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AN EXPLORATION OF FACTORS ASSOCIATED WITH PRE-DIABETES IN THE
REASONS FOR GEOGRAPHIC AND RACIAL DIFFERENCES IN STROKE
(REGARDS) STUDY COHORT

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A DISSERTATION

Submitted to the graduate faculty of The University of Alabama at Birmingham,
in partial fulfillment of the requirements for the degree of
Doctor of Philosophy in Nursing

BIRMINGHAM, ALABAMA

2012

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REASONS FOR GEOGRAPHIC AND RACIAL DIFFERENCES IN STROKE
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LORETTA T. LEE

NURSING

ABSTRACT

Pre-diabetes is a major contributor to increased morbidity and mortality in the US.. Without proper and timely intervention the majority of individuals with pre-diabetes will develop Type 2 diabetes. African Americans (AA) and people living in the Stroke Belt have increased odds of developing pre-diabetes compared to Whites and people living outside the Stroke Belt. While several covariates have been identified as contributors to the increased odds of pre-diabetes there is little consensus on which covariates may be responsible for the disparities of pre-diabetes. The reasons for disparities in pre-diabetes are complex and require further investigation. This study explored the relationship between multiple covariates in order to identify which factors might contribute to disparities in pre-diabetes in AA compared to Whites. A secondary data analysis of 19,889 normoglycemic and pre-diabetes participants from the REGARDS study was used. All participants with fasting blood glucose above 100mg/dL and below 126mg/dL were included in the study. The response variable was pre-diabetes, and covariates of interest were race, region, age, gender, income level, education level, smoking history, alcohol history, intense physical activity history, and illness perception. Univariate and multivariable logistic regression with a set of incremental models was used to identify variables associated with increased odds of pre-diabetes.

The mean age of individuals with pre-diabetes living in or outside the stroke belt was 64 years vs.65 year, as well as mean ages among AAs and Whites were 63 years vs.

65 years. The final analysis population was 37% AA males, 63% AA females, 48% White males, and 52% White females. Individuals with diabetes were excluded from the study. AAs had increased odds of pre-diabetes compared to Whites. Individuals living in the Stroke Belt also had increased odds of pre-diabetes compared to individuals not living in the Stroke Belt. Covariates of interest that increased the odds of pre-diabetes were gender (male), education level, past and current smoking history, heavy alcohol history, and illness perception.

Keywords: Pre-diabetes, disparities of pre-diabetes, REGARDS Study, disparities of pre-diabetes in African Americans, disparities of pre-diabetes in the Stroke Belt Region.

DEDICATION

I would like to express my deepest gratitude to my family for their support, especially my husband, children, and siblings who provided love and encouragement throughout the dissertation process.

I would like to thank my parents, who during their lifetime provided me with the foundation for success, “a love of God”, “love for family and friends”, sacrifice and perseverance.

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CHAPTER I

INTRODUCTION

In the National Health and Nutrition Examination Survey (NHANES) III, 1988 to 1994 data revealed that among overweight adults aged 45 to 74 years, 22.6% of participants had pre-diabetes. By the year 2000, 11.9 million overweight adults, age 45 to 74 years were reported to have pre-diabetes (Benjamin, Valdez, Geiss, Rolka, & Narayan, 2003). Cowie et al. (2006) reviewed NHANES survey data for impaired fasting glucose (IFG) from 1994 to 2002, finding that 26 % of adults, age 20 years and above and 39% of people 65 years and above had pre-diabetes as measured by IFG.

The occurrence of pre-diabetes among adults is increasing sharply, as prevalence of IFG or impaired glucose tolerance (IGT) increases, a hallmark of this disease state. Between 1988 and 1994, 33.8% of U. S adults between 40 and 74 years were diagnosed as having IFG and 14.4% with IGT. These data remained unchanged from 2003 to 2006, with 35.3% of adults in the US age 60 years or older having IFG (National Diabetes Statistics, 2007).

The American Diabetes Association (ADA) (2010) defines pre-diabetes as a fasting blood glucose level below the range defined as diabetes and above the normal range of blood glucose, specifically, a fasting blood glucose level between 100 and 125 mg/dL (ADA, 2010). Pre-diabetes occurs before most individuals develop type 2 diabetes, and it is a leading cause of heart disease and stroke (American Heart Association [AHA],

2007). Diabetes, stroke and heart disease are leading contributors to increased mortality rates, and long-term medical cost; accounting for the highest health care expenditures in the US. The total cost of diabetes in 2007 was over 200 billion dollars (American Diabetes Association [ADA], 1995-2010). Pre-diabetes doubles the risk of death during a heart attack (AHA, 2007). During the pre-diabetes stage, damage to the heart and other organs of the circulatory system may occur (ADA, 1995-2010). In the year 2004, death certificates in people 65 years of age and older indicated a co-morbid finding of heart disease in 68% of cases, and stroke in another 16% of cases (ADA, 1995-2010). Subsequently, in the year 2006, diabetes became the seventh leading cause of death listed on death certificates in the US (AHA, 2007). The AHA (2007) and the National Heart, Lung, and Blood Institute (NHLBI) (2010) estimated the cost of cardiovascular disease and stroke in the year 2009 greater than \$400 billion dollars. These data illustrate the significant effect of pre-diabetes on the nation's morbidity, mortality and health care cost.

Pre-diabetes is a significant health problem in the US and the pre-diabetes prevalence correlates with the presence of modifiable and non-modifiable risk factors. Prevalence rate for pre-diabetes is closely associated with factors such as race, age, gender, socioeconomic status (SES) and other modifiable risk factors. While pre-diabetes is an increasing problem in the entire US population, some populations have been identified in the literature for increased risk for pre-diabetes, including adults over 20 years of age, males, lower socioeconomic status (SES), residents of the Southeast region of the United States, American Indians, and African Americans (AA). The prevalence rate for pre-diabetes from 1999 to 2002 was higher in men compared to women (Cowie et al., 2006). Endevelt, Baron-Epel, Karpati, & Heymann (2009) reported a higher prevalence rate of

pre-diabetes among individuals living with lower SES when compared to individuals living with higher SES. Findings from recent research conducted by Baird (2010) and Zhang et al. (2009) revealed a higher prevalence of diabetes and pre-diabetes in the Southeast region of the US. According to the AHA (2007, 2010) and the ADA (1995-2010), the presence of modifiable risk factors such as smoking, heavy alcohol use, and increased body weight can increase the possibility of developing pre-diabetes. One additional factor associated with increased risk for pre-diabetes is perception of health (Zhang et al., 2009). Individual perception of health Zhang et al. (2009) was a modifiable risk factor that inversely correlated with prevalence of pre-diabetes or complications of pre-diabetes.

Statement of Problem

Disparities in pre-diabetes prevalence exist and are associated with race/ethnicity, age, gender, and other modifiable risk factors such as SES. Whites tend to have higher SES status than AAs (Bravata, et al., 2005). Common indicators for SES in the US are income and education (Daly, Duncan, McDonough, & Williams, 2002). Data from the Pew Research Center analysis revealed White households have 20 times the wealth of AA households (Kochhar, Fry, & Taylor, 2011). Research findings have shown that people with low SES are disproportionately represented among those with poor access to care (Kochhar et al., 2011), Shavers, Shankar, and Alberg (2002) stated that individuals having difficulty accessing health care are less likely to seek preventive health care services, and may have a high prevalence of chronic disease risks. A study examining racial disparities in various health insurance plans showed that AAs do not have equal

access to health care and equal quality of care; so health outcomes in AAs are worse than Whites in many medical conditions (Trivedi, Zaslavsky, Schneider, & Ayanian, 2006). College enrollment rates for traditional college-aged Whites in 2008 were 45% compared to 34% for college-aged AAs, and 66% of undergraduate degrees in 2007 were awarded to Whites (American Council on Education, 2010). Lower SES as measured by income level and educational attainment has been found to be associated with poorer diabetes control (Endevelt et al., 2009; Lee et al., 2011). Women with higher education are more likely to participate in intense physical activity (Albert, Glynn, Burning, & Ridker, 2006), and activity associated with reducing glycemia.

Disparities associated with diabetes have a major impact in our society and are very much a reality today in the US. In 2002, among adults 40 to 74 years old about 26 million people had pre-diabetes (Steinberg, 2002) and research has documented the development of type 2 diabetes among individuals in this population within 10 years of pre-diabetes diagnosis if lifestyle and or pharmacotherapy intervention does not slow the development of the disease (ADA, 1995-2010). Yet identifiable risk factors for pre-diabetes continue to increase in some populations. Obesity, a major risk factor for diabetes, is highest among women of racial and ethnic minorities and 60% more likely among AA women compared to White women (US Department of Health and Human Services [USDHHS], 2007). AAs are twice as likely to have diabetes as Whites and more likely to experience diabetes complications (USDHHS, 2007).

One additional modifiable risk factor that may affect the development of type 2 diabetes and pre-diabetes is living in the Stroke Belt region of the US (Voeks et al., 2008). In 2006, 56 % of the AA population lived in the Southern region of the US (US

Census Bureau, 2010), which comprises the majority of the Stroke Belt. The large population of AAs in the region is an important factor in the increased prevalence of diabetes in the Southeastern US. Findings from studies of predictor variables suggest the risk of developing pre-diabetes and subsequent type 2 diabetes increases with age greater than 45 years, male gender, and AA race/ethnicity (ADA, 1995- 2010).

