is a significant relationship between developing ESRD and having no health insurance or any health insurance type. This inevitably revealed that ESRD development is not specific to a particular type of healthcare service based on health insurance, but rather there is a relationship of ESRD with any type or status of health insurance (see Table 18).

Table 18

Chi-Square Test Results for Health Insurance Status and ESRD

	Value	df	Significance
Pearson chi-square	17.087[a]	5	.004
Likelihood Ratio	16.955	5	.005
Linear-by-linear Association	8.733	1	.003
N of Valid Cases	1661		

Note. a = 0 cells (0.0%) have expected count less than 5. The minimum expected count is 25.84.

The correlation table showed that Phi and Cramer V test also resulted in significance (p=<0.05) with a small to moderate effect size of (.101) presenting that the

relationship between developing ESRD based on health insurance status, is small to moderate (see Table 19). Data indicates there is a relationship with ESRD and all types of health insurance status thereby lending the null hypothesis related to research question three (Research Question 3) to be rejected.

Table 19

Correlation Test Results for Health Insurance Status and ESRD

		Value	Significance
Nominal by Nominal	Phi	.101	.004
	Cramer's V	.101	.004
N of Valid Cases		1661	

Research Question 4

Research Question 4: Are demographic co-factors such as gender, race, age, socioeconomic status, and education different when comparing outcomes of ESRD, inadequate health literacy, and health insurance status among diabetic participants?

H_04 -There are no differences with demographic co-factors such as gender, race, age, socioeconomic status, and education when comparing outcomes of ESRD, inadequate health literacy and health insurance status among diabetic participants

H_a4- There are differences with demographic co-factors such as gender, race, age,

socioeconomic status, and education when comparing outcomes of ESRD, inadequate health literacy and health insurance status among diabetic participants.

Research question four was analyzed in three groups of tests. For each of three groups a chi square analysis was done with all of five predictors, proceeded with a binary logistic regression for the dichotomous outcomes of ESRD (group 1) and inadequate health literacy (group 2) and a multinomial logistic regression for the six potential outcomes of health insurance status (group 3). Chi square analysis, and both binary and multinomial logistic regression were performed to explore the relationship between the predictors and membership in the three groups (ESRD, inadequate health literacy, and health insurance). The predictors' included; gender, race\ethnicity, socioeconomic status (income), education and age. The traditional .05 criterion of statistical significance was employed for all tests.

Research Question 4 Chi square analysis and ESRD (Group 1). When performing chi square analysis to explore the relationship between ESRD and the predictor variables, all of the predictors except for gender, ($\chi 2$ (1) = 2.828, $p > .05$), presented a significant relationship (race\ethnicity, $\chi 2$ (3) = 51.164, $p < .0001$, age, $\chi 2$ (5) = 46.697, $p < .0001$, income, $\chi 2$ (4) = 24.071, $p < .0001$, education, $\chi 2$ (6) = 22.238, $p < .0001$) with the outcome of ESRD (see Table 20).

Table 20

Chi-Square Tests: ESRD and Covariates

Predictor Variable	Value	Df	Sig.
Sex			
Pearson Chi-Square	2.828[a]	1	.093
Likelihood Ratio	2.838	1	.092
Linear-by-Linear Association	2.827	1	.093
N of Valid Cases	1908		
Race			
Pearson Chi-Square	51.164[a]	3	.000
Likelihood Ratio	51.722	3	.000
Linear-by-Linear Association	29.132	1	.000
Age			
Pearson Chi-Square	46.697[a]	5	.000
Likelihood Ratio	46.723	5	.000
Linear-by-Linear Association	44.432	1	.000
Income			
Pearson Chi-Square	24.071[a]	4	.000
Likelihood Ratio	24.199	4	.000
Linear-by-Linear Association	1.236	1	.266

(table continues)

Education			
Pearson Chi-Square	22.238[a]	6	.001
Likelihood Ratio	21.872	6	.001
Linear-by-Linear Association	14.460	1	.000
N of Valid Cases	1908		

Research Question 4 Binary logistic regression and ESRD (Group 1). Binary logistic regression was then performed to analyze the effects of gender, race\ethnicity, age, income, and education, on the likelihood that participants would develop ESRD. Addition of the predictors to the model that contained the intercept significantly improved the fit between the model and the data, $\chi 2$ (19) = 113.317, p < .0001 (see Table 21). The model explained 8.3% (Nagelkerke R2) of the variance of developing ESRD (see Table 22). The Classification Table displayed that the model correctly classified 72.9% of cases (see Table 23). The classification table provides sensitivity results (46 true positives), specificity results (1,344 true negatives), a positive predictive value of (8.5%) and negative predictive value of (98.2%) (see Table 23).

Table 21

Omnibus Tests of Model Coefficients ESRD

		Chi-square	df	Sig.
Step 1	Step	113.317	19	.000
	Block	113.317	19	.000
	Model	113.317	19	.000

Table 22

Model Summary ESRD

Step	-2 Log likelihood	Cox & Snell R Square	Nagelkerke R Square
1	2158.325 a	.058	.083

Note. a = Estimation terminated at iteration number 4 because parameter estimates changed by less than .001

Table 23

Classification Table ESRD

	Predicted		
	Developed ESRD (0=No, 1=Yes)		Percentage Correct
Observed	0	1	
NO ESRD (0)	1344	25	98.2%
ESRD (1)	493	46	8.5%
Overall %			72.9%

Binary logistic regression results showed that males were more likely to exhibit ESRD than females. In fact, results showed that when considering female participants, the odds ratio of developing ESRD, decreased. Females were in fact (OR= .725, or 27%) less likely than males to develop ESRD. Results showed that according to the Wald test for race (Wald=24.056, df=3, p<.0001) and for age (Wald=43.796, df=5, p<.0001) both have a highly significant effect on developing ESRD. The b coefficients for both race and age are significant and positive, indicating that certain races, and increasing age, is associated with increased odds of developing ESRD. Additionally, using Caucasian as the baseline for race, the Odds ratio showed that African Americans were (OR=1.9, 85%) times, and Hispanic participants were (OR=2.0,104%) times more likely to develop ESRD than Caucasian participants when controlling for other covariates such as gender, age, income, and education. The baseline for age was < 30 and results showed that increasing age (p=<0.05) was also associated with an increased likelihood of developing ESRD, but income and education did not seem to have a significant impact on developing ESRD (see Table 24).

Table 24

Binary Logistic Regression for ESRD

							95% C. I	
	B	S.E.	Wald	df	Sig.	Exp(B)	Lower	Upper
SEX- baseline male	-.321	.109	8.718	1	.003	.725	.586	.898
RACE_ETHNICITY_								
Baseline White			24.056	3	.000			
African American	.617	.136	20.699	1	.000	1.853	1.421	2.417
Hispanic	.715	.187	14.533	1	.000	2.043	1.415	2.951
Other (Hawaiian, Asian)	.202	.300	.453	1	.501	1.224	.680	2.203
INCOME_CAT <20,000			6.384	4	.172			
INCOME_CAT (20-50)	-.255	.145	3.090	1	.079	.775	.583	1.030
INCOME_CAT (50-100)	-.258	.182	2.013	1	.156	.773	.542	1.103
INCOME_CAT 1(>100)	-.498	.266	3.516	1	.061	.608	.361	1.023
INCOME_CAT(unknown)	-.286	.162	3.145	1	.076	.751	.547	1.031
EDU_CAT_baseline <6th			3.240	6	.778			
EDU_CAT (7-12)	-.212	.230	.851	1	.356	.809	.516	1.269
EDU_CAT (Ged\HS)	-.316	.240	1.731	1	.188	.729	.455	1.167
EDU_CAT (Tech)	-.537	.326	2.709	1	.100	.584	.308	1.108
EDU_CAT (Coll no degree)	-.220	.239	.843	1	.358	.803	.502	1.283
EDU_CAT (Coll degree)	-.250	.266	.887	1	.346	.779	.462	1.311
EDU_CAT (Prof Degree)	-.304	.305	.994	1	.319	.738	.406	1.342

(table continues)

AGE_CAT baseline <30			43.796	5	.000			
AGE_CAT (30-40)	1.175	.575	4.181	1	.041	3.237	1.050	9.983
AGE_CAT (41-50)	1.215	.282	18.539	1	.000	3.372	1.939	5.863
AGE_CAT (51-60)	1.065	.220	23.419	1	.000	2.900	1.884	4.463
AGE_CAT (61-70)	.747	.183	16.712	1	.000	2.111	1.475	3.020
AGE_CAT (>70)	.308	.183	2.850	1	.091	1.361	.952	1.946
Constant	-1.046	.322	10.563	1	.001	.351		

Note. a = Variable(s) entered on step 1: SEX, RACE_ETHNICITY_CAT2, INCOME_CAT_1, EDU_CAT_1, AGE_CAT_1.

Research Question 4 Chi square analysis and inadequate health literacy (Group 2). When performing chi square analysis and using the outcome of inadequate health literacy all the predictors, except for gender, ($\chi 2$ (1) = .030, p > .05) presented a significant relationship with inadequate health literacy (race\ethnicity, $\chi 2$ (3) = 91.252, p < .0001, age, $\chi 2$ (5) = 11.977, p< .0001, income, $\chi 2$ (4) = 57.892, p < .0001, education, $\chi 2$ (6) = 151.875, p < .0001; see Table 25).

Research Question 4 Binary logistic regression and inadequate health literacy (Group 2). The second part of the analysis to answer research question four (Research Question 4) includes performing a binary logistic regression to analyze the effects of gender, race\ethnicity, age, income, and education, on the likelihood that participants would have inadequate health literacy levels. The binary logistic regression model was again statistically significant, $\chi 2$ (19) = 171.692, p < .0001 (see Table 26). The model explained 19% (Nagelkerke R2) of the variance related to having inadequate health literacy (see Table 27).

The classification table displayed that the model correctly classified 91% of cases. The classification table showed however that sensitivity results were limited due to sample size (0 true positives), yet specificity was strong (1,736 true negatives), reflecting a positive predictive value of (0 %) and negative predictive value of (100 %; see Table 28).

Table 25

Chi-Square Test Results Health Literacy and Covariates

Predictor variables	Value	Df	Asymptotic Significance
Sex			
Pearson Chi-Square	.030[a]	1	.862
Likelihood Ratio	.030	1	.861
Linear-by-Linear Association	.030	1	.862
Race			
Pearson Chi-Square	91.252[a]	3	.000
Likelihood Ratio	93.216	3	.000
Linear-by-Linear Association	51.808	1	.000
Age			
Pearson Chi-Square	11.977[a]	5	.035
Likelihood Ratio	15.416	5	.009
Linear-by-Linear Association	8.122	1	.004
Income			
Pearson Chi-Square	57.892[a]	4	.000
Likelihood Ratio	63.888	4	.000
Linear-by-Linear Association	.351	1	.553
Education			

(table continues)

Pearson Chi-Square	151.875[a]	6	.000
Likelihood Ratio	126.988	6	.000
Linear-by-Linear Association	108.497	1	.000
N of Valid Cases	1,908		

Table 26

Omnibus Test of Model Coefficients Inadequate Health Literacy

		Chi-square	df	Sig.
Step 1	Step	171.692	19	.000
	Block	171.692	19	.000
	Model	171.692	19	.000

Table 27

Model Summary Inadequate Health Literacy

Step	-2 Log likelihood	Cox & Snell R Square	Nagelkerke R Square
1	984.088[a]	.086	.189

Table 28

Classification Table ESRD

Predicted			
	Health Literacy (1=inadequate, 2=other)		Percentage Correct
Observed	1	2	
Inadequate	0	172	.0%
Other	0	1736	100%
Overall %			91 %

Binary logistic regression results again showed something different. Binary logistic regression results with the addition of the predictors to the model however showed, gender, income, and age, did not have a significant effect on a participant's inadequate health literacy. Yet race and education did. Results showed that according to the Wald test, race (Wald=16.512, df=3, p<.0001) and education (Wald=31.558, df=6, p<.0001) are highly significant predictors of a participants' inadequate health literacy (see Table 29). The b coefficients for race and education both showed significance, and both were positive, indicating that these covariates are associated with an increased odds ratio of having inadequate health literacy levels. Results showed that when considering race and using Caucasian as the baseline, African Americans were actually (OR=3.3) times, and Hispanic participants (OR=3.4) times more likely to have inadequate health literacy (see Table 29). Education was also associated with an increased likelihood of

inadequate health literacy levels, yet when controlling for other covariates, only participants with a 7-12th grade education (no degree) resulted in a significant predictor of having inadequate health literacy. In fact, participants who have a 7-12th grade education are (OR=7.6) times more likely to have inadequate health literacy levels than participants with higher education (see Table 29).

Table 29

Variables in the Binary Logistic Regression for Inadequate Health literacy

	B	S.E.	Wald	df	Sig.	Exp(B)	Lower	Upper
SEX	-.307	.174	3.109	1	.078	.736	.523	1.035
RACE-ETHNICITY_			16.512	3	.001			
African American	1.186	.300	15.628	1	.000	3.276	1.819	5.899
Hispanic	1.234	.354	12.174	1	.000	3.436	1.718	6.874
Other (Hawaiian, Asian)	.775	.664	1.363	1	.243	2.171	.591	7.980
INCOME_<0 20,000			7.199	4	.126			
INCOME_ (20-50)	.049	.234	.044	1	.835	1.050	.663	1.663
INCOME_(50-100)	-.463	.294	2.482	1	.115	.629	.353	1.120
INCOME_(>100)	-.870	.476	3.337	1	.068	.419	.165	1.065
INCOME_(Unknown)	-.209	.599	.121	1	.728	.812	.251	2.628
EDU_baseline <6th			31.558	6	.000			
EDU_(7-12th)	2.022	.619	10.668	1	.001	7.550	2.244	25.397
EDU_(GED/HS)	1.113	.587	3.603	1	.058	3.044	.964	9.611
EDU_(Tech)	.944	.587	2.588	1	.108	2.569	.814	8.110
EDU_(No Degree)	.602	.702	.735	1	.391	1.826	.461	7.229
EDU(Coll degree)	.470	.590	.635	1	.425	1.600	.504	5.081
EDU (Prof degree)	-.406	.690	.346	1	.556	.666	.172	2.577
AGE_(<30)			7.307	5	.199			
AGE_(30-40)	17.654	10178.	.000	1	.999	46458819.0	.000	.

(table continues)

		941				45		
AGE_(41-50)	18.293	10178.	.000	1	.999	87988017.9	.000	.
		941				28		
AGE_(51-60)	18.867	10178.	.000	1	.999	156278578.	.000	.
		941				005		
AGE_(61-70)	19.036	10178.	.000	1	.999	184992453.	.000	.
		941				642		
AGE_(>70)	18.919	10178.	.000	1	.999	164589814.	.000	.
		941				807		
Constant	-	10178.	.000	1	.998	.000		
	22.410	941						

Research Question 4 Multinomial logistic regression and health insurance status (Group 3). For the final part of Research Question 4 a Chi Square analysis and a multinomial logistic regression was used to examine the relationship with the predictors (gender, race, age income and education), and the six potential outcomes of health insurance (Group 3). The traditional .05 criterion of statistical significance was employed for all tests. The chi square analysis results showed that when using the outcome of health insurance, all the variables showed a significant relationship with any or all types of a participant's health insurance (gender, ($\chi 2$ (5) = 102.618, $p < .001$) (race\ethnicity, $\chi 2$ (15) = 252.733, $p < .001$, age, $\chi 2$ (25) = 275.844, $p < .001$, income, $\chi 2$ (20) = 446.421, $p < .001$, education, $\chi 2$ (30) = 264.436, $p < .001$) (see Table 30). The Chi Square analysis results indicate that there is a significant relationship with any or all health insurance and

the predictor variables. However, there is an additional notable result that shows that African American participants more often have Medicaid or some type of public aid, and Hispanic participants more often did not have health insurance coverage compared to other races (see Figure 5).

Table 30

Chi-Square Test Results for Health Insurance Status and Covariates

Predictor Variable	Value	df	Significance
Sex			
Pearson Chi-Square	102.618[a]	5	.000
Likelihood Ratio	122.977	5	.000
Linear-by-Linear Association	8.162	1	.004
Race			
Pearson Chi-Square	252.733[a]	15	.000
Likelihood Ratio	229.322	15	.000
Linear-by-Linear Association	93.630	1	.000
Age			
Pearson Chi-Square	275.844[a]	25	.000
Likelihood Ratio	287.628	25	.000
Linear-by-Linear	21.299	1	.000

(table continues)

Association			
Income			
Pearson Chi-Square	446.421[a]	20	.000
Likelihood Ratio	470.966	20	.000
Linear-by-Linear Association	.347	1	.556
Education			
Pearson Chi-Square	264.436[a]	30	.000
Likelihood Ratio	264.572	30	.000
Linear-by-Linear Association	168.499	1	.000
N of Valid Cases	1661		

a. 1 cells (4.2%) have expected count less than 5. The minimum expected count is 3.38.

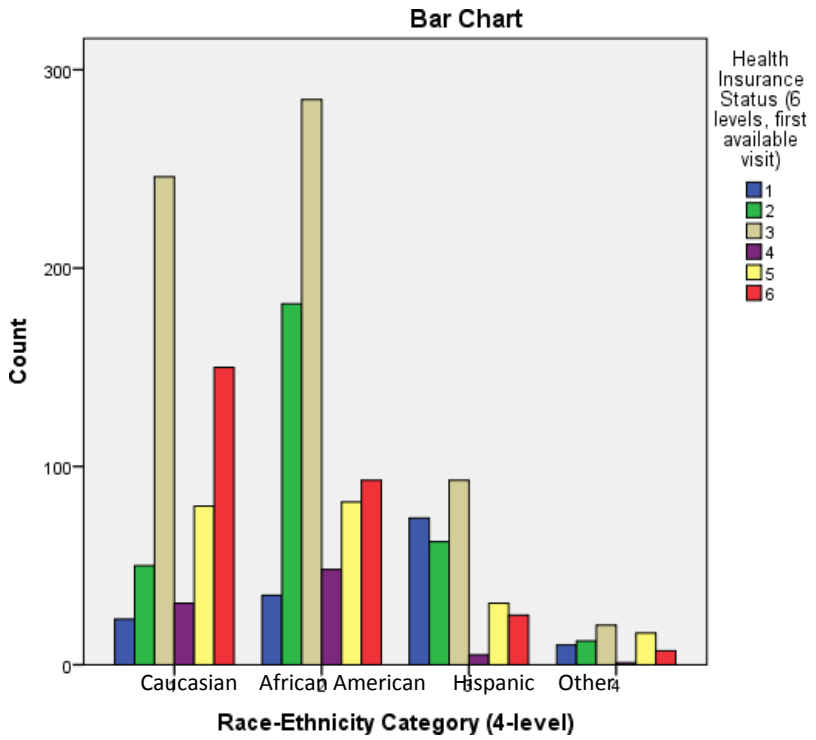

Figure 5. Health insurance status by race.

In addition to the Chi Square analysis a multinomial logistic regression was performed to model the relationship between the predictors and membership in the five categories of health insurance (Medicaid, Medicare, Military, Private, and unknown). The reference group was those participants who had no health insurance. Accordingly, each predictor (gender, race, income, education and age) has five parameters, within each category of health insurance.

When performing multinomial logistic regression, SPSS software generates a Model Summary Table. The Model Summary Table provides information that shows how well the test being used, fits the data (Field, 2009). Within the Model Summary Table, the Goodness-of-Fit test provided two measures that are used to assess how well the model fits the data (Field, 2009). The measure is the Pearson Chi Square test, which

showed that the model was significant (p<.05). However, when using the Goodness-of-Fit test, a significant value indicates that it is a poor fit for the model (Field, 2009). According to Field (2009) when performing a Goodness-of-Fit test, a large Pearson chi square result and a statistically significant p value result, indicates that the model does not fit the data well ($\chi 2$ (2660) = 3145.275, p=<.001). The other row in the goodness of fit test (Deviance) presents the Deviance chi-square statistic. According to Field (2009) these two measures (goodness of fit and deviance) might not always give the same result, however in this case both agree that the model is not a good fit (p = 1.00; see Table 31).

Table 31

Model Summary Health Insurance Status

	Model Fitting Criteria	Likelihood Ratio Tests		
Model	-2 Log Likelihood	Chi-Square	df	Sig.
Intercept Only	3580.974			
Final	3077.438	503.536	20	.000
		Goodness-of-Fit		
Pearson		3145.275	2660	.000
Deviance		2321.842	2660	1.000
		Pseudo R-Square		
Cox and Snell				.262
Nagelkerke				.273

The results from the Pearson chi Square test however contradicts the Likelihood test results within the Model Summary Table. The Likelihood tests results show that the model does in fact fit the data. Within the Model Summary table, you can see that with the addition of the predictor variables compared to the intercept-only, significantly improves the fit between model and data.

The Likelihood test shows that the model does in fact significantly predict the outcome of health insurance status based on the predictor variables (p=<.001). Additionally, the likelihood ratio table which looks at each predictor variable independently, shows that there are variables that are statistically significant to predict health insurance status. Results show that gender, race, education and age are significant predictors (p=<.05), however income is not (see Table 32).

Table 32

Likelihood Ratio Tests

	Model Fitting Criteria		Likelihood Ratio Tests	
Effect	-2 Log Likelihood of Reduced Model	Chi-Square	df	Sig
Intercept	2960.746[a]	.000	0	.000
SEX	3077.438	116.692	5	.000
RACE-ETNICITY	3047.881	87.136	5	.000
INCOME	2966.559	5.813	5	.325
EDUCATION	3098.782	138.036	5	.000
AGE	3175.592	214.846	5	.000

Note. The chi-square statistic is the difference in -2 log-likelihoods between the final model and a reduced model.

Furthermore, within the Model Summary Table the Pseudo R-Square test results showed that when performing the Nagelkerke R2, 27.3% of the variance related to a participant's health insurance status was based on the predictor variables included in the model (see Table 31). Likewise, the Cox and Snell test results show that 26.3% of the variance is explained by the model, yet approximately 70% of the remaining variance related to a participant's health insurance status, is due to other factors (see Table 31). As well, the classification table indicates that the model correctly classified 44.3% of the cases with the addition of the predictor variables (see Table 33).

Table 33

Classification of Health Insurance

Observed	None	Medicaid	Medicare	Military	Private	Unknown	% Correct
None	13	46	64	0	11	8	9.2%
Medicaid	9	75	176	0	5	41	24.5%
Medicare	11	56	544	0	6	27	84.5%
Military	0	1	77	0	0	7	0.0%
Private	6	26	124	0	14	39	6.7%
Unknown	4	24	143	0	14	90	32.7%
Overall Percentage	2.6%	13.7%	67.9%	0.0%	3.0%	12.8%	44.3%

Based on the Parameter Table 34, the multinomial logistic regression results are categorized by each type of health insurance. There are five categories of the of the dependent variable of health insurance status and they include Medicaid, Medicare,

Military, Private Insurance, and unknown (where the participant did not know their health insurance status). The category of "no health insurance" is the baseline and is used as the reference category. Each predictor variable parameter is set to zero so that order of predictor categories is consistent with the demographic tables presented earlier in this chapter (see Tables 5 and 6).

When holding all other predictors constant, I compared each predictor variable to each HIS category within the Parameter Table. Results show which predictor variables have a significant parameter to a particular type of health insurance. Predictor variables are also referred to as the coefficients (logits). As there are five sets of coefficients (called logits) within the table (gender, race, income, education, and age). When comparing each health insurance category to participants having no health insurance, we can determine which predictors are significant related to a participant's status of health insurance.

Results show that when looking at the predictor variable of gender, gender was only significant to Medicaid and Military types of Insurance (p=.05). Results show that males are less likely than females to have Medicaid when compared to having no insurance. The coefficient logit (the "B" column) shows a result of (Coef. Logit=-.523) indicating males are less likely to have Medicaid and more likely to have no insurance than females. In fact, the odds ratio results (Exp B) shows that males are (OR=.593) times or 41% less likely to have Medicaid compared to no insurance than females. Males are however, more likely to have Military Insurance compared to females (Coef. logit = 3.570), approximately thirty-five times more likely (OR=35.532) or 3,453%; see Table 34).

When I examined the predictor of education, it was only significant in relation to

Medicare and Private Health Insurance (p=<.05). Results show for each level of education that a participant increases they will more likely have Medicare (Coef. Logit = .201) than no insurance and or private health care (Coef. Logit= .485) than no insurance. The odds ratio results show that as education increases participants will be (OR= 1.222 or 22%) times more likely to have Medicare and (OR= 1.623 or 62%) times more likely to have private health insurance compared to having no health insurance (see Table 34).

The predictor variable of age shows that for each category of age that a participant increases they are more likely to have Medicare and or Military Insurance compared to no insurance (p=<.05). The parameter results show that as age increases (Coef. Logit= .888, and Coef. Logit=.501) respectively, participants are (OR=2.431, 143%), twice as likely to have Medicare and (OR=1.651, 65%) one time more likely to have Military insurance than not having insurance (see Table 34).

As presented in the Likelihood Table, these results once again show that income was not a significant coefficient (p=>0.05) to predict any of the health insurance categories. One coefficient that is statistically significant in all categories of health insurance however, is race. The coefficient value of race, the sign is consistently negative, indicating that when using Caucasian as a baseline, Caucasian participants are less likely to have no health insurance than participants of any other race. In fact, the results show that Caucasian participants are (Medicaid; OR= .557, Medicare; OR=.406, Military; OR=.346, Private; OR=.515, Unknown; OR=.313) less likely or approximately 54-68% less likely to have no health insurance than other races. In other words, participants who are African American, Hispanic, and another race other than Caucasian,

more often had no insurance compared to Caucasian participants (see Table 34).

Table 34

Parameter Multinomial Logistic Regression for Health Insurance Status

HIS (5 levels)		B	Std. Error	Wald	df	Sig.	Exp(b) Odds Ratio	95% Confidence Lower Bound	Upper Bound
Medicaid	Intercept	1.722	.601	8.200	1	.004			
	[SEX=1] MALE	-.523	.208	6.326	1	.012	.593	.394	.891
	[SEX=2] FEMALE	0b	.	.	0	.	.	.	.
	RACE\ETHNICITY	-.584	.130	20.139	1	.000	.557	.432	.719
	INCOME_CAT_1	.000	.003	.010	1	.921	1.000	.994	1.006
	EDUCATION	-.005	.060	.006	1	.940	.995	.885	1.119
	AGE	.158	.099	2.546	1	.111	1.171	.965	1.421
Medicare	Intercept	1.395	.592	5.557	1	.018			
	[SEX=1] MALE	.237	.198	1.430	1	.232	1.268	.859	1.869
	[SEX=2] FEMALE	0b	.	.	0	.	.	.	.
	RACE\ETHNICITY	-.902	.122	54.290	1	.000	.406	.319	.516
	INCOME	.001	.003	.040	1	.841	1.001	.995	1.006
	EDUCATION	.201	.056	12.852	1	.000	1.222	1.095	1.364
	AGE	.888	.100	79.587	1	.000	2.431	2.000	2.954
Military	Intercept	-4.034	1.122	12.937	1	.000			
	[SEX=1] MALE	3.570	.738	23.411	1	.000	35.532	8.366	150.918
	[SEX=2] FEMALE	0b	.	.	0		.	.	.
	RACE\ETHNICITY	1.061	.190	31.150	1	.000	.346	.239	.502
	INCOME	.005	.004	1.623	1	.203	1.005	.997	1.013
	EDUCATION	.150	.084	3.212	1	.073	1.162	.986	1.370
	AGE	.501	.143	12.251	1	.000	1.651	1.247	2.186
Private	Intercept	-.504	.644	.613	1	.434			
	[SEX=1] MALE	-.324	.227	2.026	1	.155	.724	.463	1.130
	[SEX=2] FEMALE	0b	.	.	0	.	.	.	.
	RACE \ETHNICITY	-.664	.135	24.347	1	.000	.515	.396	.670
	INCOME	-.004	.004	1.226	1	.268	.996	.989	1.003
	EDUCATION	.485	.066	54.393	1	.000	1.623	1.427	1.847
	AGE	.155	.108	2.070	1	.150	1.168	.945	1.443

(table continues)

HIS (5 levels)		B	Std. Error	Wald	df	Sig.	Exp(b) Odds Ratio	95% Confidence Upper Bound	95% Confidence Lower Bound
Unknown	Intercept	1.134	.628	3.267	1		.071		
	[SEX=1]	.142	.222	.409	1		.522	1.153	.746
	[SEX=2]	0b	.	.	0		.	.	.
RACE\ETHNICITY		1.163	.141	68.393	1	.000	.313	.237	.412
INCOME_		.000	.003	.019	1	.890	1.000	.994	1.007
EDUCATION		.464	.065	50.696	1	.000	1.590	1.399	1.806
AGE		-.016	.103	.024	1	.876	.984	.804	1.205

Note. a = The reference category is: 1.- No HIS b = This parameter is set to zero because it is redundant

The Confidence Interval (CI) for Exp (B) provides a percentage range of predictability. For this study, a standard normal distribution with a CI of 95% was used. Which allows 95% confidence that the "true "population multinomial odds ratio lies between the lower and upper limit of the interval for the outcome relative to the reference group (Field, 2009). Results show when examining the consistent predictor of race within all health insurance categories we can say with 95% confidence that results will have these outcomes. In summary, after individually analyzing each of the three groups for Research Question 4, there are differences in demographic co-factors when comparing outcomes of ESRD, inadequate health literacy, and health insurance status. This leads us reject the null hypothesis for research question four.

Summary

Data analysis was conducted on an overall sample of 3939 participants from National Institute of Health Chronic Renal Insufficiency Cohort (CRIC) study. The study examined inadequate levels of health literacy, and an individual's health care access relative to the type of health insurance possessed with the relationship of developing ESRD. The study explored whether results were explicit to participants who had diabetes and took into consideration demographic factors that may play a role. Four research questions outlined the investigative path (1) is there a relationship between inadequate levels of health literacy and ESRD when controlling for confounding factors such as gender, age, income, education and race (2) is there an association between types of health care insurance and an individual's level of health literacy related to type II diabetes (3) is there a relationship between types of health care insurance and developing ESRD

complications (4) are demographic co-factors such as gender, race, age, socioeconomic status, and education different when comparing outcomes of ESRD, levels of health literacy and health insurance status. The data was stratified by the diagnosis of diabetes mellitus (DM) and analyzed. Research questions one thru three were explored using chi square, correlation and cross-tabulation analysis, whereas research question four was evaluated using three groups of tests. For each of three groups, a Chi Square analysis was done with all of five predictors (gender, race, income, education and age), proceeded with a binary logistic regression for groups one and two, and a multinomial logistic regression for group three.

Chi square analysis revealed that there is a significant relationship between inadequate health literacy and developing ESRD among diabetic participants, as stated in research question one (Research Question 1), (p= <0.05). Correlation results showed that when comparing participants who developed ESRD to those who did not, persons with ESRD more often had inadequate levels, and less marginal and adequate levels of health literacy. Though the Chi Square Analysis revealed that there is a significant, yet small effect relationship between inadequate health literacy and the development of ERSD, it did not expose specifically what the relationship was for this phenomenon.

In addition to examining the relationship between inadequate health literacy and ESRD, the study further explored if an individual's health literacy is affected by the type of health care services they receive, by examining the relationship between health insurance status and inadequate health literacy levels. To do this I analyzed as outlined in research question two (Research Question 2) whether there is an association between

health care insurance status and inadequate health literacy levels among type II diabetes. Chi square analysis results showed that there is a significant relationship with inadequate levels of health literacy and status of health insurance. The Chi Square test revealed that there is a small to moderate effect related to inadequate health literacy and a participant's health insurance status. However, the test does not uncover what the association is, nor did it show that the association was specific to having any certain type or no health insurance.

Research question three (Research Question 3) was to be the bridge that reinforced Research Question 1 and Research Question 2 results and inquired as to whether there is a relationship between developing ESRD and a participants' health insurance status. This research question was intended to uncover data that demonstrates how health care services based on a participant's health insurance status may impact an individual's level of health literacy or place them at risk for diabetic complications such as ESRD. The Chi Square results indicated that there is a statistically significant (p=<.001) relationship between any or all types of health insurance and participants who develop ESRD. Though the results once again showed a small to moderate effect between health insurance status and ESRD, it did not provide information as to what the relationship is, or if it is related to inadequate health literacy levels. It also did not disclose which health insurance status, or whether not having health insurance had an impact on developing ESRD.

Finally, research question four (Research Question 4) was analyzed in three groups to investigate whether there are differences with demographic co-variates such as

gender, race, age, socioeconomic status (income), and education, when comparing outcomes of 1) ESRD, 2) inadequate health literacy, and 3) health insurance status among diabetic participants.

For each of three groups a chi square analysis was done with all of five predictors, proceeded with a binary logistic regression for the dichotomous outcomes of ESRD (group 1) and inadequate health literacy (group 2) and a multinomial logistic regression to look at the relationship with the six potential outcomes of health insurance status (group 3). The baseline for the dependent variable of health insurance status was having no health insurance for all three groups. Results showed there are significant differences between demographic co-variates regarding each of the three outcomes.

Regarding ERSD (group 1) binary logistic regression results showed that gender, race and age, were significant predictors of ESRD. However, income, and education were not. Results revealed that males are more likely to develop ESRD compared to females. It also showed that African Americans and Hispanic populations are approximately twice as likely as Caucasian participants to develop ESRD, and as participants age their odds for developing ESRD increases about 2-3 times more than participants under the age of 30.

The binary logistic regression for the second group (Group 2) of Research Question 4 looked at which co-variates would significantly predict inadequate health literacy among diabetic participants. The results showed that both race and education were significant predictors of inadequate health literacy, yet gender, income and age were not. The logistic regression results showed that African Americans and Hispanics were about three times more likely to have inadequate health literacy than their Caucasian

counterparts. Results also showed when using less than a 6th grade education as the baseline, lower education levels increase the odds of having inadequate health literacy approximately 7.6 times.