The prevalence of pre-diabetes in the US is increasing, thereby increasing the morbidity and mortality rate for people in high-risk populations such as AAs. The prevalence of pre-diabetes in the US is related to the accumulation of risk factors in the population (Magelhaes, Cavalcanti, & Cavalcanti, 2010). Individuals with high risk for pre-diabetes must be identified and interventions employed to prevent emergence of the disease state. Data from the Funagata Diabetes Study, a seven-year follow-up study, showed that survival rate in cardiovascular disease for individuals diagnosed with pre-diabetes, as measured by IGT, was lower than for individuals with normoglycemia (Tominaga, et al., 1999). The Collaborative Analysis of Diagnostic Criteria in Europe (DECODER) (2003), presented data that revealed the risk of cardiovascular death was increased in pre-diabetes.

Adopting healthy behaviors, including intense physical activity, weight control, smoking cessation, and limiting alcohol consumption have all been found to reduce risk of pre-diabetes (ADA, 2010). Some risk factors of pre-diabetes are minimally modifiable while some remain non-modifiable. Modifiable risk factors include SES, regionality, and perception of health, while non-modifiable risk factors are race, age and gender. Conflicting results exist in studies examining the relationship between risk factors, with some findings suggesting that access to care may not play a major role in ethnic

disparities, glycemic control and related complications (Karter et al., 2002). Yet other evidence indicates that access to care, is disproportionately low in the AA population (Harris, 2001), thereby resulting in poor pre-diabetes control. Presently, there is no consensus on the factors that cause pre-diabetes disparity between AAs and Whites. Differences in the interrelationships among these factors and ultimately the control of pre-diabetes between the White and AA populations remain poorly understood. The reasons for disparities in AAs with pre-diabetes are likely complex, requiring the need for further investigation. This study was conducted to explore the relationships between multiple factors and to identify how these factors contribute to disparities in pre-diabetes among AAs, as compared to Whites. Understanding which factors may be associated with disparity in AAs with pre-diabetes is essential, as it supports development of future interventions aimed at decreasing the prevalence of diabetes and cardiovascular disease morbidity and mortality rates among AAs.

Purpose of the Study

The purpose of this study was to identify individual, psychosocial, behavioral, and physiologic factors that are associated with pre-diabetes disparity among AAs as compared to Whites enrolled in the REasons for Geographic and Racial Differences in Stroke (REGARDS) study cohort.

Research Questions

The study examined the following questions:

1. Is there a difference in the odds of pre-diabetes in people living in the stroke belt

compared to people living outside the stroke belt?

2. Does race (AA) increase the odds of pre-diabetes after controlling for selected independent variables such as age, sex, regionality, SES (income level, education), cigarette smoking, alcohol use, intense physical activity and illness perception in the REGARDS study cohort.
3. Do older age and gender increase the odds of pre-diabetes in the REGARDS STUDY cohort?
4. Does lower SES increase the odds of pre-diabetes in AAs compared to Whites after controlling for covariates such as lifestyle choices and illness perception?
5. Do lifestyle choices, smoking, intense physical activity and alcohol intake along with illness perception increases the odds of pre-diabetes in the REGARDS study cohort?

Conceptual Framework

The Expanded Bio-behavioral Interaction Model (Figure 1), developed by Kang, Rice, Park, Turner-Henson, and Downs (2010) was used as a conceptual framework to guide the study. The Expanded Bio-behavioral Interaction Model is an integrated biobehavioral model adopted from three theoretical models: the physiological model of stress (Selye, 1974), the cognitive appraisal model of stress and coping theory (Lazarus & Folkman, 1984), and the stress, allostasis, and allostatic load model (McEwen, 1998, 2003). The Expanded Bio-behavioral Interaction model is a framework for understanding the bio-behavioral interaction between multiple clusters of bio-behavioral factors. The model consists of clusters that interact collectively to affect biological responses to shape health and health-related outcomes (Kang et al., 2009). The five domain clusters included in the

framework are the individual, environmental, psychosocial, behavioral and biological domains. Each domain is explained individually based on its effect on health outcomes, and because of the interrelatedness of these domains, each has the ability to affect change in one another.

The individual domain consists of one's individual characteristics such as income, education, age, occupation and genotype. Social norms, physical conditions, culture, access to service, and the individual's community environment are factors of the environmental domain. Factors in the psychosocial domain are stress, coping, emotions, social support, and spirituality. These factors are defined as mental characteristics of a person or group of people in a community or the interactions of a group of individuals in a community. The behavioral domain is defined as a group of behaviors that are observed in the individual, for example, diet, alcohol use, smoking, physical activity and drug use. The biological domain is the individual's organic and metabolic functioning, including immune, endocrine, cardiovascular, pulmonary and neuromuscular responses, including responses such as hyperglycemia. Responses within the biologic domain function as a mediator for each of the domains, thereby influencing health and health-related outcomes (Kang et al., 2010).

Some domains are capable of exerting influence on, and being influenced by, other domains, and are therefore described as bidirectional. For example, the biological domain is capable of bidirectional causal responses, in that biological responses both mediate and moderate psychosocial, behavioral and individual factors to influence health and health-related outcomes. Factors in the individual and environmental domains are

defined as correlational, in that these factors are related, but cannot be confirmed as having a causal influence on other factors (Kang et al., 2010).

Kang et al. (2010) represent the relationship between stress (psychosocial domain) and inflammation (biological domain) in various health-related outcomes such as atherosclerosis, cancer, and chronic obstructive pulmonary disease (COPD), in that stress activates the body's inflammatory response evidenced by an elevation of C- reactive Protein (CRP), which then influences health and health-related outcomes such as atherosclerosis (Ellins et al., 2008), COPD (Pembroke, Rasul, Hart, Smith, & Stansfeld, 2006) and breast cancer (Al Murri et al., 2006). Other psychosocial, behavioral, environmental, and individual factors are relevant to various health-related outcomes, the effects of which are mediated or moderated by biological responses (Kang et al., 2010).

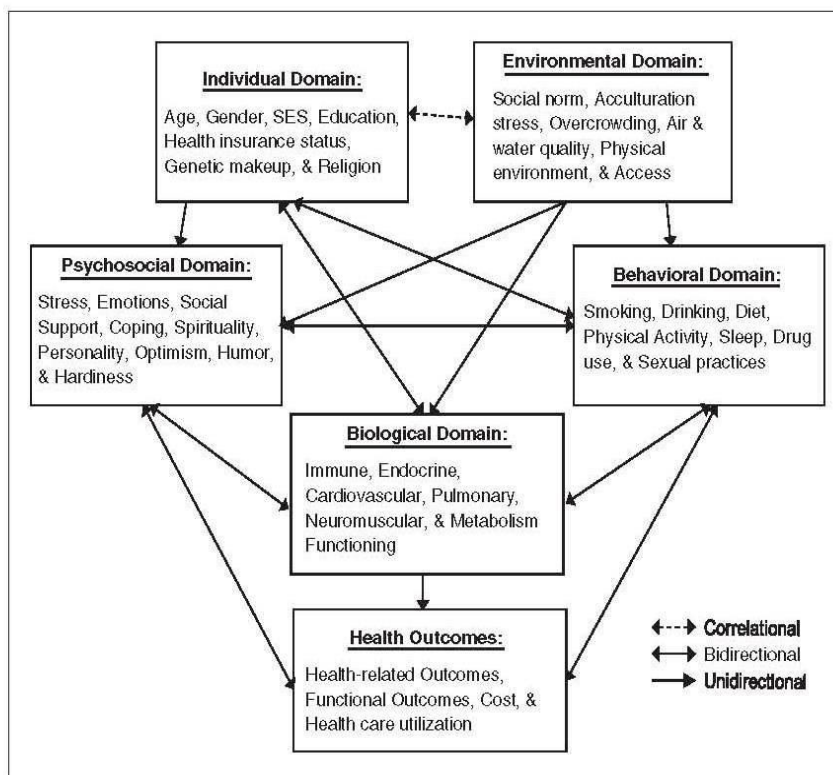


Figure 1. The Expanded Biobehavioral Interaction Model

Note: From “Stress and Inflammation: A Biobehavioral approach for nursing research” by D. H. Kang and M. Rice, 2010, *Western Journal of Nursing Research*, 32, p. 736. Copyright 2010 by Sage Publications. Reprinted with permission.

Application of Conceptual Framework

This study focused on individual, behavioral, biological, environmental, and psychosocial domains that influence disparities of pre-diabetes between AAs and Whites. The Expanded Bio-behavioral Interaction Model, (Figure 1) was used to explain the relationship among these constructs.

Pre-diabetes has been associated with several modifiable and non-modifiable risk factors, including smoking, alcohol consumption, intense exercise, age, and gender

(ADA, 2010). Additional risk factors listed in a paucity of the literature are regionality (Baird, 2010; Zhang et al., 2009), SES (Endevelt, 2007), and perception of health (Brandon, & Proctor, 2010). Risk factors that contribute to pre-diabetes are important factors because they contribute to diabetes prevalence, and complications such as stroke, and heart disease (Hu, 2002). The health care costs resulting from these co-morbidities creates significant economic burden for the US (Agency for Healthcare Research and Quality [AHRQ], 2005).

The Expanded Bio-behavioral Interaction Model provided a framework for the development of the study of pre-diabetes, the final health outcome. The model served as a guide to explain the development of pre-diabetes within six domains, five of which are pertinent to this study.

Individual Domain

Pertinent factors within the individual domain include race, SES as measured by education and income, age, and gender. Race was a key factor in each of this study's research questions, while all other individual domain factors were treated as covariates in the study (Sinsuesathul, 2008). In this study race was defined as the self-identified racial category selected by the study participant.