The final part of Research Question 4 (Group 3) was to explore whether the demographic co-variates were significant predictors of a participant's health care insurance status. For this part of Research Question 4 a multinomial logistic regression was performed to analyze the relationship between the five predictor variables and the six categories of health insurance status. Results showed that gender significantly predicted females were more likely to have Medicaid than males, and males were more likely to have Military insurance than females. The logistic regression also significantly predicted that participants with higher education levels more often had Medicare and or some type of private health insurance. The co-variate of age significantly predicted that as participants age they more likely have Medicare or Military insurance. Race was a significant predictor relative to all types of health insurance categories. In fact, using Caucasian as the baseline, results showed that Caucasian participants were less likely to have no health insurance compared to African American, Hispanic and participants of other race descents. Income was the only co-variate that was not a significant predictor related to any health insurance category. Conclusions, limitations, and recommendations of the analysis will be discussed in chapter 5.

Chapter 5: Discussion, Conclusions, and Recommendations

Introduction

The purpose of this study was to investigate the relationship between health literacy and ESRD among type II diabetics. I explored whether there was an association between diabetic populations who developed ESRD and lower levels of health literacy. I also examined the relationship between levels of health literacy and health care services using types of health insurance as variables. I explored correlations between health literacy levels and variables such as the type of health insurance that may be playing a role in diabetics developing ESRD complications. To offer an overview comparison, I initially examined both diabetic and nondiabetic participants and compared demographic data and outcomes using frequency distributions and counts. Further examination was then performed to look at the phenomenon for the specific target population (individuals with type II diabetes) outlined in Research Questions 1-4.

Secondary data collected from the National Institute of Health were used for this research. Demographics such as age, race, ethnicity, income, and education levels were examined for comparative analysis. The data were stratified and then analyzed using cross-tabulation, correlation, chi-square analysis, binary logistic regression, and multinomial logistic regression to determine whether relationships among the variables were significant. Health literacy scores were based on the STOFLA and were analyzed to determine if there was a significant relationship between inadequate health literacy levels and developing ESRD among diabetic participants. Health care services was assessed based on the participants' health insurance status collected at baseline. Health insurance

categories included whether participants had health insurance, medicaid, medicare, military, and or private health insurance. Heath insurance status was analyzed to determine if there were significant differences between health insurance categories related to inadequate health literacy levels and or developing ERSD. ESRD was determined based on the medical event questionnaire and the renal replacement therapy questionnaire, which included both a primary and follow-up instrument to determine if participants developed ESRD at any point. Demographic covariates were analyzed to determine if there were significant factors that had an impact on the outcomes of inadequate health literacy, health insurance status, and the development of ESRD. Statistical analysis was performed among diabetic participants to determine whether there were significant relationships between inadequate health literacy, health care services, and developing ESRD. Four hypotheses founded the research questions that guided the study and directed the statistical analysis to explore the relationship that health literacy has on health outcomes.

Interpretation of Findings

Hypothesis 1: Inadequate Health Literacy and ESRD

The first hypothesis in this study was designed to suggest that there is a relationship between the development of ESRD and inadequate health literacy among diabetic participants. It is well documented that type II diabetes is the most common cause of ESRD and that ESRD can be prevented if diabetes is properly managed (Sen, Chakraborty, & De, 2016). Yet even with medications, nutritional diet regimens, diabetes coaching, wellness programs, and physician follow-up, the occurrence of diabetics

developing ESRD continues (Kautzky-Willer, Harreiter, & Pacini, 2016). Like with many chronic diseases that can be controlled, evidence has led medical professionals to begin recognizing the impact literacy skills may have on health outcomes (Rudd, 2015). Over three decades, research has shown that there is a need to provide health information to patients, but what is more important is whether the information is being understood (Rudd, 2015). Therefore, I explored whether there is a relationship between diabetic individuals who developed ESRD and levels of health literacy dependent on the outcome. Data collected form the STOFLA test were categorized into two dichotomous categories of health literacy (a) inadequate and (b) other (marginal, and adequate) and analyzed to answer Research Question 1.

Results from this study revealed that there is a significant relationship with inadequate levels of health literacy and ESRD among type II diabetics. Likewise, the chi-square analysis also revealed that there is a significant relationship between inadequate health literacy and developing ESRD among diabetic participants (p = <0.05). Correlation results showed that when comparing participants who developed ESRD to those who did not, persons with ESRD more often had inadequate levels and less often had marginal and adequate (other) levels of health literacy. Chi-square analysis showed that though there is a significant relationship, literacy has a small effect on the development of ERSD. Results also did not expose what the relationship was for this phenomenon; they only showed that there is a significant relationship between inadequate health literacy levels and developing ESRD among diabetic participants. The study supports the hypothesis that diabetic participants who have lower levels of health literacy

compared to those who higher literacy levels are at a greater risk for developing ESRD. However, the results also suggest with evidence to the small effect size that there are other factors that are playing a role in the development of ESRD.

Hypothesis 2: Health Insurance Status and Inadequate Health Literacy

Hypotheses 2 was that there is an association between types of healthcare services based on health insurance and inadequate levels of health literacy among type II diabetes. After identifying that inadequate health literacy has a significant effect on the development of ERSD among diabetic populations, I wanted to explore if literacy was different depending on an individual's type of health care service, which I examined through their health insurance status. According to Devaux (2015), an individual's type of health care service is different dependent on health insurance status and socioeconomic inequalities affect health outcomes. Additionally, the National Center for Health Statistics (2017) reported that there are growing differences in morbidity, mortality, and health outcomes dependent not only on an individual's health care use but their health care access and the type of health insurance they possess.

To investigate this hypothesis, inadequate health literacy was examined based on participants' type of health insurance to explore whether individuals with certain types of health insurance more often had inadequate health literacy levels than others. The dependent variable for Research Question 2 was the binary dichotomous categorical variable of inadequate health literacy and other (marginal and adequate). The independent variable was six categories of health insurance: (a) none, (b) Medicaid or public aid, (c) Medicare, (d) military insurance, (e) private health insurance, and (f) participant did not

know if they had health insurance or if they did, what they had.

This study showed that there is a relationship between inadequate levels of health literacy and the healthcare services based on ones' status of health insurance among diabetic populations ($p = .05$). Results showed that the relationship between inadequate health literacy levels plays a small to moderate effect related to an individual's health insurance status. Despite these results, the chi-square analysis performed for Research Question 2 could not differentiate between having health insurance or the type of health insurance participants held. For discussion purposes, there was some significant relationship between health insurance status and inadequate health literacy.

Hypothesis 3: Health Insurance Status and ESRD

After investigating the differences between literacy levels and healthcare services, Hypotheses 3 was that there is also a relationship between ESRD and certain types of healthcare services based on ones' health insurance. Hypothesis 3 suggested that participants who developed ESRD would have different healthcare services based on their health insurance than those who did not have health insurance. Recent studies introduce a concept referred to as *cultural competence*., which addresses inequities related to healthcare and health outcomes. For example, literature shows that there are disparities in health care in the United States (Betancourt, Green, Carrillo, Owusu, 2016). Social differences related to health care disproportionately affect certain populations and places them at greater risk for health complications (Betancourt et al., 2016). To address issues related to inequities within the U.S. health care system, cultural competence has been recognized as a framework to adapt interventions to address cultural, racial, and

socioeconomic disparities related to health care (Betancourt et al., 2016).

Research Question 3 was intended to examine this phenomenon and bridge the gap between inadequate literacy, healthcare services based on health insurance status, and development of ERSD. Hypothesis 3 suggests that individuals with lower health literacy who develop ESRD have no health insurance or a low-income based type of health insurance receive different services and have different outcomes who have superior health insurance. The related research question was intended to investigate the effectives of health care services (based upon type of health insurance) to supply adequate health information. The chi-square analysis findings showed that there were significant relationships with all type of health insurance and developing ESRD. The results indicated a statistically significant (p = <.001) relationship between any or all types of health insurance and participants who developed ESRD. This revealed that ESRD development is not specific to a type of health insurance, but there is a small to moderate effect relationship of ESRD with any type or status of health insurance. Though this showed that ERSD is significant among any or no health insurance, it did not clearly present the findings that this hypothesis implies. These results, however, do not eliminate the previous findings that demonstrate that inadequate health literacy does plays a role in the development of ESRD and is specific to populations with certain types of health care. It also confirms that there is a relationship between ESRD and health insurance but indicates that further research is needed to examine what the differences are between health care services, access, and insurance status.

Hypothesis 4: Demographic Cofactors Relative to ESRD, Inadequate Health Literacy, and Health Insurance Status

Literature shows that social inequalities negatively affect health outcomes (Bailey et al., 2017). For example, demographics such as race not only affect an individual's environment and resources available but helps describe how it affects health care status and harms health (Bailey et al., 2017). The final hypothesis in the study implied that there are demographic cofactors such as gender, race, age, socioeconomic status (income), and education that differ when comparing outcomes of ESRD, inadequate health literacy, and health insurance status. To explore this hypothesis, Research Question 4 tested three groups using a chi-square analysis for all of five predictors, proceeded with a binary logistic regression for the dichotomous outcomes of ESRD (Group 1) and inadequate health literacy (Group 2) and a multinomial logistic regression for the six potential outcomes of health insurance status (Group 3). The predictors included gender, race/ethnicity, socioeconomic status (income), education, and age. Findings showed there were significant differences between demographic covariates regarding each of the three outcomes.

As Baily et al. (2017) emphasized when investigating inequalities, there are significant differences when looking at health outcomes when considering race. Likewise, I found that race was a significant predictor relative to inadequate health literacy, low or no health insurance, and development of ERSD. Results showed that Caucasian participants were more likely to have health insurance compared to African American, Hispanic, and participants of other races.

There were also significant differences relative to gender, age, and education levels. Income was the only covariate that was not a significant predictor in this analysis. Results showed that both race and education were significant predictors of inadequate health literacy, yet gender, income, and age were not. Binary logistic regression results showed that gender, race and age, were significant predictors of ESRD. However, income, and education were not. A multinomial logistic regression was performed to analyze the relationship between the five predictor variables and the six categories of health insurance status. These findings showed that females were more likely to have Medicaid than males, and males were more likely to have no insurance and or Military insurance than females. Logistic regression findings showed that participants with higher education levels more often had Medicare and or some type of private health insurance, compared to participants who had lower levels of education who more often had no insurance and or Medicaid. It was also identified that as participants age they more likely had Medicare or Military insurance.

Regarding income (socioeconomic status) even though income was not a significant predictor, participants who were African American or Hispanic more often had low-income health insurance types or no health insurance at all . Overall results related to this hypothesis imply that there are significant demographic differences that impact diabetic participants outcomes of ESRD, inadequate health literacy and health insurance status (p=<.05).

Summary of Findings

Current literature acknowledges that professionals have begun recognizing the

impact that social differences have on populations who struggle with chronic diseases (Kautzky-Willer, A., Harreiter, J., & Pacini, G., 2016). Recent research outlines there are social determinants that are affecting health outcomes (Kautzky-Willer, A., Harreiter, J., & Pacini, G., 2016). Literature shows that medical and public health professionals are becoming increasingly aware of the social differences that impact chronic disease (Kautzky-Willer, A., Harreiter, J., & Pacini, G., 2016). With evidence to support that there are more than simply genetic and behavior components that play a role in chronic diseases, the social determinants of health have become evident. Yet the effect these social factors on health literacy is still unclear. As are the answers of whether health literacy impacts complications related to chronic disease that could otherwise be prevented.

This study explored the hypothesis that chronic disease complications could be prevented if diabetics had higher levels of health literacy and looked at influences surrounding inadequate health literacy. I focused on the relationship between health literacy and ESRD related to type II diabetes. I looked at what socioeconomic factors and social determinants are impacting one's health literacy, based on health care insurance, and demographics such as age, gender, education, race, and income. This study first showed the relationship between health literacy and ERSD. I then explored the question of whether there are differences regarding healthcare services, or whether there are inequities in the services being delivered based on health insurance status, and if there is an impact on literacy and ESRD complications.

As Devaux (2015) who performed a global study that examined the concept of

health inequities based on healthcare services and health insurance status showed, individuals with higher socioeconomic statuses, have better health care and better health outcomes. In fact, Devaux (2015) points out that more inequities exist among countries without a universal healthcare system in place due to the uneven distribution of services. Devaux (2015) also claims that the inequities negatively affect health.

Other literature has shown that health literacy varies among people dependent on their environmental situations (Rudd, 2015). Rudd (2015) emphasizes the importance of considering the ecological model, and to consider the physical, social, and political systems affecting our level of literacy. Even early studies done by Rothman et al. (2004) indicated that diabetic populations with lower levels of health literacy struggled to manage their disease. Rothmans' early study provided a foundation for current literature that studies the impact health literacy has on health outcomes.

Greenhalgh (2015) points out that there is an evolution of health literacy, and highlights the need to further identify its impact on health outcomes. Furthermore, (as cited in Greenhalgh, 2015) correlating data from the World Health Organization now defines health literacy as "the personal characteristics and social resources needed for individuals and communities to access, understand, appraise and use information and services to make decisions about their health." Greenhalgh (2015) challenges medical and public health professionals to approach literacy deficiencies with a new systematic approach, an approach that includes considering the social determinants of health, inequities and access to health care. This new research shows the vital impact that health literacy can have on Diabetic complications. It begins the process of filling in the gaps

from previous research such as Al Sayah et al., (2013), who acknowledged years ago the need to investigate the impact of health literacy on long-term health outcomes.

This study presents findings that clearly indicate a significant relationship between inadequate levels of health literacy and long- term outcomes such as ESRD. The findings of this study confirmed that there is a relationship between inadequate health literacy levels and the development of ESRD among type II diabetic populations. Results show a significant relationship with ESRD and inadequate health literacy among diabetic participants, relative to their health insurance status. Chi Square analysis performed in research questions one thru three, also displayed a significant relationship. The details however, of the relationships could not be determined from the Chi square analysis test alone. The multinomial logistic regression analysis, which was performed on three groups in research question four, revealed that there are significant relationships with various demographic variables, social determinants of health, and outcomes related to an individuals' development of diabetic complications, such as ESRD, inadequate health literacy levels, and one's health insurance status.

Findings show that the relationship predominately affects African American males between the ages of 51-70 with lower levels of education. It also revealed that though ESRD occurs among patients with or without diabetes it is more prevalent among type II diabetics. As well, data shows that diabetic populations who developed ESRD, had inadequate health literacy more often than those who did not develop ESRD. Comparisons also showed that diabetic participants who had inadequate health literacy more often had no insurance and or Medicaid, more often than diabetic participants who

had marginal or adequate levels of literacy (other). While diabetic participants who had inadequate levels of literacy more often had no health insurance and or Medicaid, they also less often had private health insurance compared to diabetic participants who had marginal or adequate levels of literacy. Data presented in this study identifies a relationship between diabetic populations with inadequate health literacy and ESRD related to other various demographic social determinants. It shows that there is a significant relationship between inadequate health literacy and ESRD and ones' health insurance status, even though we do not know the specific relationship, we know that there is a relationship. A relationship that signifies that minority populations with diabetes of lower education levels and socioeconomic statuses more often have no health insurance and or are on some type of public aid or Medicaid services, and more often have inadequate health literacy, which places them at greater risk for developing ESRD. This research creates a bridge for further research to explore the social determinants and the relationship between health literacy and health outcomes.

As outlined in Chapter 2, Inzucchi et al., (2012) identified years ago, that there are other variables that play a role in negative health outcomes. This is supported by current literature that now recognizes there are multifaceted layers related to health literacy such as knowing what to do with the information, and social support (Greenhalgh, T., 2015). As the conceptual framework of health literacy, health status, and health service utilization suggests, an individual's health literacy is not simply impacted by cognitive skills and learned methods, it is also affected by our cultural and social environment.

Limitations of the Study

Though this study made an exerted attempt to avoid limitations by exceeding the effect size, using a 95 % confidence interval (CI), thereby reducing the margin of error (MOE) of ~ 2% and including a larger overall randomly selected sample of (*N=3908*) and further randomly stratifying the sample (*N=1908*), limitations still emerged. Initially, one limitation that arose, was the lack of availability of certain secondary data planned to be used from the NIH, CRIC. The health care utilization survey which was intended to be used to determine the method and level of disease management, patient/ provider relationships, and method of disease management, was not released nor available for use for this research. To compensate for analysis of disease management methods based on the Health Care Utilization Survey, disease management methods and healthcare services was based on the available data using the Health insurance status survey. The replacement survey however, did not provide details originally planned to include in the research. For example, the participants level of medical services or utilization was not included, but instead data related to whether participants had health insurance and if so, the type of health insurance, allowing some assumptions to be based on limited data.

Though findings indicate a significant relationship between inadequate levels of health literacy and ESRD, the association between health insurance status and inadequate health literacy and ESRD remain limited. Results confirm there is a significant relationship, but there are further answers needed to determine what exactly the relationship is between inadequate health literacy, ESRD, and health insurance status. The variable of health insurance status presents inconclusive results as to what specific

associations and or relationships exist regarding development of ESRD and or inadequate health literacy levels. Though results uncover there are significant relationships among demographic co-variates related to Health insurance status, data is insufficient to claim that one's type of health insurance is indicative to the type of healthcare services received, and or whether that impacts ESRD or literacy outcomes directly.

The results cannot confirm that health literacy or one's healthcare service is impacted by an individual's type of health insurance. It can simply suggest there is an association and provide evidence there is some type of relationship which cannot be determined with this study alone. Data does not differentiate whether individuals with no health insurance, compared to any type, predisposes them for developing ESRD. Even though results show that more often participants with low-income health insurance did have ESRD, results related to the covariate of income was not significant. Results showed that individuals with any, or no health insurance, develop ESRD. Though inadequate health literacy levels are relative to ESRD, the specific relationship with health insurance status cannot be determined from this study. Further research is needed to explore other potential social determinants of health that may be impacting inadequate health literacy, and development of ESRD. More research also needs to examine socioeconomic status and inequities related to health care services, taking a more comprehensive look at differences between health care services and health care insurance status. There is also more research needed to explore how inequalities and social determinants are impacting health outcomes.

Generalizability of this study is limited due to the sample size of participants who

developed ESRD. When performing binary regression after stratification of data based on the conditions of having type II diabetes, sample size of participants who completed the STOFLA were low, potentially impacting the power of the regression analysis. The overall number of participants who developed ESRD was (*N=539*). There were also predominately more participants who had other (marginal and adequate levels) of literacy *(N=1002)* compared to those who had inadequate levels of literacy (*N=172).* In fact, the number of participants who developed ESRD, took the STOFLA, and had inadequate health literacy levels was small*(N=67*). Another potential limitation reflects potential gender bias. After stratification, the number of diabetic participants who were male *(N= 1064)* was greater than the number of female

(N=844) participants.

Another limitation includes the contradiction between the Pearson chi Square result within the Goodness of fit test, and the Likelihood model summary for the Multinomial logistic regression analysis for group 3 of research question four (Research Question 4). The inconsistency related to the model summaries of the six categories of health insurance status with the predictors (gender, race, age income and education) left inconclusive findings. Results questionably found that income was not a significant predictor whereas all other co-variates were, even regarding low-income health insurance statuses. The results as mentioned above also leave gaps that cannot confirm if, or how health insurance directly impacts literacy or one's health care services.

As well, data was secondary data that had been originally collected from the NIH CRIC, where participants were selected based on health-risk factors that may have

predisposed them for development of ESRD, due to potentially having some type of renal deficiency. Likewise, due to the use of secondary data, addressing issues that arise such as limitations to self-collection of certain data surveys, the sample collection process, and missing data, lacked control over collection and was at the discretion of the original researcher which may produce some unavoidable bias and data limitations.

Recommendations for Action

Recommendations generated from this research are based on findings that revealed there is a significant relationship between inadequate health literacy levels and type II diabetic populations developing ESRD. Recommendations regarding these findings are to ensure efforts are made to disseminate this information through publication. Through limitations identified that ESRD is not dependent of whether an individual has health insurance or a specific type of health insurance, the research uncovered that there are socioeconomic variables and inequalities among populations that do have an impact on health literacy as well as their health insurance status. It is recommended that health care and public health professionals recognize the impact that socioeconomic variables may play, in ones' level of health literacy and their health outcomes. It is also critical to ensure that public health interventions are developed with respect to the fact that ones' health outcomes can be impacted by their level of health literacy. Recommendations are to assess patients' levels of health literacy when developing disease management plans and implement tools that respectfully evaluate individuals appropriately. These recommendations include implementing holistic interventions and services that take into consideration ones' socioeconomic status, and

variables such as education, income and or race that may be affecting ones' level of health literacy. Recommendations from this study align with past research that claims health literacy is more than reading pamphlets and making appointments, it is being able to access health information to its capacity and being able to effectively utilize it. Additionally, it is important that there is awareness and recognition relative to how social determinants significantly impact ones' health literacy. There is a need for public health programs and providers to incorporate disease management methods that address these factors to prevent negative health outcomes and related heath complications.

Recommendations for Future Research

ESRD significantly impacts individuals with type II diabetes, and this research demonstrates that inadequate health literacy has a significant relationship in that development. Though data from this study showed significance related to inadequate health literacy levels and ESRD among diabetic participants, it left a limited definitive understanding of the relationship related to health insurance status. It is recommended to strengthen the reliability and the validity of the outcomes; that further studies be performed specific to the impact that social determinants and socioeconomic conditions have regarding one's health care insurance status and the health care services received.

Due to limitations of the availability of the health care utilization survey, as mentioned previously, alternative data was used as a replacement to investigate the relationship between health care services and health literacy. This adjustment brought added information, but left room for further investigations to be explicitly researched. It is recommended that future research evaluates methods of disease management and the

effectiveness related to health literacy. This will provide a better understanding of the effectiveness of current disease management methods and public health interventions and identify areas for improvement.

Additionally, this research identified specific socioeconomic factors that influence health literacy levels. Data revealed that there are substantial inequalities related to race, health insurance status, literacy levels and education that pose a greater risk for development of ESRD.

Research shows that social determinants of health such as race, ethnicity, education, and income have all been well defined by data to pose a threat to positive health outcomes. In fact, results show that individuals who struggle with one or more social determinants, more likely have limited health literacy, less access to quality health care, and poor health outcomes. Furthermore, experts suggest that if we do not address these social inequalities with a framework referred to as "Cultural Competence," over the next decade poor health outcomes across the U.S. will continue to soar. Recommendations include extending research that examines the relationship between social determinants related to gender, age, race, ethnicity, socioeconomic levels, education levels and health literacy, and further evaluate the impact disparities have on health outcomes.

Implications for Social Change

The implications for social change, at the individual level are to utilize this information to improve efforts that allow individuals to recognize the importance of having the ability to be able to manage their own health. It is important for individuals to

recognize that they play a key role in the management of their disease and the outcomes of their health. Individuals need to recognize the importance of being an advocate for themselves. It is critical that individuals are given the necessary tools to be able to understand information and options being presented to them in order to alter behaviors and make healthier choices. The framework for this study emphasizes that exact concept. As Lee, Arozullah, Cho, Crittenden, and Vicencio (2009) have outlined within the framework of this study, the four pathways that link health literacy to health outcomes include self-care knowledge, disease management, compliance, and individual behaviors. It is essential for individuals with Type II Diabetes to recognize the risks of ESRD if they do not adequately manage their disease.

At a societal level, it is important that public health and medical professionals use this research as a foundation to work towards encouraging individuals with chronic diseases to be an active participant in their own health. Adequate health literacy is fundamental to prevent further complications of chronic diseases which can impair individuals' quality of life. It is also crucial that public health and medical professionals recognize the importance of adequate health literacy and continue to work towards interventions and health care services that ensure it. Additionally, this research brings recognition of socioeconomic variables such as race, income, education level, and access to health care among vulnerable populations in this country, and the impact inequalities have on one's health literacy and therefor their ability to manage their health.

Conclusion

This study suggests that there is a significant relationship between inadequate

levels of health literacy and developing ESRD among type II diabetic populations. The study cannot confirm that health insurance status plays a direct role in ESRD and inadequate health literacy due to limitations of accessible variables. However, it does show evidence that supports a significant relationship between certain types of health insurance and inadequate literacy levels as well as an increased prevalence of ESRD. Data exposed a relationship between inadequate levels of health literacy and no health insurance and or low-income health insurance types. It also revealed that many contributing socioeconomic factors are related to inadequate levels of health literacy and the development of ESRD. Data suggests that more research is needed to investigate disparities that place individuals at high-risk, such as race, low-income, low education, health care access and or the health care services being delivered.

In today's turbulent world of health care debate, there is a need for future research to explore the social determinants of health in relation to levels of health literacy and the impact on health outcomes. The social change implications of the research presented in this study demonstrates the impact that health literacy can have on health outcomes. This research brings attention to the need for future research to addresses socioeconomic variables, the social determinants of health, and health inequities that may be negatively impacting health outcomes.

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Appendix A: Medical Event Questionnaire

Participant ID:_____-_____-_____ Participant Initials: _____

Clinical Center:_____ Site:_____ Visit Number: _____

CRF Date:_____/_____/_____ RC ID: _____

PERSONAL MEDICAL HISTORY:

PERSONAL MEDICAL HISTORY:

1. Has a doctor or other health professional ever told you that you have any of the conditions listed below?

a. Diagnosed or treated for any cancer within the last 5 years? ☐1 Yes ☐0 No ☐88 Don't know

If ***YES,*** was it:

Cancer of the bladder?	☐1 Yes	☐0 No
Breast cancer?	☐1 Yes	☐0 No
Colon or rectal cancer?	☐1 Yes	☐0 No
Cancer of the uterus?	☐1 Yes	☐0 No
Cancer of the head and neck?	☐1 Yes	☐0 No
Blood cancer?	☐1 Yes	☐0 No
Lung cancer?	☐1 Yes	☐0 No
Cancer of the lymph nodes?	☐1 Yes	☐0 No
Melanoma or skin cancer?	☐1 Yes	☐0 No
Cancer of the ovaries?	☐1 Yes	☐0 No
Prostate cancer?	☐1 Yes	☐0 No
Any other type of cancer?	☐1 Yes	☐0 No

If ***YES, specify***: _____

b. Asthma or reactive airway disease?	☐1 Yes	☐0 No	☐88 Don't know
c. Chronic Obstructive Pulmonary Disease (emphysema)?	☐1 Yes	☐0 No	☐88 Don't know
d. Hepatitis (B or C) infection?	☐1 Yes	☐0 No	☐88 Don't know
e. Rheumatoid Arthritis?	☐1 Yes	☐0 No	☐88 Don't know
f. Gout?	☐1 Yes	☐0 No	☐88 Don't know

For female participants only.
Male participants skip to Question #12 – RENAL HISTORY.

These next questions ask about your reproductive history and your general health as a woman.

2. How old were you when you had your first menstrual period? _____years old
☐88 Don't know

3. What was the date of your last menstrual period? _____/_____/_____
MM DD YYYY
☐88 Don't know

4. Have you ever been pregnant? ☐1 Yes ☐0 No

If ***NO***, skip to Question ***#8***.

5. How many live births have you had? _____live births

If ***"0"***, skip to Question ***#7***.

6. How old were you at your first live birth? _____years old
☐88 Don't know

Participant ID:_____-_____-_____ Participant Initials: _____

Clinical Center:_____ Site:_____ Visit Number: _____

CRF Date:_____/_____/_____ RC ID: _____

MEDICAL HISTORY

7. Has a doctor or other health professional ever told you that you had pre-eclampsia during one or more of your pregnancies?	☐1 Yes	☐0 No ☐88 Don't know
8. Have you had surgery to remove your ovaries?	☐1 Yes	☐0 No
a. If ***YES***, how many ovaries were removed?	☐1 One	☐2 Both ☐88 Don't know
9. At what age did you complete your menopause (no menstrual period for 1 year)?	_____years old ☐88 Don't know ☐99 I still have menstrual periods	
10. Do you take or did you ever take estrogen either as pill, injection or patch? *(Do not include creams or birth control containing estrogen)*	☐1 Yes	☐0 No ☐88 Don't know
a. If ***YES***, how many years have you taken estrogen?	_____years ☐88 Don't know	
11. Do you or did you ever take progestin with estrogen? *(Do not include creams)*	☐1 Yes	☐0 No ☐88 Don't know
a. If ***YES***, how many years have you taken progestin with estrogen?	_____years ☐88 Don't know	

RENAL HISTORY:

RENAL HISTORY:

12. When were you first made aware of your kidney problem or protein in the urine?	☐1 During CRIC evaluation ☐2 Within the previous 6 months ☐3 6 months to under 1 year ago ☐4 1 year to under 3 years ago ☐5 3 years to under 5 years ago ☐6 5 years ago or longer ☐88 Don't know	
13. Has a doctor or other health professional ever told you that your kidney disease was caused by diabetes?	☐1 Yes	☐0 No ☐88 Don't know
14. Has a doctor or other health professional ever told you that your kidney disease was caused by High blood pressure?	☐1 Yes	☐0 No ☐88 Don't know
15. Has a doctor or other health professional ever told you that your kidney disease was caused by glomerulonephritis?	☐1 Yes	☐0 No ☐88 Don't know
If ***YES*** to glomerulonephritis, ***check one:***		
i. IgA nephropathy:	☐1 Yes	☐0 No ☐88 Don't know
ii. Lupus nephritis:	☐1 Yes	☐0 No ☐88 Don't know
iii. Other:	☐1 Yes	☐0 No ☐88 Don't know

Participant ID:_____-_____-_____ Participant Initials: _____

Clinical Center:_____ Site:_____ Visit Number: _____

CRF Date:_____/_____/_____ RC ID: _____

MEDICAL HISTORY

16. Has a doctor or other health professional ever told you that your kidney disease was caused by kidney stones or multiple kidney infections or kidney blockage? ☐1 Yes ☐0 No ☐88 Don't know

17. Has a doctor or other health professional ever told you that your kidney disease was caused by another condition? ☐1 Yes ☐0 No ☐88 Don't know

If ***YES***, ***specify***: _____

18. Have you ever had:

a. A kidney arteriogram/X-ray of your kidney with contrast dye? ☐1 Yes ☐0 No ☐88 Don't know

If ***YES***, when? _____/_____ (MM/YYYY) ☐88 Don't know

b. A kidney biopsy (removal of a small piece of the kidney)? ☐1 Yes ☐0 No ☐88 Don't know

If ***YES***, when? _____/_____ (MM/YYYY) ☐88 Don't know

c. A kidney ultrasound (pictures of the kidney taken with sound waves)? ☐1 Yes ☐0 No ☐88 Don't know

If ***YES***, when? _____/_____ (MM/YYYY) ☐88 Don't know

For Research Coordinator use only:
If YES is checked for Question # s 18 a, b, and/or c, complete EVENT CRF.

19. Have you ever seen a nephrologist or a kidney doctor? ☐1 Yes ☐0 No ☐88 Don't know

If ***NO*** or ***DON'T KNOW***, skip to Question ***#20***.

a. If ***YES***, when did you first see a nephrologist or a kidney doctor about your kidney problem?
- ☐1 During CRIC evaluation
- ☐2 Within the previous 6 months
- ☐3 6 months to under 1 year ago
- ☐4 1 year to under 3 years ago
- ☐5 3 years to under 5 years ago
- ☐6 5 years ago or longer
- ☐88 Don't know

b. If ***YES***, when did you last see a nephrologist or a kidney doctor about your kidney problem?
- ☐1 During CRIC evaluation
- ☐2 Within the previous 6 months
- ☐3 6 months to under 1 year ago
- ☐4 1 year to under 3 years ago
- ☐5 3 years to under 5 years ago
- ☐6 5 years ago or longer
- ☐88 Don't know

Participant ID:_____-_____-_____ Participant Initials: _____

Clinical Center:_____ Site:_____ Visit Number: _____

CRF Date:_____/_____/_____ RC ID: _____

MEDICAL HISTORY

c. After seeing a nephrologist or a kidney doctor for your kidney problem, were any of the following things recommended, ordered, or prescribed:

i. Medical or laboratory procedures? ❑1 Yes ❑0 No ❑88 Don't know

If ***YES***, check all that apply:
- ❑ Measure the level of protein in your urine
- ❑ Measure your kidney function by a 24-hour urine test or iothalamate clearance test
- ❑ Kidney ultrasound
- ❑ Kidney biopsy
- ❑ Other blood tests
- ❑ Gave you one or more vaccines to prevent bacterial infections

ii. Medications/prescriptions? ❑1 Yes ❑0 No ❑88 Don't know

If ***YES***, check all that apply:
- ❑ Told to avoid anti-inflammatory drugs (e.g., NSAIDs) or other drugs that might harm your kidneys
- ❑ Started or changed doses of drugs to lower your blood pressure
- ❑ Started drugs to raise your blood counts (i.e., treat anemia)
- ❑ Started or changed doses of drugs to treat your cholesterol levels
- ❑ Started or changed doses of drugs to treat diabetes or high blood sugar
- ❑ Started drugs to lower phosphate levels in your blood

iii. Life style changes? ❑1 Yes ❑0 No ❑88 Don't know

If ***YES***, check all that apply:
- ❑ Told to cut down on the amount of protein you eat
- ❑ Told to cut down on the amount of salt or sodium you eat
- ❑ Told to cut down on the amount of potassium you eat
- ❑ Referred you to a nutritionist or someone to review your diet
- ❑ Told you to stop smoking tobacco
- ❑ Told you to cut down on alcohol use

20. Have you ever seen any ***other*** doctor or health professional about your kidney problem? ❑1 Yes ❑0 No ❑88 Don't know

If ***NO*** or ***DON'T KNOW***, skip to Question ***#21***.

a. If ***YES***, when did you first see the ***other*** doctor or health professional about your kidney problem?
- ❑1 During CRIC evaluation
- ❑2 Within the previous 6 months
- ❑3 6 months to under 1 year ago
- ❑4 1 year to under 3 years ago
- ❑5 3 years to under 5 years ago
- ❑6 5 years ago or longer
- ❑88 Don't know

Participant ID:_____-_____-_____ Participant Initials: _____

Clinical Center:_____ Site:_____ Visit Number: _____

CRF Date:_____/_____/_____ RC ID: _____

MEDICAL HISTORY

b. If ***YES***, when did you last see the ***other*** doctor or health professional about your kidney problem?