Some research findings suggest that type 2 diabetes is related to race (ADA, 1995-2010). The correlation between race and type 2 diabetes relates to factors of the behavioral domain such as lifestyle risk factors, including diet and limited participation in intense physical activity. Risk factors that link type 2 diabetes and race are also risk

factors for pre-diabetes, thereby linking the individual domain factor, race, with the health outcome, pre-diabetes.

Socioeconomic status is a determinant of health status disparities between AAs and Whites (Kawachi, Daniels, & Robinson, 2005). Research findings suggest that AAs have lower socioeconomic status compared to Whites (Polsky, 2008; US Census Bureau, 2010), and that people with lower SES are more likely to have unhealthy lifestyle factors, unequal access to care, unequal quality of care, more material deprivation and a stressful psychosocial environment (Von dem Knesebeck, Luschen, Cockerham, & Siegrist, 2003), illustrating the interactiveness of domains in the study framework. Brown and colleagues (2005) demonstrated that higher socioeconomic status correlates with better glycemic control in patients diagnosed with diabetes, and income (Von dem Knesebeck et al., 2003) and educational level (Snittker, 2004) are SES indicators of health disparities. The NHANES III survey data revealed an inverse association between income level and diabetes control in AA females. The bidirectional relationship between the individual and biological domains in the Expanded Bio-behavioral Interaction Model is illustrated by the inverse relationship among both income and educational levels with glycemic control. People age 45 years and older have an increased risk for developing pre-diabetes (ADA, 2010). Cowie and colleagues (2006) found that males have a higher risk of pre-diabetes compared to females. Combined, these findings illustrate the contribution of both age and gender to the bidirectional relationship between the individual and biological domain.

Environmental Domain

The environmental domain variable considered in this study was regionality. Regionality was determined by the participant's responses to the 'Residential History' Questionnaire used in the REGARDS study. Regionality can affect pre-diabetes prevalence. Baird (2010) and Zhang et al. (2009) report a higher prevalence of pre-diabetes in the Southern region of the US compared to other regions of the country. The relationship between regionality and pre-diabetes prevalence is moderated by the individual domain factor of race. The Southeast region of the US has an increased population of AAs compared to other regions of the country (US Census Bureau, 2010). Diabetes and pre-diabetes is more common among AAs compared to many other populations (ADA, 2010), therefore the relationship between race and regionality may provide one explanation for the effect of regionality on pre-diabetes.

Southern states have many rural counties. For example, 55 of the 67 counties in Alabama are classified as rural (Alabama Rural Health Association, 2007), and 65 of Mississippi's 82 counties are classified as rural (Mississippi State Department of Health, 2007). Rural counties can be medically underserved due to a limited number of health care providers or limited health care facilities (Hicks, Bublitz, Emserman, & Westfall, 2009), which in turn imposes limitations on access to care and health outcomes.

Behavioral Domain

Several factors of the behavioral domain may also affect glycemic level. Recent findings have suggested that cigarette smoking, alcohol use and physical activity were associated with glycemic control (Gunton, Davies, Wilmshurst, Fulcher, & McElduff,

2002; Thamer, Haap, Fritsche, Haering & Stumvoll, 2004). Cigarette smoking decreases insulin sensitivity (Borggreve, DeVries, & Dullaart, 2003). Other researchers suggest that intense physical activity and moderate alcohol intake have a positive effect on insulin sensitivity (Sigal, Kenny, Wassermann, Castaneda-Sceppa, & White, 2006; Thamer et al., 2004).

Psychosocial Domain

Within the psychosocial domain, illness perception and stress may affect glycemic levels. Stress can alter blood glucose by decreasing a person's health promotion behaviors and or altering blood glucose levels directly. Illness perception was the only psychosocial domain variable explored in this study. Illness perception may be affected by stress and exert influence on individual health care behaviors. Illness perception can also influence coping behaviors used to manage illness (Leventhal, Brissette, Leventhal, Cameron, & Leventhal, 2003), and in turn, these behaviors influence health outcomes. According to Paschalides et al. (2004) a patient's perception of his/her diabetes can influence diabetes self-management behaviors, thus affecting glycemic control (Griva, Myers, & Newman, 2000; Hampson, Glasgow, & Strycker, 2000).

Biological Domain

The biological domain variable that was considered for this study is disordered blood glucose metabolism. Prolonged unhealthy blood glucose metabolism or disordered blood glucose metabolism can significantly affect health (Silverman, *n.d*). The continuum of disordered blood glucose metabolism results in microangiopathy, increased

cardiovascular risk and a sustained level of glycemia above normal glycemia and below the level of diabetes (Klein, 1995; Laakso, 1999; Haffner & Cassells, 2003) .

Disordered blood glucose metabolism occurs as a natural stage in the progression from normal glycemia to glycemic threshold values below which few diabetic complications occur and above which diabetic complications occur (Silverman, *n.d.*). Therefore, disordered blood glucose metabolism is a crucial variable to evaluate in terms of glycemic control and pre-diabetes.

Health Outcome

The health outcome or dependent variable of interest in this study was pre-diabetes. Inadequate control of blood glucose level may be attributed to several domains or interrelationships among the domains of the Expanded Bio-behavioral Interaction Model. The model was modified to reflect a unidirectional relationship with the domains of the model that contained the covariates of interest for this study (Figure 2). The modified model explains the interrelatedness of the domain variables identified above to improve the understanding of factors contributing to the development of pre-diabetes in the REGARDS cohort.

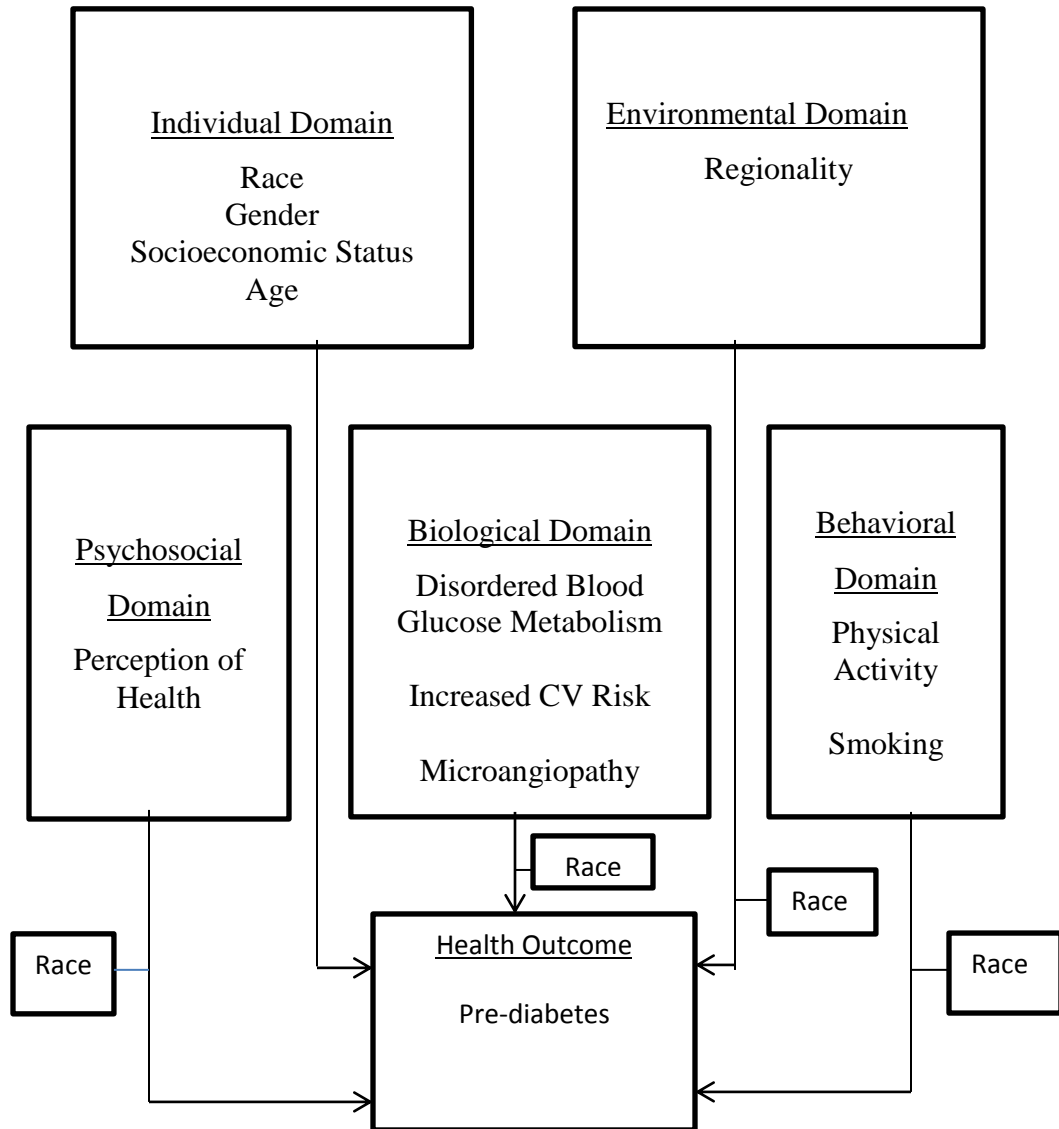


Figure 2. The Expanded Biobehavioral Interaction Model Modified.

In conclusion, the etiology of normal range glycemia depends on multiple factors including biological, environmental, psychological, and behavioral factors (Nathan et al., 2009). In this study, the association among multiple factors such as race, age, SES, lifestyle behaviors (smoking, alcohol consumption, and physical activity), gender, and regionality is theoretically sound and may affect the occurrence of pre-diabetes in the study cohort. In addition, race (AA) may moderate the relationships between factors in multiple domains and the health outcome of pre-diabetes.