- ❑ 1 During CRIC evaluation
- ❑ 2 Within the previous 6 months
- ❑ 3 6 months to under 1 year ago
- ❑ 4 1 year to under 3 years ago
- ❑ 5 3 years to under 5 years ago
- ❑ 6 5 years ago or longer
- ❑ 88 Don't know

c. After seeing ***another*** doctor or health professional for your kidney problem, were any of the following things recommended, ordered, or prescribed:

i. Medical or laboratory procedures? ❑ 1 Yes ❑ 0 No ❑ 88 Don't know

If ***YES***, check all that apply:

- ❑ Measure the level of protein in your urine
- ❑ Measure your kidney function by a 24-hour urine test or iothalamate clearance test
- ❑ Kidney ultrasound
- ❑ Kidney biopsy
- ❑ Other blood tests
- ❑ Gave you one or more vaccines to prevent bacterial infections

ii. Medications/prescriptions? ❑ 1 Yes ❑ 0 No ❑ 88 Don't know

If ***YES***, check all that apply:

- ❑ Told to avoid anti-inflammatory drugs (e.g., NSAIDs) or other drugs that might harm your kidneys
- ❑ Started or changed doses of drugs to lower your blood pressure
- ❑ Started drugs to raise your blood counts (i.e., treat anemia)
- ❑ Started or changed doses of drugs to treat your cholesterol levels
- ❑ Started or changed doses of drugs to treat diabetes or high blood sugar
- ❑ Started drugs to lower phosphate levels in your blood

iii. Life style changes? ❑ 1 Yes ❑ 0 No ❑ 88 Don't know

If ***YES***, check all that apply:

- ❑ Told to cut down on amount of protein you eat
- ❑ Told to cut down on the amount of salt or sodium you eat
- ❑ Told to cut down on the amount of potassium you eat
- ❑ Referred you to a nutritionist or someone to review your diet
- ❑ Told you to stop smoking tobacco
- ❑ Told you to cut down on alcohol use

Participant ID:_____-_____-_____ Participant Initials: _____

Clinical Center:_____ Site:_____ Visit Number: _____

CRF Date:_____/_____/_____ RC ID: _____

MEDICAL HISTORY

CARDIOVASCULAR HISTORY:
CARDIOVASCULAR HISTORY:

21. Have you ever been diagnosed with or has a doctor or other health professional ever told you that you have:

a.	Coronary artery disease (heart attack, angina)?	☐1 Yes	☐0 No	☐88 Don't know
b.	Prior revascularization of your heart blood vessels (e.g. balloon angioplasty, coronary stenting, coronary bypass surgery)?	☐1 Yes	☐0 No	☐88 Don't know
c.	Heart failure?	☐1 Yes	☐0 No	☐88 Don't know
d.	Atrial fibrillation or atrial flutter (an irregular heart rhythm)?	☐1 Yes	☐0 No	☐88 Don't know
e.	Stroke?	☐1 Yes	☐0 No	☐88 Don't know
f.	Peripheral vascular disease (claudication, amputation or procedure to open up blood vessels in arms or legs)?	☐1 Yes	☐0 No	☐88 Don't know

22. Do you have pain or cramping in your calves or legs when walking ***(not due to arthritis)*** that is relieved by resting? ☐1 Yes ☐0 No ☐88 Don't Know

23. Have you had a toe(s) or foot surgically amputated due to infection or poor circulation? ☐1 Yes ☐0 No ☐88 Don't Know

24. Have you had a leg surgically amputated due to infection or poor circulation? ☐1 Yes ☐0 No ☐88 Don't Know

25. Have you had a procedure to open blood vessels in your arms or legs (angioplasty, surgical vascular by-pass)? ☐1 Yes ☐0 No ☐88 Don't Know

Hypertension History:
Hypertension History:

26. How long has it been since you last had your blood pressure taken by a doctor or other health professional?
- ☐0 Never
- ☐1 Within the previous 6 months
- ☐3 6 months to under 1 year ago
- ☐4 1 year to under 3 years ago
- ☐5 3 years to under 5 years ago
- ☐5 5 years ago or longer
- ☐88 Don't know

If ***NEVER***, skip to Question ***#28***.

27. Has a doctor or other health professional ever told you that you have hypertension or high blood pressure? ☐1 Yes ☐0 No

If ***NO***, skip to Question ***#28***.

a. If ***YES***, how old were you when you were first told you had this condition? _____ years old ☐88 Don't know

b. Do you currently take prescribed medication for your hypertension or high blood pressure? ☐1 Yes ☐0 No ☐88 Don't know

Participant ID:_____-_____-_____ Participant Initials: _____

Clinical Center:_____ Site:_____ Visit Number: _____

CRF Date:_____/_____/_____ RC ID: _____

MEDICAL HISTORY

High Cholesterol History:
High Cholesterol History:

28. How long has it been since you had your blood cholesterol measured by a doctor or other health professional?
- ❑0 Never
- ❑1 Within the previous 6 months
- ❑3 6 months to under 1 year ago
- ❑4 1 year to under 3 years ago
- ❑5 3 years to under 5 years ago
- ❑5 5 years ago or longer
- ❑88 Don't know

If ***NEVER***, skip to Question ***#30 – DIABETIC HISTORY***.

29. Has a doctor or other health professional ever told you that your blood cholesterol level was high? ❑1 Yes ❑0 No ❑88 Don't know

If ***NO*** or ***DON'T KNOW,*** skip to Question ***#29b***.

a. If ***YES***, how old were you when you were first told you had this condition? _____ years old ❑88 Don't know

b. Do you currently take prescribed medication for your high blood cholesterol? ❑1 Yes ❑0 No ❑88 Don't know

DIABETIC HISTORY:

DIABETIC HISTORY:

30. Has a doctor or other health professional ever told you ***(except during pregnancy)*** that you have diabetes or high blood sugar? ❑1 Yes ❑0 No ❑88 Don't Know

If ***NO*** or ***DON'T KNOW,*** skip to instructions before Question ***#35***.

a. How old were you when a doctor first told you that you had diabetes? _____ years old ❑88 Don't know

b. Are you on a weight loss or exercise program to control your blood sugar? ❑1 Yes ❑0 No ❑88 Don't Know

c. Are you currently taking insulin? ❑1 Yes ❑0 No

d. Do you currently take diabetes pills to lower your blood sugar? (These are sometimes called oral agents or oral hypoglycemic agents.) ❑1 Yes ❑0 No

e. How old were you when you started taking diabetes medications? _____ years old ❑88 Don't know

Participant ID:_____-_____-_____ Participant Initials: _____

Clinical Center:_____ Site:_____ Visit Number: _____

CRF Date:_____/_____/_____ RC ID: _____

MEDICAL HISTORY

31. When was the last time you had your eyes examined a doctor? (***If known, write number and check either days, weeks, months or years***)

_____ ❑1 Days ago by
❑2 Weeks ago
❑3 Months ago
❑4 Years ago
❑0 Never
❑88 Don't Know

32. Has a doctor ever told you that diabetes has affected your eyes or that you have retinopathy? ❑1 Yes ❑0 No ❑88 Don't Know

33. Has a doctor ever told you that you have diabetic neuropathy, that is, diabetes has affected the nerves of your hands or feet or any other parts of your body? ❑1 Yes ❑0 No ❑88 Don't Know

34. Do you have (or had) any of these problems that may be related to your diabetes?

a. Numbness or tingling in your hands or feet (other than falling asleep because you laid on your arm or leg)? ❑1 Yes ❑0 No ❑88 Don't Know
b. Loss of sensation in your hands or feet? ❑1 Yes ❑0 No ❑88 Don't Know
c. Decreased ability to feel the hotness or coldness of things you touch? ❑1 Yes ❑0 No ❑88 Don't Know
d. Sores or ulcers on your feet or ankles? ❑1 Yes ❑0 No ❑88 Don't Know

If you do not have hypertension/high blood pressure, high blood cholesterol, diabetes, skip to Question #36.

35. Because of your hypertension/high blood pressure, high blood cholesterol and/or diabetes, are you currently:

a. Controlling or trying to lose weight? ❑1 Yes ❑0 No
b. Exercising? ❑1 Yes ❑0 No
c. Restricting alcohol use? ❑1 Yes ❑0 No
d. Quitting smoking? ❑1 Yes ❑0 No
e. Reducing tension/stress? ❑1 Yes ❑0 No
f. Using less salt or sodium in your diet? ❑1 Yes ❑0 No
g. Consuming low fat diet? ❑1 Yes ❑0 No
h. Making other diet changes? ❑1 Yes ❑0 No
i. Doing anything else? ❑1 Yes ❑0 No

Specify: _____

Participant ID:_____-_____-_____ Participant Initials: _____

Clinical Center:_____ Site:_____ Visit Number: _____

CRF Date:_____/_____/_____ RC ID: _____

MEDICAL HISTORY

SOCIAL HISTORY:

Smoking History:

36. Have you smoked at least 100 cigarettes during your entire life? ***(approximately 5 packs)*** ☐1 Yes ☐0 No

If ***NO***, skip to Question ***#41***.

37. How old were you when you first started smoking cigarettes regularly *(3 or more times a week)*?

_____years old
☐0 Never smoked regularly
☐88 Don't Know

38. Do you smoke cigarettes now? ☐1 Yes ☐0 No

a. If ***NO***, at what age did you quit smoking cigarettes? _____years old ☐88 Don't Know

If you DO NOT smoke cigarettes now, skip to Question #41.

39. How many cigarettes do you smoke per day? (***If known, write number and check either cigarettes/day or packs/day***)

_____☐1 cigs/day
☐2 packs/day
☐1 Less than 1 per day
☐2 Varies

40. How long have you smoked this amount? (***If known, write number and check either months or years***) _____☐1 months ☐2 years

41. Have you ever smoked at least 20 cigars in your entire life? ☐1 Yes ☐0 No

If ***NO***, skip to Question ***#44 – Alcohol Use History***.

42. Do you currently smoke cigars? ☐1 Yes ☐0 No

If ***NO***, skip to Question ***#44 – Alcohol Use History***.

43. How many cigars do you smoke per day? _____cigars

Participant ID:_____-_____-_____ Participant Initials: _____

Clinical Center:_____ Site:_____ Visit Number: _____

CRF Date:_____/_____/_____ RC ID: _____

MEDICAL HISTORY

Alcohol Use History:

44. During the past 12 months, how often have you had a drink of any kind of alcoholic beverage?

- ☐ 8 Every day or almost every day
- ☐ 7 5 - 6 times a week
- ☐ 6 3 - 4 times a week
- ☐ 5 1 - 2 times a week
- ☐ 4 2 - 4 times a month
- ☐ 3 Once a month
- ☐ 2 Less than once a month but at least once in the past 12 months
- ☐ 1 Not at all in the past 12 months ***(Skip to Question #46 – Recreational Drug Use History.)***
- ☐ 0 Never had any beverage containing alcohol ***(Skip to Question #46 – Recreational Drug Use History.)***

a. If you had a drink in the past 12 months, on an average how many drinks did you consume? ***(1 drink = a 12-oz can of beer, 4 oz. of wine or a 1 oz. shot of hard liquor)*** _____drinks

45. What is the largest number of drinks containing alcohol that you had in any single day during the last 12 months?

- ☐ 5 12 to 23 drinks
- ☐ 4 At least 8, but less than 12 drinks
- ☐ 3 5 to 7 drinks
- ☐ 2 3 to 4 drinks
- ☐ 1 1 to 2 drinks
- ☐ 98 Don't wish to answer ***(Skip to Question #46)***

a. Based on the largest number of drinks on any single day as responded in **Question #45** in the last 12 months how often did you have that many drinks?

- ☐ 8 Every day or nearly every day
- ☐ 7 3 to 4 times a week
- ☐ 6 Once or twice a week
- ☐ 5 1 to 3 times a month
- ☐ 4 7 to 11 times in the past year
- ☐ 3 3 to 6 times in the past year
- ☐ 2 Twice in the past year
- ☐ 1 Once in the past year

Participant ID:_____-_____-_____ Participant Initials: _____

Clinical Center:_____ Site:_____ Visit Number: _____

CRF Date:_____/_____/_____ RC ID: _____

MEDICAL HISTORY

Recreational Drug Use History:

a. Marijuana?	☐1 Yes ☐0 No ☐88 Don't Know	☐1 1 to 2 times ☐2 3 to 10 times ☐3 11 to 99 times ☐4 100 times or more	☐1 Yes ☐0 No ☐88 Don't Know
b. Methamphetamines?	☐1 Yes ☐0 No ☐88 Don't Know	☐1 1 to 2 times ☐2 3 to 10 times ☐3 11 to 99 times ☐4 100 times or more	☐1 Yes ☐0 No ☐88 Don't Know
c. Cocaine (snorted, smoked/inhaled)?	☐1 Yes ☐0 No ☐88 Don't Know	☐1 1 to 2 times ☐2 3 to 10 times ☐3 11 to 99 times ☐4 100 times or more	☐1 Yes ☐0 No ☐88 Don't Know
d. Injected cocaine?	☐1 Yes ☐0 No ☐88 Don't Know	☐1 1 to 2 times ☐2 3 to 10 times ☐3 11 to 99 times ☐4 100 times or more	☐1 Yes ☐0 No ☐88 Don't Know
e. Injected heroin?	☐1 Yes ☐0 No ☐88 Don't Know	☐1 1 to 2 times ☐2 3 to 10 times ☐3 11 to 99 times ☐4 100 times or more	☐1 Yes ☐0 No ☐88 Don't Know
f. Other injected street drugs? ~~*If YES, specify:*~~ _____	☐1 Yes ☐0 No ☐88 Don't Know	☐1 1 to 2 times ☐2 3 to 10 times ☐3 11 to 99 times ☐4 100 times or more	☐1 Yes ☐0 No ☐88 Don't Know

Participant ID:_____-_____-_____ Participant Initials: _____

Clinical Center:_____ Site:_____ Visit Number: _____

CRF Date:_____/_____/_____ RC ID: _____

MEDICAL HISTORY

FAMILY HISTORY:

47. How many half or full brothers and sisters do/did you have?
(include those who died) ___ ___

Has a health care provider ever diagnosed ***your mother or father*** or ***your siblings or children*** with any of the following conditions?

[Check for ***all*** medical conditions that apply. If ***YES***, enter the ***earliest*** age for your parents or any of the siblings and/or children when the condition ***first*** occurred or was ***first*** diagnosed. If the age is not known, check ***"Don't know"***. If you don't have siblings or children, check ***"N/A"*** in the appropriate column.]

Condition	Mother	Father	Any siblings (Brothers and Sisters)	Any children
48. Heart attack, coronary artery bypass surgery, or balloon angioplasty (PTCA)?	☐ 1 Yes ☐ 0 No ☐ 88 Don't know	☐ 1 Yes ☐ 0 No ☐ 88 Don't know	☐ 1 Yes ☐ 0 No ☐ 88 Don't know ☐ 99 N/A	☐ 1 Yes ☐ 0 No ☐ 88 Don't know ☐ 99 N/A
a. If ***YES***, at what age were they first diagnosed?	_____ (age) ☐ 88 Don't know	_____ (age) ☐ 88 Don't know	_____ (age) ☐ 88 Don't know	_____ (age) ☐ 88 Don't know
49. Stroke?	☐ 1 Yes ☐ 0 No ☐ 88 Don't know	☐ 1 Yes ☐ 0 No ☐ 88 Don't know	☐ 1 Yes ☐ 0 No ☐ 88 Don't know ☐ 99 N/A	☐ 1 Yes ☐ 0 No ☐ 88 Don't know ☐ 99 N/A
a. If ***YES***, at what age were they first diagnosed?	_____ (age) ☐ 88 Don't know	_____ (age) ☐ 88 Don't know	_____ (age) ☐ 88 Don't know	_____ (age) ☐ 88 Don't know
50. Heart failure?	☐ 1 Yes ☐ 0 No ☐ 88 Don't know	☐ 1 Yes ☐ 0 No ☐ 88 Don't know	☐ 1 Yes ☐ 0 No ☐ 88 Don't know ☐ 99 N/A	☐ 1 Yes ☐ 0 No ☐ 88 Don't know ☐ 99 N/A
51. High cholesterol?	☐ 1 Yes ☐ 0 No ☐ 88 Don't know	☐ 1 Yes ☐ 0 No ☐ 88 Don't know	☐ 1 Yes ☐ 0 No ☐ 88 Don't know ☐ 99 N/A	☐ 1 Yes ☐ 0 No ☐ 88 Don't know ☐ 99 N/A
52. High blood pressure?	☐ 1 Yes ☐ 0 No ☐ 88 Don't know	☐ 1 Yes ☐ 0 No ☐ 88 Don't know	☐ 1 Yes ☐ 0 No ☐ 88 Don't know ☐ 99 N/A	☐ 1 Yes ☐ 0 No ☐ 88 Don't know ☐ 99 N/A

Participant ID:_____-_____-_____ Participant Initials: _____

Clinical Center:_____ Site:_____ Visit Number: _____

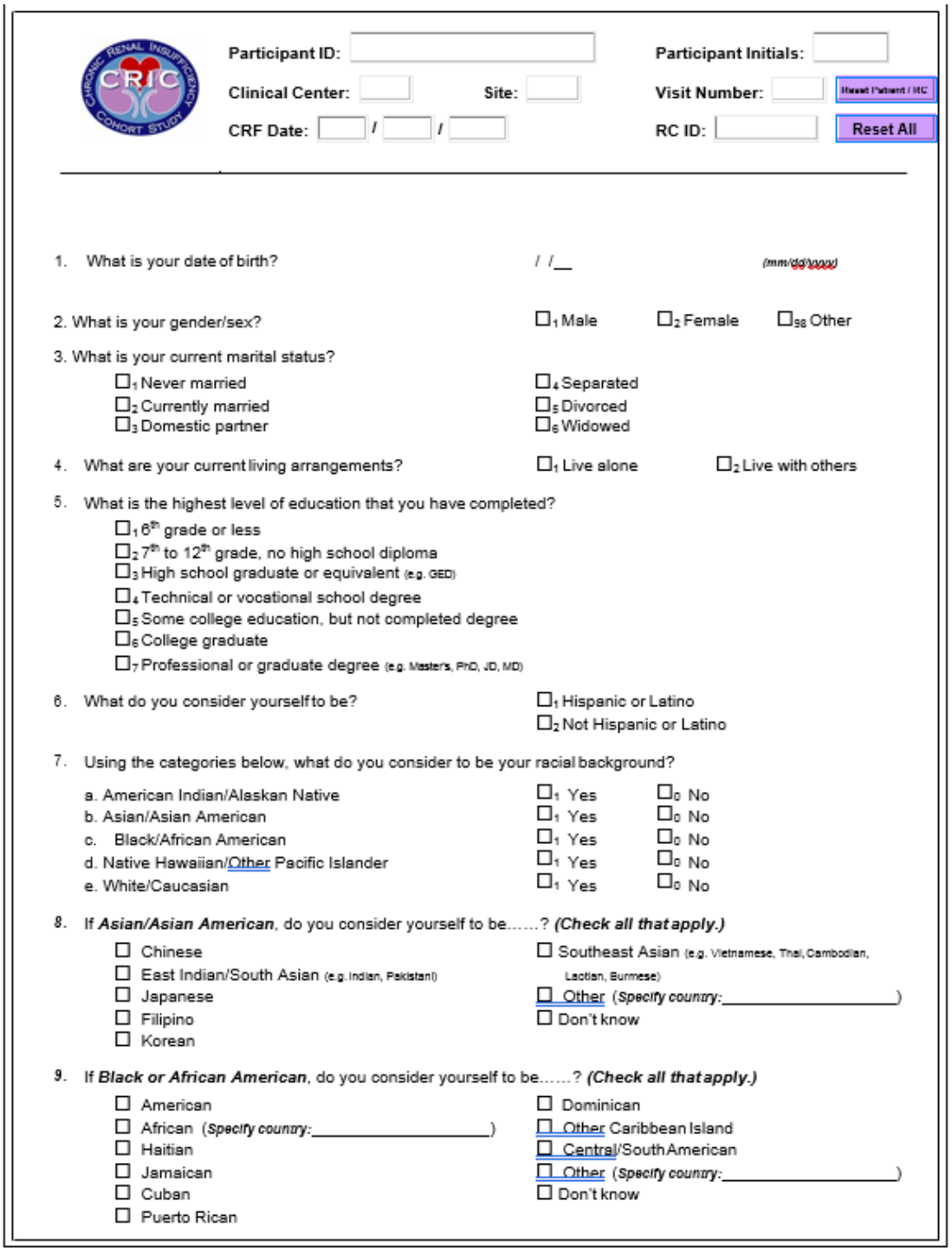
CRF Date:_____/_____/_____ RC ID: _____

MEDICAL HISTORY

Condition	Mother	Father	Any siblings (Brothers and Sisters)	Any children
53. Diabetes or high blood sugar?	❑ 1 Yes ❑ 0 No ❑ 88 Don't know	❑ 1 Yes ❑ 0 No ❑ 88 Don't know	❑ 1 Yes ❑ 0 No ❑ 88 Don't know ❑ 99 N/A	❑ 1 Yes ❑ 0 No ❑ 88 Don't know ❑ 99 N/A
54. Peripheral vascular disease (poor circulation in toes, feet and legs)?	❑ 1 Yes ❑ 0 No ❑ 88 Don't know	❑ 1 Yes ❑ 0 No ❑ 88 Don't know	❑ 1 Yes ❑ 0 No ❑ 88 Don't know ❑ 99 N/A	❑ 1 Yes ❑ 0 No ❑ 88 Don't know ❑ 99 N/A
55. Treated for kidney failure with dialysis?	❑ 1 Yes ❑ 0 No ❑ 88 Don't know	❑ 1 Yes ❑ 0 No ❑ 88 Don't know	❑ 1 Yes ❑ 0 No ❑ 88 Don't know ❑ 99 N/A	❑ 1 Yes ❑ 0 No ❑ 88 Don't know ❑ 99 N/A
a. If ***YES***, at what age were they <u>first</u> treated?	_____ (age) ❑ 88 Don't know	_____ (age) ❑ 88 Don't know	_____ (age) ❑ 88 Don't know	_____ (age) ❑ 88 Don't know
56. Treated for kidney failure with kidney transplantation?	❑ 1 Yes ❑ 0 No ❑ 88 Don't know	❑ 1 Yes ❑ 0 No ❑ 88 Don't know	❑ 1 Yes ❑ 0 No ❑ 88 Don't know ❑ 99 N/A	❑ 1 Yes ❑ 0 No ❑ 88 Don't know ❑ 99 N/A
a. If ***YES***, at what age were they <u>first</u> treated?	_____ (age) ❑ 88 Don't know	_____ (age) ❑ 88 Don't know	_____ (age) ❑ 88 Don't know	_____ (age) ❑ 88 Don't know

For Research Coordinator use only: CRF was: ❑ 1 Self-administered ❑ 2 Interviewer-administered

Appendix B: Demographic Information



Participant ID: _____ Participant Initials: _____

Clinical Center: _____ Site: _____ Visit Number: _____ Reset Patient / RC

CRF Date: ____ / ____ / ____ RC ID: _____ Reset All

1. What is your date of birth? / /__ (mm/dd/yyyy)

2. What is your gender/sex? ☐1 Male ☐2 Female ☐98 Other

3. What is your current marital status?
   - ☐1 Never married
   - ☐2 Currently married
   - ☐3 Domestic partner
   - ☐4 Separated
   - ☐5 Divorced
   - ☐6 Widowed

4. What are your current living arrangements? ☐1 Live alone ☐2 Live with others

5. What is the highest level of education that you have completed?
   - ☐1 6th grade or less
   - ☐2 7th to 12th grade, no high school diploma
   - ☐3 High school graduate or equivalent (e.g. GED)
   - ☐4 Technical or vocational school degree
   - ☐5 Some college education, but not completed degree
   - ☐6 College graduate
   - ☐7 Professional or graduate degree (e.g. Master's, PhD, JD, MD)

6. What do you consider yourself to be?
   - ☐1 Hispanic or Latino
   - ☐2 Not Hispanic or Latino

7. Using the categories below, what do you consider to be your racial background?

a. American Indian/Alaskan Native	☐1 Yes	☐0 No
b. Asian/Asian American	☐1 Yes	☐0 No
c. Black/African American	☐1 Yes	☐0 No
d. Native Hawaiian/Other Pacific Islander	☐1 Yes	☐0 No
e. White/Caucasian	☐1 Yes	☐0 No

8. If ***Asian/Asian American***, do you consider yourself to be.....? ***(Check all that apply.)***
   - ☐ Chinese
   - ☐ East Indian/South Asian (e.g. Indian, Pakistani)
   - ☐ Japanese
   - ☐ Filipino
   - ☐ Korean
   - ☐ Southeast Asian (e.g. Vietnamese, Thai, Cambodian, Laotian, Burmese)
   - ☐ Other (*Specify country:*_____)
   - ☐ Don't know

9. If ***Black or African American***, do you consider yourself to be.....? ***(Check all that apply.)***
   - ☐ American
   - ☐ African (*Specify country:*_____)
   - ☐ Haitian
   - ☐ Jamaican
   - ☐ Cuban
   - ☐ Puerto Rican
   - ☐ Dominican
   - ☐ Other Caribbean Island
   - ☐ Central/South American
   - ☐ Other (*Specify country:*_____)
   - ☐ Don't know

Participant ID: Participant Initials:

Clinical Center: Site: Visit Number: Reset Patient / RC

CRF Date: / / RC ID: Reset All

DEMOGRAPHIC INFORMATION

10. If you checked ***Hispanic or Latino***, do you consider yourself to be……? ***(Check all that apply.)***

- ☐ Mexican American or Mexican
- ☐ Central American
- ☐ South American
- ☐ Puerto Rican
- ☐ Cuban
- ☐ Dominican
- ☐ Spaniard or Portuguese
- ☐ Other (*Specify country:*_____)
- ☐ Don't know

11. What is your current employment status? ***(Check all that apply)***

- ☐ Employed part-time
- ☐ Employed full-time
- ☐ Student
- ☐ Temporarily laid off/on strike
- ☐ On temporary medical leave
- ☐ Permanently disabled
- ☐ Retired, not currently working
- ☐ Full-time home maker
- ☐ Unemployed

a. If ***not*** currently employed, when was the last time you were employed? ____ /_____*(mm/yyyy)*

12. What type of work do you/did you primarily do?

- ☐$_1$ Professional, executive occupation, business owner
- ☐$_2$ Manager, technical occupation
- ☐$_3$ Clerical, sales, administrative support occupation, technician
- ☐$_4$ Skilled labor (e.g. certified electrician, carpenter, welder)
- ☐$_5$ Semi-skilled labor (e.g. construction help, mechanic's help)
- ☐$_6$ Unskilled labor (e.g. porters, bell hops, manual labor)
- ☐$_7$ Home maker
- ☐$_{98}$ Other (*Specify work:*_____)

13. What is your total annual household income?

- ☐$_1$ $20,000 or under
- ☐$_2$ $20,001 – $50,000
- ☐$_3$ $50,001 – $100,000
- ☐$_4$ More than $100,000
- ☐$_{97}$ Don't wish to answer

14. Have you been diagnosed with diabetes mellitus? ☐$_1$ Yes ☐$_0$ No

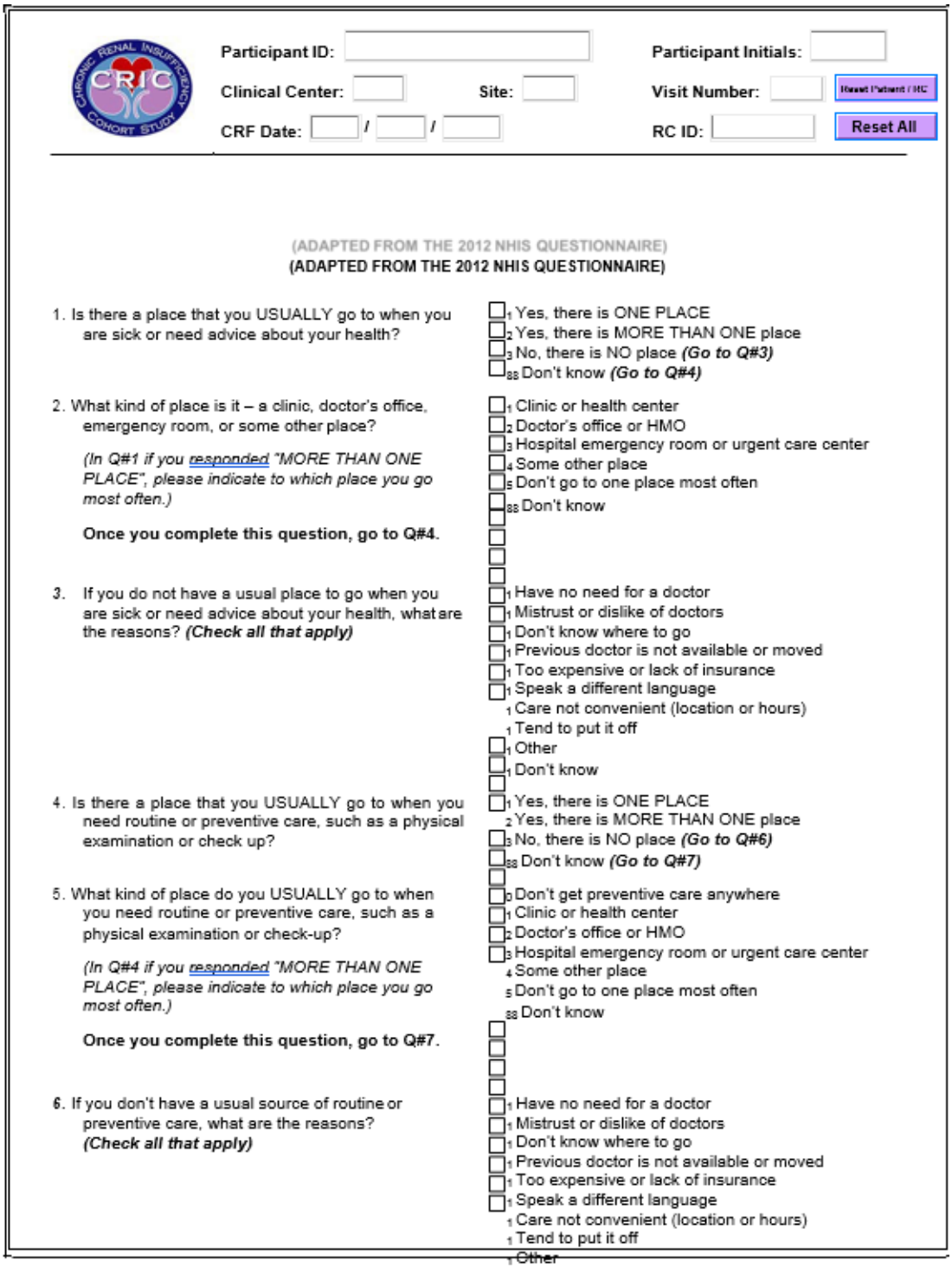
a. If ***YES***, are you treating your diabetes mellitus with oral medications, insulin or through diet control? ☐$_1$ Yes ☐$_0$ No

For Research Coordinator use only: CRF was: ☐$_1$ Self-administered ☐$_2$ Interviewer-administered

DEMO

DEMO

Appendix C: Health care Use Survey



Participant ID: _____ Participant Initials: _____

Clinical Center: _____ Site: _____ Visit Number: _____ Reset Patient / RC

CRF Date: ____ / ____ / ____ RC ID: _____ Reset All

(ADAPTED FROM THE 2012 NHIS QUESTIONNAIRE)

(ADAPTED FROM THE 2012 NHIS QUESTIONNAIRE)

1. Is there a place that you USUALLY go to when you are sick or need advice about your health?

☐ 1 Yes, there is ONE PLACE
☐ 2 Yes, there is MORE THAN ONE place
☐ 3 No, there is NO place ***(Go to Q#3)***
☐ 88 Don't know ***(Go to Q#4)***

2. What kind of place is it – a clinic, doctor's office, emergency room, or some other place?

(In Q#1 if you responded "MORE THAN ONE PLACE", please indicate to which place you go most often.)

Once you complete this question, go to Q#4.

☐ 1 Clinic or health center
☐ 2 Doctor's office or HMO
☐ 3 Hospital emergency room or urgent care center
☐ 4 Some other place
☐ 5 Don't go to one place most often
☐ 88 Don't know

3. If you do not have a usual place to go when you are sick or need advice about your health, what are the reasons? ***(Check all that apply)***

☐ 1 Have no need for a doctor
☐ 1 Mistrust or dislike of doctors
☐ 1 Don't know where to go
☐ 1 Previous doctor is not available or moved
☐ 1 Too expensive or lack of insurance
☐ 1 Speak a different language
1 Care not convenient (location or hours)
1 Tend to put it off
☐ 1 Other
☐ 1 Don't know

4. Is there a place that you USUALLY go to when you need routine or preventive care, such as a physical examination or check up?

☐ 1 Yes, there is ONE PLACE
2 Yes, there is MORE THAN ONE place
☐ 3 No, there is NO place ***(Go to Q#6)***
☐ 88 Don't know ***(Go to Q#7)***

5. What kind of place do you USUALLY go to when you need routine or preventive care, such as a physical examination or check-up?

(In Q#4 if you responded "MORE THAN ONE PLACE", please indicate to which place you go most often.)

Once you complete this question, go to Q#7.