Definition of Terms

The following terms were operationally defined for the purpose of this study.

Stroke Belt

Stroke Belt was defined as a region of increased stroke mortality in the Southeast region of the US (Borhani, 1965; Lanska, 1993) that includes North Carolina, South Carolina, Georgia, Alabama, Mississippi, Tennessee, Louisiana and Arkansas.

Stroke Buckle

Stroke Buckle was defined as a region in the Stroke Belt along the coastal plain of North Carolina, South Carolina, and Georgia that has a higher stroke mortality rate than the remainder of the Stroke Belt (Howard, 1997).

Pre-diabetes

Pre-diabetes was defined as a 10 to 12 hour FBG level between 100 and 125 mg/dL (ADA, 2010) in REGARDS study cohort participant, during the in-home examination that occurred during the active phase of the REGARDS study.

Fasting Blood Glucose

Fasting blood glucose was measured in the REGARDS study by a Central Laboratory at the University of Vermont, from blood collected by Examination Management Services, Inc (EMSI) personnel, through phlebotomy using standardized methods.

Diabetes

Diabetes was defined as a 12 hour fasting plasma glucose level at or above the level of 126 mg/dL or above 200 mg/dL non-fasting as defined by the ADA, and /or current diabetes treatment with insulin or pills. It was also defined by a self-report positive response provided by a REGARDS subject to “has a doctor ever told you that you have diabetes or high blood sugar”.

Age

Age was based on self-reported birth date provided by REGARDS subjects. Self-reported birth date was then converted into the nearest whole year of age.

Race and Gender

Race and Gender was based on self-report provided by REGARDS subjects.

Regionality

Regionality was defined by REGARDS participants' responses to the 'Residential History' Questionnaire.

Socioeconomic Status

Socioeconomic status was defined as years of education (less than high school, high school graduate, some college, college graduate) and income status (< \$25,000, \$25,000 to \$50,000, > \$50,000) as reported by REGARDS subjects.

Cigarette Smoking

Cigarette Smoking was defined as REGARDS subjects' self-reporting of their cigarette smoking habit- categorically as never, past or current.

Alcohol

Alcohol use was defined as REGARDS subjects' self-reported status- categorically as none, moderate or heavy.

Intense Physical Activity

Intense Physical Activity was defined categorically by REGARDS subjects' answer to the question; "How many times per week do you engage in intense physical activity-

enough to work up a sweat” none, one to three times per week, or four or more times per week?

Illness Perception

Illness Perception was defined by the REGARDS participant’s self-reported health status- categorically as excellent, very good, good, fair or poor.

Assumptions

For the purpose of this study, the assumptions were as follows:

1. Individuals have a desire to maintain optimal health
2. Assisting people living with pre-diabetes to reduce their risk of type 2 diabetes and diabetes complications, such as stroke, and cardiovascular disease is within the scope of nursing practice.
3. Participants in the REGARDS cohort answered questionnaires truthfully, reflecting their actual beliefs, health habits, health history and health resources.

Limitations

The limitations of this study were as follows:

1. A non-randomized sample was used for this study. Therefore, the findings from the study may not be generalizable to other populations that do not share similar characteristics of the study participants.
2. Some study variables were reliant on self-report. Participants may not answer truthfully, or may answer with responses deemed socially acceptable. Therefore, the

potential exists for bias and decreased external validity.

3. The study was not able to address cause and effect between study variables because of the limitations of cross-sectional study design.

CHAPTER 2

REVIEW OF LITERATURE

The purpose of this chapter is to review the current research literature related to the study. The chapter is divided into two sections. Section one provides an overview of the REGARDS Study and provides a framework for understanding the origination of data used in the study. The second section presents an overview of the relationship between the study variables in the five domains that influence pre-diabetes in AAs and Whites within the conceptual model for the study.

The Regards Study

The REGARDS Study is described in several publications (Howard et al., 2005; Voeks, et al., 2008; Glasser et al., 2011). This section is an overview of the background and methods used for data collection in the REGARDS Study. The section starts with a discussion of the historical development of the study and a current description of the study.

History

The REGARDS Study is a population-based study of over 30,000 AA and White subjects age 45 years and over. The study was initiated January 2003 in response to excess stroke mortality in the Southeast region of the US. The Southeast region of the

US was first identified as the “Stroke Belt” in 1965 because of its high stroke mortality rate (Borhani, 1965), dating back to 1940 (Lanska, 1993). The REGARDS Study allowed for creation of a national cohort to address geographic and ethnic differences in stroke. At study initiation, stroke mortality among AAs was 50 % higher compared to White subjects in the Stroke belt (Howard et al., 1994; Broderick et al., 1998). At least two different hypotheses had been published that attempted to explain the increased stroke mortality in the region (Perry & Roccella, 1998; Howard, 1999). Howard (1999) hypothesized increased stroke mortality was related to individual lifestyle selections, SES, quality of health care, and variations in cardiovascular risk factors. Despite the overall regional and AA increased stroke mortality in the Stroke Belt, and this published hypothesis, little research had been published prior to the REGARDS Study that explored increased mortality rates or other aspects of Howard’s (1999) published hypothesis (Kannel, 2000; Melton, 1996).

The Greater Cincinnati Northern Kentucky Stroke Study (GCNKSS) provided data on stroke incidence in a racially diverse population indicating a significant risk for stroke among AAs. Incidence rate among AAs was 411 per 100,000 (95% CI), compared to Whites which was 179 per 100,000 (95% CI) (Broderick et al., 1998). The National Health and Nutrition Examination Survey provided national data on prevalence of risk factors by ethnic groups, but did not focus on stroke risk factors (Vital Health Statistics, 1994). The limited data available to explain higher stroke mortality in the southeastern US led to a call from the Center for Disease Control (CDC) (Gillum, 1999) for population-based research on stroke mortality in AAs. The REGARDS study responded

to this call in an attempt to elucidate underlying causes of increased stroke mortality in the Stroke Belt, Stroke Buckle, and among AAs (Howard et al., 2005).

Methods

The primary aim of the REGARDS Study is to determine the cause of increased stroke mortality in the Stroke Belt region of the US and among AAs (Howard et al., 2005).

REGARDS uses a prospective cohort design and has assembled a national cohort of over 30,000 AA and White subjects 45 years and older. Recruitment consisted of participants from every region in the continental US, with 30% derived from the Stroke Belt, and 20% from the Stroke Buckle. Data collection from the cohort began in 2003, and while the cohort is now fully assembled, prospective data collection is ongoing. Data collection is supported by three methods, computer assisted telephone interview, in-home exam and self-administered questionnaires (Howard et al., 2005), with variables that include medical history, demographic data, socioeconomic status, physical activity, diet, perceived health, medication history, residential history, and prospective health outcomes.

Pre-diabetes

The ADA (2010) defines pre-diabetes as blood glucose levels below the range defined as diabetes and above the normal range of blood glucose, specifically, a fasting glucose level between 100 and 125 mg/dL. The individual diagnosed with pre-diabetes may have IGT or IFG (ADA, 2010). The ADA (1995- 2010) and the World Health Organization (WHO) (2006) define IGT as plasma glucose between 140 mg/dL and 199 mg/dL at two

hours post glucose load. The ADA defines IFG as plasma glucose between 100mg/dL and 110mg/dL, while the WHO defines IFG as a fasting glucose of at least 110 mg/dL. Diagnostic tests that define IGT and IFG are the Oral Glucose Tolerance Test (OGTT) or the Fasting Plasma Glucose Test (FPGT). Therefore, pre-diabetes should be considered a collective term that describes the presence of IGT, IFG, or a combination of both IGT and IFG (Aroda & Ratner, 2008).

Pre-diabetes can be asymptomatic or have few signs and symptoms recognizable by the patient or health care provider (CDC, 2005) and because of this, pre-diabetes increase the probability of microvascular and macrovascular pathology leading to co- morbid cardiovascular disease and complications in high-risk populations such as AAs (ADA, 2010). Gillies et al. (2008) found that early pre-diabetes intervention could result in prevention of diabetes or a delay in disease onset. Progression from pre-diabetes to diabetes occurs over several years and is largely dependent on the presence of risk factors such as age, family history and body weight (Aroda & Ratner, 2008). Gerstein et al. (2007) found that the average annual risk for developing diabetes in subjects with pre-diabetes was 5 % to 10%, while the average annual risk for developing diabetes in normoglycemic subjects was 0.7%.

The delay or total prevention of diabetes with intervention can be up to 58 % when compared to individuals without effective intervention (ADA, 2010). Aroda and Ratner (2008) found that diabetes can be delayed or prevented with intensive lifestyle modification combined with pharmacotherapy. Until recent years there were few recommendations for diagnosis or early intervention for patients with pre-diabetes (Garber et al., 2008), however most current scientific findings support early identification

management of risk factors for diabetes, including pre-diabetes (Engelgau, Narayan, & Herman, 2000; ADA, 2007; Fonseca, 2008). The ADA (2007), Indian Health Services (2008) and both the Australian Diabetes Society and Australian Diabetes Educators Association (Twigg, Kamp, Davis, Neylon, & Flack, 2007) have published guidelines for the approach to caring for patients with pre-diabetes. While these guidelines differ slightly based on the presence of physiologic factors and disease progression state, they are consistent with the importance of early identification of risk factors for diabetes and cardiovascular diseases.