☐ 0 Don't get preventive care anywhere
☐ 1 Clinic or health center
☐ 2 Doctor's office or HMO
☐ 3 Hospital emergency room or urgent care center
4 Some other place
5 Don't go to one place most often
88 Don't know

6. If you don't have a usual source of routine or preventive care, what are the reasons? ***(Check all that apply)***

☐ 1 Have no need for a doctor
☐ 1 Mistrust or dislike of doctors
☐ 1 Don't know where to go
☐ 1 Previous doctor is not available or moved
☐ 1 Too expensive or lack of insurance
☐ 1 Speak a different language
1 Care not convenient (location or hours)
1 Tend to put it off
1 Other

Participant ID: Participant Initials:

Clinical Center: Site: Visit Number: Reset Patient / RC

CRF Date: / / RC ID: Reset All

HEALTH CARE UTILIZATION

(ADAPTED FROM THE 2012 NHIS QUESTIONNAIRE)

(ADAPTED FROM THE 2012 NHIS QUESTIONNAIRE)

7. During the past 12 months, did you receive care AT HOME from a nurse or other health care professional?

☐ 1 Yes ☐ 0 No ☐ 88 Don't know

8. During the past 12 months, how many times have you seen a doctor or other health care professional about your own health **at a doctor's office, a clinic, or some other place**? *(Do not include times you were hospitalized overnight, visits to hospital emergency rooms, home visits, dental visits, dialysis centers, or telephone calls)*

☐ 0 None
☐ 1 1
☐ 2 2-3
☐ 3 4-5
☐ 4 6-7
☐ 5 8-9
☐ 6 10-12
☐ 7 13-15
☐ 8 16 or more
☐ 88 Don't know

9. About how long has it been since you last saw or talked to a doctor or other health care professional about your own health? *(Include doctors seen while a patient in a hospital.)*

☐ 0 Never
☐ 1 6 months or less
☐ 2 More than 6 months, but not more than 1 year ago
☐ 3 More than 1 year, but not more than 2 years ago
☐ 4 More than 2 years, but not more than 5 years ago
☐ 5 More than 5 years ago
☐ 88 Don't know

For Research Coordinator use only: CRF was: ☐ 1 Self-administered ☐ 2 Interviewer-administered

Appendix D: Clinic Visit Questionnaire

Participant ID: Participant Initials:

Clinical Center: Site: Visit Number: Reset Patient / RC

CRF Date: / / RC ID: Reset All

RC completes this form to document what type of visit occurred and what was completed at this visit.

1. Type of Contact:
   - ☐ 1 Clinic (in person)
   - ☐ 2 Phone
   - ☐ 3 Offsite (in person)

   a. If **"Clinic or Offsite"** contact, where did the visit take place?
   - ☐ 1 Home
   - ☐ 2 Doctor's office or healthcare clinic
   - ☐ 3 Hospital
   - ☐ 4 Nursing home/hospice
   - ☐ 5 Dialysis unit
   - ☐ 6 Other care facility
   - ☐ 7 ~~No in-person~~ contact, phone only
   - ☐ 8 CRIC Research Location
   - ☐ 88 Other location

2. Were any Spanish versions of the CRFs administered at this visit? ☐ 1 Yes ☐ 0 No
   (***If yes to this question, please complete the LANGUAGEII CRF***)

3. Which of the following case report forms/processes were completed during this visit? ***(Check all that apply)***

   A. **Physical measures:**
   - ☐ 1 Anthropometry (***PHYASSESS***)
   - ☐ 1 Ankle Brachial Index (***PHYASSESS***)
   - ☐ 1 Bioelectric Impedance Assessment (***PHYASSESS***)
   - ☐ 1 Blood pressure (***BP***)
   - ☐ 1 Electrocardiograph (***ECGTRANS***)
   - ☐ 1 Hand Grip Dynamometer (***GRIP)***
   - ☐ 1 Physical Performance Testing (***PERFORM)***
   - ☐ 1 Balance Testing (***BALANCE)***
   - ☐

   B. **Specimen collection:**
   - ☐ 1 Blood draw (***LABCBC, SPECIMEN, SPEC70***)
   - ☐ 1 Urine specimen collection for proteomics (***PROTRANS,PROTRANS_R***)
   - ☐ 1 24 hour urine specimen collection (***SPECIMEN, SPEC70***)
   - ☐ 1 Spot urine specimen collection (***SPECIMEN, SPEC70***)
   - ☐

   C. **Research Coordinator completed case report forms:**
   - ☐ 1 Amputation Information (***AMPUT***)
   - ☐ 1 Ancillary Studies: Participation Information (***ANCILLRY***)
   - ☐ 1 Concomitant Medications information (***CMED***)
   - ☐ 1 Modified Min-Mental Status Exam (***MMSE***)
   - ☐ 1 Renal Replacement Therapy – Primary Survey (***RRTPRIM***)
   - ☐ 1 Renal Replacement Therapy – Follow-Up Survey (***RRTFUP***)
   - ☐ 1 Renal Replacement Therapy – Dialysis Unit Data Collection (***RRTHD/RRTPD***)
   - ☐ 1 General Health Questionnaire (***HEALTH***)
   - ☐ 1 Buschke Selective Reminding Test (***SRT***)
   - ☐

V3.0.20131211 Page 1 of 2 VISIT

Participant ID: Participant Initials:

Clinical Center: Site: Visit Number: Reset Patient / RC

CRF Date: / / RC ID: Reset All

CLINIC VISIT STATUS

RC completes this form to document what type of visit occurred and what was completed at this visit.

C. Research Coordinator completed case report forms: (Continued)

- ☐ 1 Buschke SRT Recall (***SRTREC***)
- ☐ 1 Trails A (***TRAILS_A***)
- ☐ 1 Trails B (***TRAILS_B***)
- ☐ 1 CRIC Study Re-Consent Status ***(CONSENTII)***
- ☐ 1 Proxy Information ***(PROXY)***
- ☐ 1 Medical Event Questionnaire (***EVENTSII***)
- ☐ 1 Encryption Information (Baseline only) (***ENCRP***)
- ☐ 1 Fracture Questionnaire (entry into Phase III) (***FRACTURE)***
- ☐ 1 Fracture Follow-up Questionnaire (***FRACTUP)***

D. Participant completed case report forms:

- ☐ 1 Beck Depression Inventory (***BDI***)
- ☐ 1 Diet History Questionnaire (***DHQ***)
- ☐ 1 Kidney Disease and Quality of Life (***KDQOL***)
- ☐ 1 Medical History (Baseline Assessment) (***MEDHXII***)
- ☐ 1 Medical History - Update (***MEDHXUPIII***)
- ☐ 1 Physical Activity Assessment (***PHYACT***)
- ☐ 1 Symptoms List (***SXLIST***)
- ☐ 1 Short Test of Functional Health Literacy in Adults (***STOFHLA***)
- ☐ 1 Lubben Social Network Scale (***LUBBEN***)
- ☐ 1 Adult Access to Health Care and Utilization (***HCARE***)
- ☐ 1 Self-Efficacy Questionnaire (***EFFICACY***)
- ☐

Appendix E: Self-Efficacy Quality of Life Questionnaire

Your Health
– and –
Well-Being

Kidney Disease and Quality of Life (KDQOL™-36)

This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Thank you for completing these questions!

Study of Quality of Life
For Patients on Dialysis

What is the purpose of the study?

This study is being carried out in cooperation with physicians and their patients. The ~~purpose is to assess the quality of life of patients~~ with kidney disease.

What will I be asked to do?

For this study, we want you to complete a survey today about your health, how you feel and your background.

Confidentiality of information?

We do not ask for your name. Your answers will be combined with those of other participants in reporting the findings of the study. Any information that would permit identification of you will be regarded as strictly confidential. In addition, all information collected will be used only for purposes of the study, and will not be disclosed or released for any other purpose without your prior consent.

How will participation benefit me?

The information you provide will tell us how you feel about your care and further understanding about the effects of medical care on the health of patients. This information will help to evaluate the care delivered.

Do I have to take part?

You do not have to fill out the survey and you can refuse to answer any question. Your decision to participate will not affect your opportunity to receive care.

Your Health

This survey includes a wide variety of questions about your health and your life. We are interested in how you feel about each of these issues.

1. **In general, would you say your health is: [Mark an ☒ in the one box that best describes your answer.]**

Excellent	Very good	Good	Fair	Poor
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

The following items are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much? [Mark an ☒ in a box on each line.]

	Yes, limited a lot	Yes, limited a little	No, not limited at all
2. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐ 1	☐ 2	☐ 3
3. Climbing several flights of stairs	☐ 1	☐ 2	☐ 3

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

	Yes	No
4. Accomplished less than you would like	☐ 1	☐ 2
5. Were limited in the kind of work or other activities	☐ 1	☐ 2

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	Yes	No
6. Accomplished less than you would like	☐ 1	☐ 2
7. Didn't do work or other activities as carefully as usual	☐ 1	☐ 2

8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

Not at all	A little bit	Moderately	Quite a bit	Extremely
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the past 4 weeks…

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
9. Have you felt calm and peaceful?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
10. Did you have a lot of energy?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
11. Have you felt downhearted and blue?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

12. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Your Kidney Disease

How true or false is each of the following statements for you?

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
13. My kidney disease interferes too much with my life	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
14. Too much of my time is spent dealing with my kidney disease	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
15. I feel frustrated dealing with my kidney disease	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
16. I feel like a burden on my family	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

During the past 4 weeks, to what extent were you bothered by each of the following?

	Not at all bothered	Somewhat bothered	Moderately bothered	Very much bothered	Extremely bothered
17. Soreness in your muscles?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
18. Chest pain?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
19. Cramps?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
20. Itchy skin?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
21. Dry skin?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
22. Shortness of breath?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
23. Faintness or dizziness?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
24. Lack of appetite?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
25. Washed out or drained?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
26. Numbness in hands or feet?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
27. Nausea or upset stomach?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
28[a]. (Hemodialysis patient only) Problems with your access site?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
28[b]. (Peritoneal dialysis patient only) Problems with your catheter site?..	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Effects of Kidney Disease on Your Daily Life

Some people are bothered by the effects of kidney disease on their daily life, while others are not. How much does kidney disease bother you in each of the followingareas?

		Not at all bothered	Somewhat bothered	Moderately bothered	Very much bothered	Extremely bothered
29.	Fluid restriction?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
30.	Dietary restriction?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
31.	Your ability to work around the house?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
32.	Your ability to travel?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
33.	Being dependent on doctors and other medical staff?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
34.	Stress or worries caused by kidney disease?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
35.	Your sex life?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
36.	Your personal appearance?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Thank you for completing these questions!

Appendix F: Mini-Mental Status Examination

The Mini-Mental Status Examination offers a quick and simple way to quantify cognitive function and screen for cognitive loss. It tests the individual's orientation, attention, calculation, recall, language and motor skills.

Each section of the test involves a related series of questions or commands. The individual receives one point for each correct answer.

To give the examination, seat the individual in a quiet, well – lit room. Ask him/her to listen carefully and to answer each question as accurately as he/she can.

Don't time the test but score it right away. To score, add the number of correct responses. The individual can received a maximum score of 30 points.

A score below 20 usually indicates cognitive impairment.

The Mini-Mental Status Examination

Name _____ DOB _____
Years of School _____ Date of Exam _

Orientation to Time	Correct	Incorrect
What is today's date?	☐	☐
What is the month?	☐	☐
What is the day of the week today?	☐	☐
What is the year?	☐	☐
What season is it?	☐	☐
	Total:	

Orientation to Place	Correct	Incorrect
Whose home is this?	☐	☐
What room is this?	☐	☐
What city are we in?	☐	☐
What county are we in?	☐	☐
What state are we in?	☐	☐
	Total:	

Ask if you may test his/her memory. Then say "ball", "flag", "tree" clearly and slowly, about 1 second for each. After you have said all 3 words, ask him/her to repeat them – the first repetition determines the score (0-3):

Immediate Recall	Correct	Incorrect
Ball	☐	☐
Flag	☐	☐
Tree	☐	☐
	Total:	

A. Ask the individual to begin with 100 and count backwards by 7. Stop after 5 subtractions. Score the correct subtractions.

Attention	Correct	Incorrect
93	☐	☐
86	☐	☐
79	☐	☐
72	☐	☐
65	☐	☐
	Total:	

B. Ask the individual to spell the "WORLD" backwards. The score is the number of letters in the correct position.

Attention	Correct	Incorrect
D	☐	☐
L	☐	☐
R	☐	☐
O	☐	☐
W	☐	☐
	Total:	

Ask the individual to recall the 3 words you previously asked him/her to remember.

Delayed Verbal Recall	Correct	Incorrect
Ball	☐	☐
Flag	☐	☐
Tree	☐	☐
	Total:	

Show the individual a wristwatch and ask him/her what it is. Repeat for pencil.

Naming	Correct	Incorrect
Watch	☐	☐
Pencil	☐	☐
	Total:	

Ask the individual to repeat the following:

Repetition	Correct	Incorrect
"No if, ands, or buts"	☐	☐

Give the individual a plain piece of paper and say, "Take the paper in your hand, fold it in half, and put it on the floor."

3 Stage Command	Correct	Incorrect
Takes	☐	☐
Folds	☐	☐
Puts	☐	☐
	Total:	

Hold up the card reading: "Close your eyes" so the individual can see it clearly.
Ask him/her to read it and do what it says. Score correctly only if the individual actually closes his/her eyes.

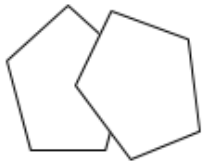
Reading	Correct	Incorrect
Closes his/her eyes.	☐	☐

Give the individual a piece of paper and ask him/her to write a sentence. It is to be written spontaneously. It must contain a subject and verb and be sensible.

Writing	Correct	Incorrect
Write sentence containing a subject and verb and is sensible	☐	☐

Give the individual a piece of paper and ask him/her to copy a design of two intersecting shapes. One point is awarded for correctly copying the shapes. All angles on both figures must be present, and the figures must have one overlapping angle.

Copying	Correct	Incorrect
Copy a design of two intersecting shapes	☐	☐



Total Score:_____

Appendix G: The Short Test of Functional Health Literacy Assessment (STOFHLA)

CRIC

STOFHLA_score

Functional Health Literacy Total Score
APPENDIX G

DATA SOURCE

Person Level

WORKING DATA

Variable STO_SCORE from file STOFHLA

DESCRIPTION

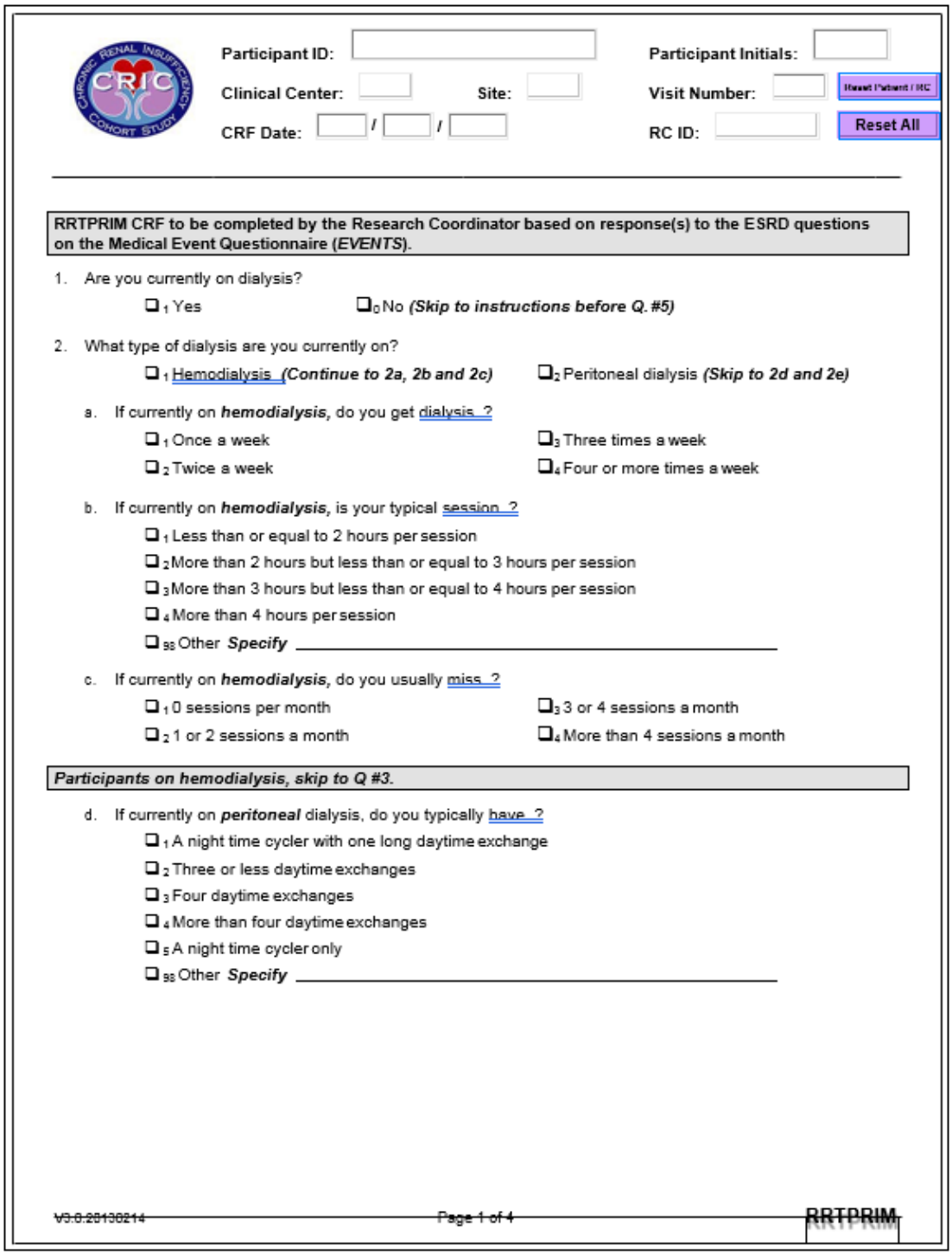
STOFHLA_score represents the total score for Passages A and B on the STOFHLA, the Short Test of Functional Health Literacy in Adults*. The range of available scores is from 0 (0 correct) to 36 (all 36 correct.) Note that a patient who self-reports that he or she cannot read, or who declines to take the assessment for any other reason will have a missing value for this score.