Interactive Model Domains Related to Pre-diabetes

Few studies have examined factors that influence pre-diabetes, while those factors that influence diabetes or type 2 diabetes are the focus of multiple research studies. This limits an ability to draw conclusions about how different factors may influence pre-diabetes alone. Nonetheless, a review of physiological, behavioral, environmental, and psychosocial factors with the potential to influence pre-diabetes should be considered, given their strong association with type 2 diabetes disease states. Variables that influence type 2 diabetes and are likely to influence pre-diabetes development may be organized by the domains of the Interactive Model as follows: individual domain (race, age, gender, SES); environmental domain (regionality); psychosocial domain (perception of health); biological domain (disordered glucose metabolism); and behavioral domain (physical activity, smoking, and alcohol).

The Individual Domain and Pre-diabetes

Race

An exhaustive review of the literature revealed few studies focus on race alone, in relation to pre-diabetes, although a substantial body of science exists in the area of type 2 diabetes in relation to both race and ethnicity. This body of science is focused on co-morbid diseases that are physiologically linked to diabetes, as well as the development of complications. According to the ADA (2010), AAs are more prone to develop diabetes and pre-diabetes compared to Whites. Some evidence also exists to suggest that AAs have a higher prevalence of risk factors that can cause type 2 diabetes (Brancati, Kao, Folsom, Watson, & Szklo, 2000).

Risk factors for the development of type 2 diabetes that are commonly associated with AA race include obesity, hypertension, physical inactivity, low SES, and a family history of diabetes (Brancati et al., 2000). Kahn and Flier (2000), as well as Srinivasan, Myers, and Berenson (2002) found a direct relationship between adiposity/obesity and insulin resistance supporting the development of pre-diabetes. Pereira et al. (2002) suggest that racial differences in diabetes, and therefore, development of pre-diabetes, may directly relate to fasting hyperglycemia and impaired glucose metabolism in patients with metabolic syndrome. Ping et al. (2005) found a genetic link between race and pre-diabetes, however according to the ADA (2010), genetics alone do not explain the predisposition for pre-diabetes or diabetes among races. Predisposition to type 2 diabetes, and therefore pre-diabetes, is instead thought to be more closely related to environmental factors and adaptation of a sedentary lifestyle (ADA, 2010).

Gender

Literature is lacking in the area of gender assignment in relationship to a finding of pre-diabetes, however a few studies have focused specifically on IGT and/or IFG in relation to gender (Williams et al., 2003; Unwin, Shaw, & Albert, 2002; Qiau, Hu, Tuomilehto, Balkau, & Bord-Johnsen, 2002). Williams et al. (2003) studied gender differences in the characteristics and prevalence of various categories of glucose tolerance in Mauritius, finding that isolated IFG was more common among men than women. These investigators found that men were 5.1% times more likely to have IFG, as compared to women (2.9%), after controlling for age, weight, and plasma lipid levels. Additionally, these investigators found that isolated IGT in men was 9.0% compared to 13% in women.

In the International Diabetes Federation Consensus Workshop, Unwin and colleagues (2002) summarized the scientific findings and interjected expert opinion concluding that a higher prevalence for IFG existed in males, while there was a higher prevalence for IGT among women. Additionally, this panel of experts concluded that IGT was more common than IFG, and that few people have both IGT and IFG.

Age

The literature does not reflect studies that examine the relationship between ages and pre-diabetes although a large amount of evidence suggest that age is a risk factor for diabetes (ADA, 1995-2012; Mayo Clinic Staff, 1998-2012; Lindstrom & Tuomilehto, 2003). Nevertheless pre-diabetes is a precursor for diabetes and findings for diabetes is the same in pre-diabetes.

A common theme in the literature is that aging is a physiologic factor that results in physiologic changes. Most of the literature supports the fact that physiologic changes related to aging affects diabetes. Gambert and Pinkstaff (2006) reported that diabetes was an age prevalent disease and that the possibility of being diagnosed with diabetes increased with age. The past and current literature emphasizes that the risk of diabetes increases significantly after age 45 years old (Mayo Clinic Staff, 1998-2012; ADA, 1995-2012). According to research conducted by DeFronzo (2004), 90% of older adults had diabetes that was characterized by insulin resistance and insulin deficiency. Germino (2011) reported that 42 % of individuals with diabetes in the US were 65 years old and older. A longstanding theory found in much of the literature is that the pancreas ages as the individual ages (Anon, 1991) . This aging process results in less pump function of the pancreas and ends in less pumping efficiency of insulin. This theory provides support for the reports from the researchers aforementioned in this paper. In conclusion, the ADA (2002) reported that a decrease in insulin sensitivity with aging is associated with lack of physical activity. Therefore, the effects of aging on diabetes may be physiological but the effects may be modified by physical activity.

Socioeconomic Status

Some research findings suggest that individuals with lower SES fare poorly on several health indices (Bravata et al., 2005; Liu & Nunez, 2010), including type 2 diabetes (Connolly, Unwin, Sherriff, Bilous & Kelly, 2000). Much of the literature on SES and diabetes or pre-diabetes has been conducted in populations outside the US, nonetheless, findings from these studies are similar to findings from US studies. According to Deaton

(2003), higher SES has a protective effect on health. This protective effect may exist because of the inverse relationship between SES and presence of health depriving behaviors such as smoking, excessive alcohol intake, obesity and poor exercise habits. Additionally, those with lower SES have higher prevalence rates for chronic diseases, such as diabetes (Ross, Gilmour. & Dasgupta, 2010; Tang, Chen, & Krewski, 2003).

Educational level and income are two variables that are closely associated with SES (Tang et al., 2003). In the US, SES historically has been defined as a combination of these two variables (Braveman et al., 2005). However, Braveman and colleagues (2005) suggest that total accumulated economic resources, or wealth, may be a better indicator of SES and not income. According to Deaton and Paxson (1999), education and income promote health differently. Education makes it easier to use and understand health information and technology, whereas high income generally makes life easier, thereby reducing stress and its effects on the human body. Deaton and Lubotsky (2001) demonstrated the association between SES in their work, showing that cities with higher levels of education and income adequacy had lower mortality rates.

Liu and Nunez (2010) conducted research on cardiometabolic syndrome (CMS) and education using data from the 2007 Pennsylvania Behavior Risk Factor Surveillance System (BRFSS) survey. This cross sectional study included a sample of over 12,000 non-institutionalized Pennsylvania residents age 18 years and older. Study findings revealed lower educational attainment was associated with higher odds of having CMS or pre-diabetes.

Kowell and colleagues (2011) studied the association of subjective and objective SES and type 2 diabetes or pre-diabetes incidence in elderly Germans using a prospective

cohort design. Over 12,000 subjects age 55 to 74 years at baseline were enrolled, with approximately 800 subjects participating in the seven year follow-up phase of the study. Regression analyses were performed to determine what factors predicted incidence of type 2 diabetes and pre-diabetes. These investigators found a non-significant trend for pre-diabetes in association with lower SES, with measures of subjective SES more closely associated with pre-diabetes, as compared to objective measures of SES.

According to Ross et al. (2010), SES is a predictor of type 2 diabetes risk. These investigators reviewed data from over 12,000 National Population Health Survey respondents 18 years and older, focusing on the 14-year incidence rate of type 2 diabetes. Male participants were more likely to have higher levels of income and education, but were also more likely to be overweight/obese, heavy smokers and drinkers, as well as less physically active. Their findings did suggest an association between low income and incidence of type 2 diabetes, however, among women the relationship between SES and type 2 diabetes was mediated by presence of risk factors that included being overweight, obese and of an ethno-cultural background.

Tang and colleagues (2003) studied the impact of SES on prevalence of self-reported diabetes among men and women, using data collected from the National Population Health Survey from 1996- 1997. Their study sample consisted of over 30,000 men and women aged 40 years and older. Education attainment and income adequacy were used to define SES. After adjustment for age, area of residence, body mass index, and physical activity, the prevalence of diabetes in men was determined to be 6.6% and in women was 5.5%. Prevalence of diabetes increased in both men and women as income adequacy decreased and education level decreased, however, the odds ratio for income

and education in relation to diabetes prevalence was only statistically significant in women.

According to Kanjilal et al. (2006) SES has modest impact on diabetes prevalence. These investigators collected data from various waves of the NHANES from 1976 to 2002 on adults aged 25 to 70 years. Socioeconomic status was measured by years of education and family income. After controlling for multiple co-variants such as race, smoking history, exercise history, age, and weight these investigators concluded that the primary forces leading to higher diabetes prevalence over time were excessive weight, obesity, and diabetes inheritance. Findings revealed a small association between educational attainment overtime with the development of diabetes, while income was found to have even less of an impact over time on development of diabetes.

In summary the literature supports a relationship between SES and diabetes, although study findings are sometimes in conflict. Several investigators have concluded that lower SES is a barrier to adequate diabetes prevention and disease control, while others suggest that lower SES is associated with a higher prevalence for risk factors linked to the development of diabetes.

The findings in these studies emphasize the multidimensional nature of SES. Most studies mentioned above used only a standard measure of SES (education and income). Braveman and colleagues (2005) suggest that there are limitations associated with use of standard measures and recommend use of as many indicators as possible for measures of SES, as well as validation of SES measures across all populations for use in healthcare research.

Additional limitations of the studies above include the use of cross sectional designs. The nature of cross sectional designs yields difficulty in determining a causal relationship between SES and diabetes or pre-diabetes.