SOURCE VARIABLES

PROGRAMMING INSTRUCTIONS

SAS CODE

Appendix H: Primary Renal Replacement Therapy Questionnaire



Participant ID: Participant Initials:

Clinical Center: Site: Visit Number:

CRF Date: / / RC ID:

Reset All

RRTPRIM CRF to be completed by the Research Coordinator based on response(s) to the ESRD questions on the Medical Event Questionnaire (*EVENTS*).

1. Are you currently on dialysis?

   ❑ 1 Yes ❑ 0 No ***(Skip to instructions before Q. #5)***

2. What type of dialysis are you currently on?

   ❑ 1 Hemodialysis ***(Continue to 2a, 2b and 2c)*** ❑ 2 Peritoneal dialysis ***(Skip to 2d and 2e)***

   a. If currently on ***hemodialysis,*** do you get dialysis ?

      ❑ 1 Once a week ❑ 3 Three times a week

      ❑ 2 Twice a week ❑ 4 Four or more times a week

   b. If currently on ***hemodialysis,*** is your typical session ?

      ❑ 1 Less than or equal to 2 hours per session

      ❑ 2 More than 2 hours but less than or equal to 3 hours per session

      ❑ 3 More than 3 hours but less than or equal to 4 hours per session

      ❑ 4 More than 4 hours per session

      ❑ 96 Other ***Specify*** _____

   c. If currently on ***hemodialysis,*** do you usually miss ?

      ❑ 1 0 sessions per month ❑ 3 3 or 4 sessions a month

      ❑ 2 1 or 2 sessions a month ❑ 4 More than 4 sessions a month

Participants on hemodialysis, skip to Q #3.

   d. If currently on ***peritoneal*** dialysis, do you typically have ?

      ❑ 1 A night time cycler with one long daytime exchange

      ❑ 2 Three or less daytime exchanges

      ❑ 3 Four daytime exchanges

      ❑ 4 More than four daytime exchanges

      ❑ 5 A night time cycler only

      ❑ 96 Other ***Specify*** _____

V3.0.20130214 Page 1 of 4 RRTPRIM

Participant ID: Participant Initials:

Clinical Center: Site: Visit Number:

CRF Date: / / RC ID:

RENAL REPLACEMENT THERAPY - PRIMARY SURVEY

e. If currently on ***peritoneal*** dialysis, do you typically exchange ?

- ❑ 1 Less than or equal to 1 liter in volume per dwell period
- ❑ 2 More than 1 liter but less than or equal to 2 liters in volume per dwell period
- ❑ 3 More than 2 liters but less than or equal to 2.5 liters in volume per dwell period
- ❑ 4 More than 2.5 liters but less than or equal to 3 liters in volume per dwell period
- ❑ 5 More than 3 liters in volume per dwell period
- ❑ 88 Other ***Specify*** _____

3. What type of dialysis **accesses** do you currently have (even if you do not use it)? ***(Check all that apply)***

- ❑ None
- ❑ Venous catheter
- ❑ Arteriovenous graft
- ❑ Arteriovenous fistula
- ❑ Peritoneal catheter

4. What is the name and address of your current dialysis center?

Name: _____

Address: _____

_____

Participants currently on dialysis, skip to Q. #6.

Question #5: For participants currently not on dialysis.

5. Have you been on dialysis in the past?

- ❑ 1 Yes
- ❑ 0 No ***(Skip to Q. #13)***

6. Your first dialysis type was ?

- ❑ 1 Hemodialysis
- ❑ 2 Peritoneal dialysis

a. What type of dialysis ***access*** was used to start your ***first*** dialysis treatment?

- ❑ 1 Venous catheter
- ❑ 2 Arteriovenous graft
- ❑ 3 Arteriovenous fistula
- ❑ 4 Peritoneal catheter

Participant ID: Participant Initials:

Clinical Center: Site: Visit Number:

CRF Date: / / RC ID: Reset All

RENAL REPLACEMENT THERAPY - PRIMARY SURVEY

If you are currently on dialysis or have received dialysis in the past:

7. Was the day you first started dialysis ?

❑ 1 Planned or Maintenance ❑ 2 Emergency ❑ 88 Don't Know

a. What was the date of your first ever dialysis treatment?

____ / _____
MM YYYY

Please remember to do the dialysis unit data collection when the participant starts dialysis for the first time.

8. What was the reason for starting dialysis? ***(Check all that apply)***

❑ Congestive heart failure which is typically associated with shortness of breath, swelling or even being on the ventilator

❑ Kidney failure, build up of uremic (kidney) toxins which typically cause symptoms like nausea, vomiting, loss of appetite, itching, hiccups or abnormal findings on your laboratory tests

❑ Result of a procedure such as surgery or cardiac catheterization

❑ Other ***Specify*** _____

9. When did you last see a nephrologist, prior to your first regular dialysis treatment?

❑ 0 Never

❑ 1 Less than 3 months, prior to starting dialysis

❑ 2 From 3 months up to 1 year, prior to starting dialysis

❑ 3 1 year or more, prior to starting dialysis

10. What type of education did you receive prior to starting dialysis? ***(Check all that apply)***

❑ One on one discussion with your doctor
❑ Group sessions with other patients
❑ Meeting with a dietician
❑ Videotapes
❑ Visit to the dialysis center
❑ Meeting with a dialysis nurse
❑ Reading material
❑ Other ***Specify*** _____
❑ None ***(Skip to Q#12)***

11. Indicate your level of satisfaction with your dialysis education prior to starting dialysis:

❑ 1 Extremely dissatisfied
❑ 2 Dissatisfied
❑ 3 No opinion either way
❑ 4 Satisfied
❑ 5 Extremely satisfied

Participant ID: Participant Initials:

Clinical Center: Site: Visit Number:

CRF Date: / / RC ID:

Reset Patient / RC

Reset All

RENAL REPLACEMENT THERAPY - PRIMARY SURVEY

12. Are your native kidneys working again, so that you are not on dialysis at this time?

❑ 1 Yes ❑ 0 No *(Skip to Q#13)*

If "Yes" to Q#12, complete Q#12a and STOP. Please note that if "Yes" to Q#12, complete another RRTPRIM form when the participant goes back on dialysis.

a. What is the last date that you received dialysis? ____/____ *(mm/yyyy)*

Kidney transplant:

13. Did you have a kidney transplant?

❑ 1 Yes ❑ 0 No *(Skip to Q#18)*

a. What was the date of your transplant?

____ / ____
MM YYYY

14. What was the source of your transplant?

❑ 1 Donor was a living related donor

❑ 2 Donor was any living unrelated donor

❑ 3 The donor was someone who had died and donated their kidney

15. Did you need dialysis prior to the transplant?

❑ 1 Yes ❑ 0 No *(STOP)*

16. What was the first dialysis type that you received prior to the transplant?

❑ 1 Hemodialysis ❑ 2 Peritoneal dialysis

17. What was the date of your first dialysis treatment prior to the transplant?

____ / ____
MM YYYY

Participants who received a kidney transplant, STOP.

18. Which of the following plans for a kidney transplant have been made for you? ***(Check all that apply)***

❑ I am on the transplant waiting list/cadaver waiting list

❑ I am being prepared for a living donor transplant

❑ I have been told I am not medically suitable for transplant

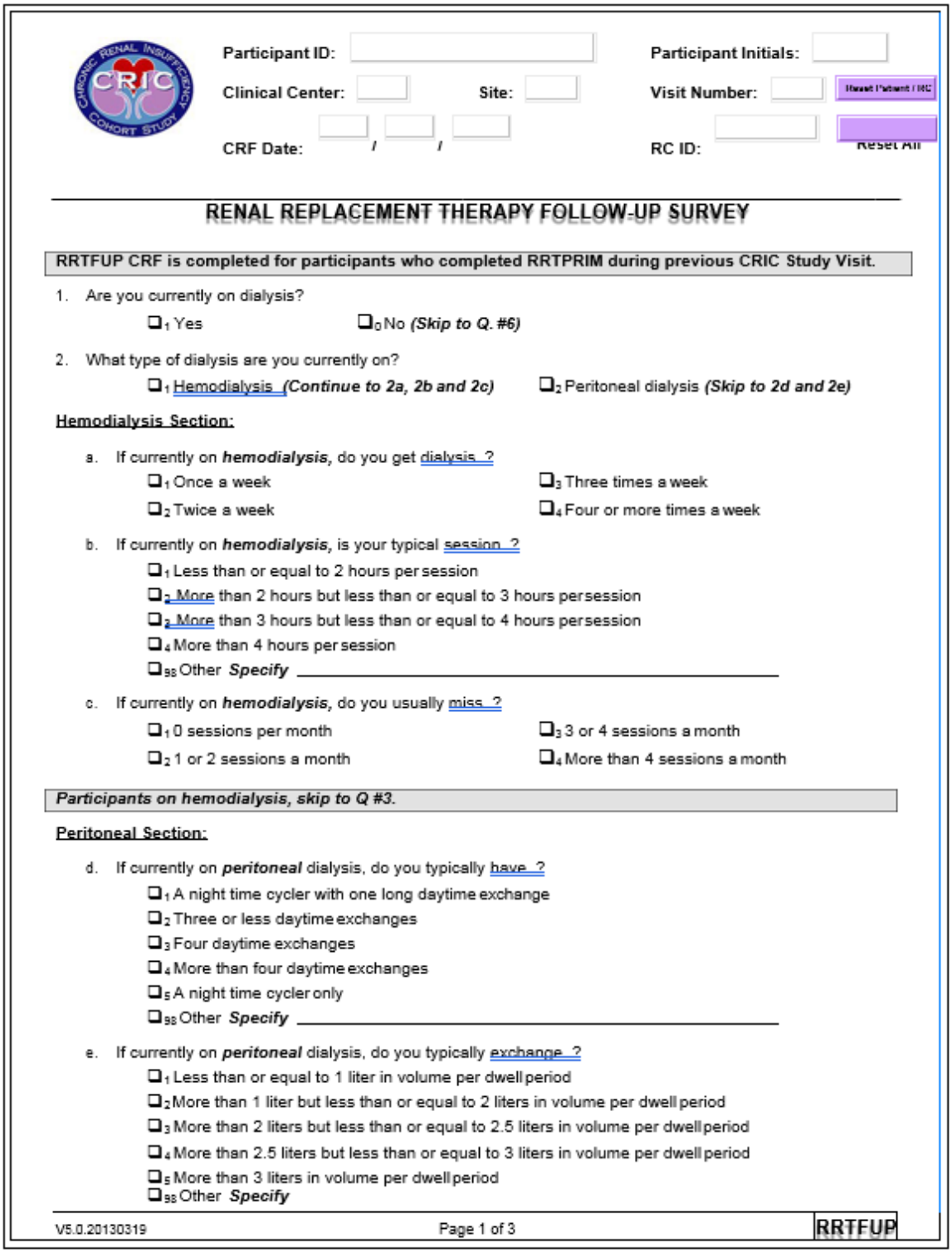
❑ I have not been offered transplant as an option

❑ I don't know

❑ Other *Specify* _____

❑ I am not interested in a transplant

Appendix I: Renal Replacement Follow-up Survey



Participant ID: Participant Initials:

Clinical Center: Site: Visit Number:

CRF Date: / / RC ID:

Reset All

RENAL REPLACEMENT THERAPY FOLLOW-UP SURVEY

RRTFUP CRF is completed for participants who completed RRTPRIM during previous CRIC Study Visit.

1. Are you currently on dialysis?

   ☐1 Yes ☐0 No ***(Skip to Q. #6)***

2. What type of dialysis are you currently on?

   ☐1 Hemodialysis ***(Continue to 2a, 2b and 2c)*** ☐2 Peritoneal dialysis ***(Skip to 2d and 2e)***

Hemodialysis Section:

a. If currently on ***hemodialysis,*** do you get dialysis ?

   ☐1 Once a week ☐3 Three times a week

   ☐2 Twice a week ☐4 Four or more times a week

b. If currently on ***hemodialysis,*** is your typical session ?

   ☐1 Less than or equal to 2 hours per session

   ☐2 More than 2 hours but less than or equal to 3 hours per session

   ☐3 More than 3 hours but less than or equal to 4 hours per session

   ☐4 More than 4 hours per session

   ☐98 Other ***Specify*** _____

c. If currently on ***hemodialysis,*** do you usually miss ?

   ☐1 0 sessions per month ☐3 3 or 4 sessions a month

   ☐2 1 or 2 sessions a month ☐4 More than 4 sessions a month

Participants on hemodialysis, skip to Q #3.

Peritoneal Section:

d. If currently on ***peritoneal*** dialysis, do you typically have ?

   ☐1 A night time cycler with one long daytime exchange

   ☐2 Three or less daytime exchanges

   ☐3 Four daytime exchanges

   ☐4 More than four daytime exchanges

   ☐5 A night time cycler only

   ☐98 Other ***Specify*** _____

e. If currently on ***peritoneal*** dialysis, do you typically exchange ?

   ☐1 Less than or equal to 1 liter in volume per dwell period

   ☐2 More than 1 liter but less than or equal to 2 liters in volume per dwell period

   ☐3 More than 2 liters but less than or equal to 2.5 liters in volume per dwell period

   ☐4 More than 2.5 liters but less than or equal to 3 liters in volume per dwell period

   ☐5 More than 3 liters in volume per dwell period

   ☐98 Other ***Specify***

Participant ID: Participant Initials:

Clinical Center: Site: Visit Number:

CRF Date: / / RC ID:

Reset All

RENAL REPLACEMENT THERAPY FOLLOW-UP SURVEY

3. Has your dialysis type changed since your last CRIC study contact?

❑1 Yes ❑0 No *(Go to Q. #4)*

a. When did this change occur?

____ / _____
MM YYYY

b. What was the reason for this change? *(Check all that apply)*

- ❑ Inadequate clearance
- ❑ Poor access
- ❑ Infection
- ❑ Loss of your dialysis assistant
- ❑ Transplant failure
- ❑ Other *Specify* _____

4. What type of dialysis access do you currently have?

- ❑1 Venous catheter
- ❑2 Arteriovenous graft
- ❑3 Arteriovenous fistula
- ❑4 Peritoneal dialysis catheter

5. Has your dialysis **access** changed since your last CRIC contact?

❑1 Yes ❑0 No (*Skip to Q.#8)*

a. If ***YES***, was it changed because the previous access (can apply to either peritoneal or hemodialysis) was…? *(Check all that apply)*

- ❑ Clotted
- ❑ Infected
- ❑ No longer provided adequate dialysis
- ❑ Was painful when used
- ❑ Other *Specify* _____

Study participants on chronic/maintenance dialysis skip to Q#8.

For participants currently not on dialysis:

6. You are not on dialysis because…?

- ❑1 You have a functioning kidney transplant *(Skip to Q. #7)*
- ❑2 Your native kidneys began working again *(Skip to Q. #8)*
- ❑3 You chose to terminate any form of kidney replacement therapy *(STOP)*

Participant ID: Participant Initials:

Clinical Center: Site: Visit Number: Reset Patient / RC

CRF Date: / / RC ID: Reset All

RENAL REPLACEMENT THERAPY FOLLOW-UP SURVEY

For participants with kidney transplant:

7. Have you had a new kidney transplant since your last CRIC contact?

☐ 1 Yes *(Go to Q. #7a)* ☐ 0 No *(STOP)*

a. If ***YES***, what was the date of your new transplant?

____ / _____
MM YYYY

b. What was the source of your transplant?

☐ 1 Donor was a living related donor

☐ 2 Donor was any living unrelated donor

☐ 3 The donor was someone who had died and donated their kidney

For participants without kidney transplant:

8. Which of the following plans for a kidney transplant have been made for you? ***(Check all that apply)***

☐ I am on the transplant waiting list/cadaver waiting list

☐ I am being prepared for a living donor transplant

☐ I have been told I am not medically suitable for transplant

☐ I have not been offered transplant as an option

☐ I don't know

☐ Other ***Specify*** _____

☐ I am not interested in a transplant