The Environmental Domain and Pre-diabetes

Regionality

The prevalence of diabetes varies by state of residence. Higher prevalence rates are commonly found in the Southeast region of the US, which may be related to an increased population of AAs, increased prevalence of risk factors, or more states in the region with multiple rural counties. High blood sugar, a risk factor for diabetes, also varies by state of residence (Danaei et al., 2010). Southern rural AA have a higher rate of mortality compared to White Americans which is significantly related to the presence of high blood sugar and other cardiovascular risk factors (Danaei et al., 2010) prevalent in Southern states. The high population of AAs, increased risk factors for diabetes, and multiple rural counties provide evidence that diabetes, and therefore pre-diabetes incidence, have a geographic dimension worthy of further investigation. The CDC (2009) identified several southeastern states for high prevalence of diabetes, including the Appalachian counties of Tennessee, much of the Mississippi Delta, and a southern belt extending across Louisiana, Mississippi, middle Alabama, southern Georgia, and the coastal regions of the Carolinas. Data from the 2006 to 2008 Behavioral Risk Factor Surveillance System (BRFSS) telephone survey of health behaviors and the 2000 US Census Bureau were used to determine diabetes prevalence after age-adjustment in over

3,000 counties in the US. Among counties in Alabama, Georgia, Louisiana, Mississippi, and South Carolina, 73% were in the top quintile for diabetes prevalence (CDC, 2009).

Studies are lacking that identify the Southeast region of the US as the single independent variable for increased prevalence or incidence of diabetes, although regionality or geography are identified as a covariate for increased rates of diabetes (CDC, 2009). The Southeastern states have many rural counties. Mississippi has 65 rural counties (Mississippi State Department of Health, 2007) and Alabama has 55 rural counties (Alabama Rural Health Association, 2003). It has been well documented that many rural areas lack the necessary resources to provide ideal care for some chronic diseases such as diabetes. Additionally some researchers have shown that the increased incidence rate of type 2 diabetes in rural areas is independent of race (Mainous, King, Garr, & Pearson, 2004).

A recent national epidemiological study found a significant correlation between type 2 diabetes and particulate matter 2.5 levels of air pollution (ambient air pollutant) (Pearson, Bachireddy, Shyamprasad, Goldfine, & Brownstein, 2010). Study investigators focused exclusively on fine particulates that are common components of haze, smoke and motor vehicle exhaust; data were obtained from the Environmental Protection Agency (EPA) on particulate pollution, and correlated with CDC and US Census Bureau diabetes prevalence data. Investigators analyzed data using multivariate regression techniques with adjustment for race, obesity, exercise, geographic latitude, and population density, finding a strong and consistent relationship between particulate concentration and diabetes. Of note, the EPA data revealed that the areas with the highest particulate pollution were consistently Southern States (Person et al., 2010). These findings are

consistent with previous laboratory studies that found an increase in insulin resistance in obese mice exposed to particulates, and an increase in markers of inflammation which may contribute to insulin resistance in both the mice and obese diabetic patients after particulate exposure (Sun et al., 2009).

Health disparity in chronic disease is widely seen in many countries (Baldwin, Chan, Andrilla, Huff, & Hart, 2010; Ellerbeck, Bhimaraj, & Perpich, 2004; Ntandou, Delisle, Agueh, & Fayomi, 2009), with much of this attributed to a lack of evidence-based diabetes care. In the US, difference in diabetes care exists between rural and urban areas, within and across states and by regions (Weingarten et al., 2006). Regional differences may correlate with SES, in that Harriman (2001) suggests rural populations are socioeconomically disadvantaged. In turn, SES influences health status. States like Mississippi have many rural areas, lower income levels, fewer employment opportunities, lower educational attainment rates, and high rates of poverty (Woods, & Bischak, 2000). Similarly, states with similar large pockets of rurality experience lower income, decreased employment, lower educational achievement and decreased accessibility to health care and services (Hicks et al., 2009).

The Psychosocial Domain and Pre-diabetes

Illness Perception

Self-reported illness perception or perception of health status, is a widely used measure for general health status, and has been shown to affect both self-care behaviors (Wichowski, & Kubsch, 1997), and health seeking behaviors (Leslie, Urie, Hooper, & Morrison, 2000), as well as morbidity and mortality (Dowd, & Zajacova, 2007).

Frostholm and colleagues (2006) studied the effect of illness perception on health outcome. These investigators sampled 1,785 primary care patients with recurrent or new health problems. The study participants completed an adapted version of the Illness Perception Questionnaire and Medical Outcomes Study 36-Item Short Form Health Survey (SF-36) at baseline and at three, twelve and twenty-four months' follow-up. Findings revealed a significant association between negative perceptions of health with poor physical and mental health at baseline of the study. During follow-up assessment, illness perception predicted a change in health status, and patients that had more medically unexplained symptoms had more negative illness perception. .

Self-reported illness perception has also been studied in subjects with chronic diseases such as diabetes (Kartal, & Inci, 2011). Petricek et al.(2009) conducted a cross sectional study to investigate illness perception in patients with type 2 diabetes and its association with individual control over cardiovascular risk factors. A total of 276 subjects age 18 years or older completed the Brief Illness Perception Questionnaire (IPQ), a standardized instrument developed to assess cognitive and emotional illness representation (Broadbent, Petrie, Main & Weinman, 2006). The 9-item questionnaire includes assessment of the following cognitive illness domains: Consequences; Timeline; degree of personal control over the disease; treatment control; and, identity. Emotional domains include: Concern; emotional response; and, illness understanding. Subjects with high scores on the questionnaire reflect those with strongly-held beliefs about the serious consequences of the illness, its more pronounced chronic nature, highly positive beliefs in the “controllability” of the illness, recognition of a greater number of symptoms attributed to the illness, a higher level of emotional distress arising from the illness, and better

personal understanding of the illness. In this particular study, the investigators substituted the word “illness” in the survey with “type 2 diabetes”. Subjects’ cardiovascular risk factors were also collected alongside survey data through abstraction from medical records. These data included measures of glycemic control, lipid profiles, prescribed medications, physical examination findings such as arterial blood pressure and BMI, and interview data related to lifestyle.

Forty-three of the 46 physician offices (250 patients) returned completed patient surveys. The results of the study revealed that subjects viewed their diabetes as a chronic disease that could be controlled with appropriate treatment. Additionally, these subjects were emotionally detached and did not view diabetes as having serious consequences. Seventy-two percent of the surveyed patients believed the main cause of their diabetes was stress, and 56% believed their disease was caused by diet. Forty-five percent attributed their disease to heredity, 21% to family problems or worry, 13% believed chance or bad luck caused their disease, and 12 % believed their personal behavior or lifestyle (smoking and or diet) was the causative factor of their disease. Subjects who reported having control over their disease had lower total and low-density cholesterol and lower blood pressure. Additionally, those who believed they had greater treatment control over their illness had significantly lower fasting blood glucose and hemoglobin A1C, compared to subjects reporting concern about their diabetes. Multivariate logistic regression analyses demonstrated that: 1) subjects’ concern about their illness was a significant predictor of BMI; 2) subjects’ perception of control over their illness and concern about illness were predictors of fasting blood glucose; 3) subjects’ perception of treatment to control illness was a predictor of total cholesterol; 4)

subjects' understanding of illness was a predictor of arterial blood pressure. A more favorable objective measure of diabetes was associated with positive beliefs of subjects' ability to control of disease.

Healthcare provider illness perception may also have an impact on health outcomes in chronic disease or pre-chronic disease states. While there is not a great body of literature in this area, Diabetes Attitudes, Wishes and Needs (DAWN), a large cross-sectional study, is worthy of mention. The DAWN study aimed to examine both patient- and provider-psychosocial problems, alongside barriers to effective self-care and resources for eliminating these barriers. The study used face-to-face and telephone questionnaire interviews with both diabetic patients and both generalist and specialist healthcare providers. Questionnaires included the WHO-5 Wellbeing index (Bonsignore, Barkow, Jessen, & Heun, 2001) and additional questions developed specifically for the study. The study sample consisted of subjects from 13 countries of which patient subjects had either type 1 or type 2 diabetes. The data collected consisted of patient perception of access to care and quality of care, as well as healthcare provider perception of their personal practice behaviors and treatment-related attitudes.

Study findings revealed many similar responses among patients and providers. Diabetes regimen adherence among patients was reported as low with the exception of those under the care of a provider in India. The lowest overall adherence was for diet and exercise. Provider estimates of patient self-care activities fell significantly below patient reported self-care behaviors. Interestingly, both providers and patients reported diabetes related worries, with providers indicating that most patients had psychological problems that affected diabetes self-care, as well as a lack of resources to manage these problems.

The EUCCLID study is a prospective European study proposed to examine care and complications in people with type 2 diabetes in primary care. The study is composed of three secondary studies examining actual clinical practice, patient's perception of diabetes care, and general practitioners' perceptions of diabetes care (Bobbink et al., 2007). The study sample will include approximately 12,000 patients. While this study is ongoing, it is hoped that findings will shed light on providers' perceptions of barriers to effective delivery of diabetes care.

The Behavioral Domain and Pre-diabetes

Physical Activity

About 25% of adults 45 years old and older have pre-diabetes (Benjamin, Valdez, Geiss, Rolka, & Narayan, 2003; Dunstan et al., 2002; Glumer, Jorgensen, Borch-Johnsen, 2003), and many of these individuals will develop type 2 diabetes unless they receive and adhere to appropriate medical care. Regular participation in physical activity (PA) in combination with modest weight loss can prevent development of type 2 diabetes. Evidence suggests that participating in 150 minutes of moderate physical activity (PA) per week in combination with 5 to 10 percent weight loss will prevent or delay the development of type 2 diabetes and help maintain weight loss in patients with pre-diabetes (ADA, 2010; Hamman et al., 2006; Pan, 1997). The ADA published guidelines suggest a weight maintenance program in the prevention of type 2 diabetes. While benefits associated with PA in pre-diabetes are widely published, there are very few data available on the actual rates of participation in PA among patients with pre-diabetes. It is also unknown how PA affects the quality of life in individuals with pre-diabetes,

although quality of life has been shown to be improved in other patient populations through increased participation in PA (Bize, Johnson & Plotnikoff, 2007).

The Finnish Diabetes Prevention Study (DPS) is a randomized controlled trial (RCT) of diet and exercise as interventions to prevent onset of type 2 diabetes. Study subjects are diagnosed with pre-diabetes. Findings from this study demonstrate a significant benefit of adoption of improved nutrition and PA as a successful prevention intervention (Lindstrom et al., 2003). The Diabetes Prevention Program (DPP), an even larger RCT was able to reproduce the same results as the DPS, finding that PA and diet or weight reduction of at least 7% was more effective compared to a medication intervention in the prevention of type 2 diabetes (Diabetes Prevention Program Research Group, 2002). In the DPP study, 30 minutes of exercise a day coupled with a 5% to 10% weight reduction produced a 58% reduction in the development of diabetes. These 2 important studies support the basis for the ADA's PA guidelines recommendations in patients with a diagnosis of pre-diabetes.

Taylor et al. (2010) conducted a cross-sectional study to determine if differences exist between health related quality of life in individuals with pre-diabetes who were physically active compared to individuals with pre-diabetes who were not physically active. The researchers defined physically active as achieving 600 MET minutes or more per week. The study sample consisted of English-speaking residents of Northern Alberta, Canada who were currently participating in a pre-diabetes education class, were 18 years of age or older, and diagnosed by a physician or nurse with pre-diabetes, IFG, or IGT. Survey questions included demographic, current health related items, current self-

reported activity levels, and health related quality of life assessed by the RAND-12 Health STATUS Inventory (Hays, 1998).

A total of 232 surveys were returned, revealing that 38% of the participants were meeting the recommended PA guidelines. Multivariate analyses were conducted adjusting for covariates including age, gender, income, BMI, and smoking. Findings indicated that among those achieving PA guidelines physical and mental health were rated significantly higher compared to those not achieving the recommended PA guidelines.

Physical inactivity and obesity result in insulin resistance that stresses beta cells, causing increase insulin secretion. Beta cell dysfunction is an important early pathophysiologic defect in type 2 diabetes, and it begins in the pre-diabetes phase of disease development (DeFronzo, 2009). Increased PA in individuals diagnosed with pre-diabetes slows or halts disease progression, and has a positive effect on physical functioning and health related quality of life.

Smoking

There are limited data on the effect of smoking on pre-diabetes, although there is an abundance of evidence related to the effects of smoking on diabetes, as well as smoking in combination with diabetes as a risk factor for chronic cardiovascular disease. The ADA (2010) published guidelines identify smoking as one of several risk factors for diabetes. Cigarette smoking increases the risk of type 2 diabetes (Xie, Liu, Wu, & Wakuij, 2009; Willi, Bodenmann, Ghali, Faris, and Cornuz, 2007).

In the United Kingdom Prospective Diabetes Study, smoking was reported as one of the major risk factors in people with diabetes for cardiovascular disease (United Kingdom Prospective Diabetes Study Group, 1998). More recently, research has focused on the direct impact of smoking on diabetes incidence. There is growing consensus that individuals that smoke are also prone to insulin resistance and exhibit many aspects of insulin resistant syndrome (Eliasson, 2003)

Evidence also suggests that cigarette smoking has a negative effect on glucose and lipid metabolism in people with diabetes (Patsch, 1992; Jeppesen, 1995; Borggreve, DeVries, & Dullart, 2003; Despre, & Lemieux, 2006). Findings from the Health Professionals Study showed the risk for diabetes among men that smoked at least 25 cigarettes a day was higher compared to non-smoking men (Rimm et al., 1995). Similar results were found in another study conducted by Wannamethee, Shaper, and Perry (2001) which included a 17-year follow-up showing a reduction in risk of diabetes around year five with smoking cessation, and a normalization of risk by 20 years after smoking cessation. Similar results have been replicated in other smoking cessation studies (Manson et al., 2000; Ko et al., 2001).

Alcohol Consumption

Much of the literature denies any untoward effect of moderate alcohol consumption in type 2 diabetes (Maclure, 1993; Koppes, Dekker, Hendriks, Bouter, & Heine, 2005), and evidence is lacking on alcohol consumption in patients diagnosed with pre-diabetes. It is thought that the inverse relationship between moderate alcohol consumption and type 2 diabetes may be attributed to lower levels of both inflammatory markers and endothelial

dysfunction (Meigs, Hu, Rafai, & Manson, 2004; Hu, Meigs, Li, Rafai, & Manson, 2004). While some have hypothesized that moderate alcohol consumption improves insulin sensitivity, data are inconsistent in this area (Davies et al., 2002; Bell, Myer-Davies, Martin, D'Agostino, & Haffner, 2000). Another mechanism that has been hypothesized is lower BMI and less weight gain in women is related to moderate consumption of alcohol (Wannamethee, Field, Colditz, & Rimm, 2004). Lower weight gain and lower BMI is related to decreased risk of type 2 diabetes, but additional research is needed to offer a comprehensive explanation of how moderate alcohol consumption is linked directly to type 2 diabetes risk.

Beulens et al. (2008) conducted a nested case control study to examine the relationship between adiponectin concentration, biomarkers of inflammation, endothelial dysfunction, insulin resistance and alcohol consumption. Cases consisted of 705 women with diabetes and were matched to 787 control women. Data consisted of questionnaire responses and laboratory values. Increased adiponectin concentrations explained a significant decreased risk for type 2 diabetes with a moderate amount of alcohol consumption, while the other markers (inflammation, endothelial dysfunction, and fasting insulin) were not significantly associated with moderate alcohol intake and decreased risk of type 2 diabetes. Additional study findings have also shown that moderate alcohol consumption results in increased adiponectin concentrations (Beulens et al., 2007; Pischon et al., 2005), strengthening acceptance of how moderate alcohol intake may modify type 2 diabetes risk.

The Biological Domain and Pre-diabetes

Disordered Glucose Metabolism

The biological domain includes physiological factors related to disordered metabolic functioning that affect health outcomes such as pre-diabetes. Few studies focus on disordered glucose metabolism and pre-diabetes. Most research studies focus on metabolic functioning and diabetes or type 2 diabetes. Disordered glucose metabolic functioning can result in Islet cell dysfunction and peripheral insulin resistance (Giugliano, Ceriello & Esposito, 2008). Islet cell dysfunction and peripheral insulin resistance prohibit glucose from entering cells, and result in high levels of glucose in the blood (Gannon & Nuttall, 2006), namely hyperglycemia. This hyperglycemic state can cause target organ damage including cardiovascular disease, retinopathy, neuropathy and nephropathy (Giugliano, Ceriello & Esposito, 2008). The untoward effect of disordered metabolic functioning serves as an indicator of pre-diabetes.

Health Outcome

Pre-diabetes

Fasting blood glucose is also known as fasting plasma glucose and is a reliable measure for diabetes and pre-diabetes (Stern, Williams, & Haffner, 2002; McNeely, Boyko, Leonetti, Kahn, Fujimoto, 2003). ADA defines pre-diabetes as IFG with a fasting glucose concentration of 100mg/dL but less than 126mg/dL. Historically the oral glucose tolerance test (OGTT) has been the gold standard to assess pre-diabetes and type 2 diabetes, however, OGTT is inconvenient and time consuming. Fasting blood glucose testing in addition to fasting lipid profile, medical history and anthropometric measures

have been shown to be effective measures of pre-diabetes and type 2 diabetes (Stern et al., 2002; McNeely et al., 2003; Aekplakorn et al., 2006; Wannamethee et al., 2005; Kanaya et al., 2005; Lindstrom & Tuomilehto, 2003). Evidence suggests some limitations of fasting blood glucose, in particular the day-to-day variability of these values which has been shown to be between 12% to 15% (Petersen et al., 2005) and the variability in values affected by some laboratories (Christopher et al., 2008). These findings point to the need to combine fasting blood glucose with additional diagnostics when making the diagnosis of pre-diabetes.

Summary

Pre-diabetes is a disease state that precedes development of type 2 diabetes. Many factors have been associated with prevention of type 2 diabetes, but the research on pre-diabetes patients is still largely incomplete. Although it may be theoretically sound to generalize findings from studies of patients with type 2 diabetes to patients with pre-diabetes, there remains a tremendous need for additional research to ensure a thorough understanding of disease mechanisms, methods for prevention, and the effect of this important disease state on overall health and well-being.

CHAPTER 3

METHODOLOGY

The purpose of this study was to identify individual, psychosocial, behavioral, environmental and physiologic factors that are associated with pre-diabetes in AA compared to White subjects enrolled in the REasons for Geographic and Racial Differences in Stroke (REGARDS) study cohort. The design used for this study was a cross-sectional descriptive analysis of the REGARDS data including subjects enrolled from 2003 to 2007. The study's research questions were:

1. Is there a difference in the odds of pre-diabetes in people living in the stroke belt compared to people living outside the stroke belt?
2. Does race (AA) increase the odds of pre-diabetes after controlling for selected independent variables such as age, sex, regionality, SES (income level, education), cigarette smoking, alcohol use, intense physical activity and illness perception in the REGARDS study cohort?
3. Do older age and gender increase the odds of pre-diabetes in the REGARDS study cohort?
4. Does lower socioeconomic status increase the odds of pre-diabetes in AAs compared to Whites after controlling for covariates such as lifestyle choices and illness perception?

5. Do lifestyle choices, smoking, intense physical activity and alcohol intake along with illness perception increase the odds of pre-diabetes in the REGARDS study cohort?

This chapter discusses the methods that were used to answer these research questions, including a review of the original methods supporting REGARDS, as these influenced our methods, and ultimately our findings.

Research Design

A subset of data from the REGARDS study was used in this study. The REGARDS study is an ongoing national population based longitudinal cohort study. The study was designed to explore the possible causes for geographic and racial differences in stroke mortality. The primary aims of REGARDS are to provide national data on stroke incidence and stroke mortality and examine geographic and racial differences in these measures (Howard et al., 2005). Additional aims of the study include providing national data on stroke prevalence and risk factors; assessing the extent that geographic and racial variation, case fatalities, and mortality correlate with variations in risk factor prevalence; assessing the magnitude of geographic and racial variations on prevalence of stroke risk factors; assessing the effect of migration on stroke incidence, case fatality, and mortality; and, to create a resource for future studies by creating a blood, urine and a DNA repository (Howard et al., 2005).

REGARDS is led by investigators at the University of Alabama at Birmingham (UAB) and comprises several participating institutions across the US. The primary operations consist of an Operations Center, Survey Research Unit (SRU) and an

Executive Committee that includes all principal investigators from the subcontracting institutions. The study is funded through a grant from the National Institutes of Health's National Institute of Neurological Disorders and Stroke (NINDS). A central laboratory at the University of Vermont and an electrocardiogram-reading center at Wake Forest University are also components of REGARDS. Examination Management Services, Inc. provides the in-home exam component of the study and a team of stroke experts from across the US provides stroke adjudication services.

Protection of Human Subjects

REGARDS is approved by the Institutional Review Board (IRB) of the University of Alabama at Birmingham (UAB), all collaborating IRBs, and is supported by an external observation study monitoring board appointed by the funding agency. This secondary analysis study received approval of the REGARDS executive committee, followed by UAB IRB approval. We used REGARDS 2003 through 2007 data that was de-identified to ensure confidentiality of subjects.

Setting

The setting for the REGARDS study was in-home participant visits throughout the 48 contiguous US states, as well as Survey Research Unit (SRU) computer- assisted telephone interviews (CATI) for collection of medical histories. CATI were conducted during the day, evening, weekday, and weekend calling shifts (Howard et al., 2005). The in-home setting was used to collect physical measurements, blood and urine specimens, as well as collection of participant self-administered questionnaires after in-home visits

were completed. EMSI technicians conducted in-home visits Monday through Thursday mornings to enhance fasting status, specimen processing and specimen shipping, and all subjects completed written informed consent prior to in-home examinations.

This study was a secondary analysis of the REGARDS database and took place entirely at the UAB. The UAB School of Public Health collaborating investigators on our study maintained strict control of the REGARDS database and its use for this project to ensure data integrity

Population and Sample

REGARDS was established using a commercially available nationwide list of potential subjects purchased from Genesys, Inc. The list was stratified to reflect the desired age, race, sex, and geographic strata. Sample listings were purchased in batches of 50,000 households to ensure the most current telephone numbers and addresses. The desired recruitment goal was 30,000 people older than 45 years, equally divided among AAs, Whites, men and women (Howard et al., 2005). The study sample was limited to the 48 contiguous US states. Twenty percent of the study sample was targeted to be selected from the coastal southeastern US Stroke Buckle, and 30 % from the Stroke Belt. The remaining 50 % were selected from the remaining 40 states. The final cohort of 30,239 comprised 21% from the stroke buckle, 35% from rest of stroke belt area, and 44% from the other 40 contiguous states, and is 42% AA, and 55% female.

Inclusion criteria were used to support the mail and telephone contact databases. Willing participants were asked demographics and medical history. A letter and study brochure was sent to potential participants 2 weeks before telephone contact. Personnel

from the SRU made up to 15 contact attempts during day, evening, weekday and weekend calling shifts. Upon reaching a household resident, the household was enumerated and one resident aged 45 years or older was randomly selected and screened for eligibility. Exclusion criteria included race other than AA or White, active treatment for cancer, medical conditions that would prevent long-term participation, cognitive impairment judged by the telephone interviewer, residence in or currently on a waiting list for a nursing home, or inability to communicate in English. If potential participants responded ‘don’t know’ to questions about medical conditions they were considered eligible (Howard et al., 2005).

The existing data from the study cohort screened and enrolled in the 2003 to 2007 period made up the cohort that was used for this study. Because the focus of this study was factors associated with pre-diabetes, an additional exclusion criterion was added: Participants with diabetes (defined as blood glucose ≥ 126 mg/dL fasting or > 200 mg/dL non-fasting, current diabetes treatment with insulin or pills, or self-reported diabetes).

Power Analysis

In the design of the REGARDS study, investigators performed a power analysis using data from the Greater Cincinnati Northern Kentucky Stroke Study (GCNKSS) (Howard et al., 2005; Broderick et al., 1998). The GCNKSS sample of AAs and Whites allowed for adequate race representation in a biracial population, and estimations of anticipated stroke incident rates in both races (Kissela, 2004), producing the number of anticipated strokes per 1,000 person-years exposure for male and female AAs and Whites. The detectable hazard ratio was calculated as a function of the prevalence of the predictor risk

factor. Details of the power analysis have been reported elsewhere (Howard et al., 2005). Since our study is a secondary data analysis, our sample size was determined a priori by the REGARDS study methods.

Instruments

A variety of instruments was used to collect data in REGARDS. REGARDS investigators included methods to ensure the accuracy and consistency of the data collected, including standardized data collection procedures and standardized training of personnel. Some of the study variables such as smoking status were collected as a single item on a questionnaire, which precludes reliability analysis. Measures for fasting blood glucose were based on the guidelines and procedures that have been established as being valid by the ADA (ADA, 1995-2010). Because our study used data from the REGARDS database, cited below is a brief overview of the methods for data collection used in REGARDS.

Computer-Assisted Telephone Interviews (CATI)

The format and content of data collected by CATI, was similar to previous studies of cardiovascular and cerebrovascular risk factors (Howard et al., 2005), such as both The Framingham Study (Kannel, 2000) and The Cardiovascular Health Study (Fried, 1991). Telephone interviews lasted for 30 to 45 minutes. Some of the variables collected by CATI included, age, sex, race, cigarette smoking status, alcohol status, physical activity level, access to care, and SES (defined by income and education).

MOS Short Form-12

General health status was collected using the MOS Short Form-12 during the CATI. The MOS Short Form-12 (Ware & Kosinski, 1996), a 12-item short-form health survey: has demonstrated good internal consistency reliability with a Chronbach's alpha exceeding the recommended level of 0.70 and acceptable construct validity in patients with low back pain (Luo et al., 2003). The tool also has been used successfully in patients with specific diagnoses (Luo et al.; Johnson & Maddigan, 2004), and in patients of various ages and ethnic groups (Hoffmann et al., 2005). Lastly, the instrument has been used successfully in telephone surveys (Hoffmann et al.).

In-Home Assessment

During the 45 to 60 minute in-home assessment, medication inventory and physical measurements were assessed using standardized methods, and venipuncture was performed to collect blood specimens. Additionally, a self-administered questionnaire was left with subjects to complete on their own time after the in-home assessment (the focus of this questionnaire was on the subject's usual source of medical care).

Data Handling and Processing in Regards

Blood samples from REGARDS were centrifuged at 20,000g at room temperature and stored in a refrigerator until picked-up for shipment to the core lab by courier (Howard et al., 2005). Samples were shipped overnight on ice. The signed informed consent, bar code labeled ECG and other paperwork were sent to the central laboratory, and blood samples had to be received within 24 hours or redrawn. Within the core lab, technicians

logged samples and re-centrifuged the serum and plasma. Study paperwork was sent to the Operations Center and ECGs were sent to the ECG Reading Center (Howard et al., 2005).

Procedure for Collecting Data

The REGARDS database was used to conduct this cross-sectional descriptive study after IRB approval. Data for our study consisted of 3 parts: CATI data, in-home assessment data, and self-administered questionnaire data.

Pre-diabetes was the outcome variable for our study. The primary predictor variable was race. Individual domain factors age, gender, and SES (level of education, level of income), and the environmental domain variable regionality served as covariates. Additional covariates were factors in both the psychosocial and behavioral domains, including perception of health or self-reported health status, smoking status, alcohol consumption status, and participation in intense physical activity.

Data Analysis

SAS Software Version 9.1 (SAS Institute, Inc., Cary, NC) was used to analyze data for our study. The analytic strategy was first to examine the frequency and percentage distributions of each variable and then to examine multivariate relationships between the outcome variable and each covariate of interest. Variables with a p -value for interaction ≤ 0.050 were considered significant. Multivariable logistic regression models were used to calculate odds ratios and corresponding 95% confidence intervals for the association between pre-diabetes and covariates of interest. Multiple logistic regression was used to

address these research questions because the dependent variable was dichotomous (pre-diabetes: no/yes). The association between predictor variables was considered in a set of incremental logistic models, where associations with pre-diabetes were considered, 1) with race and region, 2) with further adjustment for age and sex, 3) after adjustment for indices of SES (income and education), 4) after adjustment for lifestyle choices (smoking, alcohol and intense physical activity), and, 5) after adjustment for illness perception- self-reported health status.

CHAPTER 4

FINDINGS

The findings from the analysis of data relevant to the five research questions are reviewed in this chapter. The total REGARDS cohort consisted of 30,239 subjects. The following cases were excluded from the cohort for this study (Figure 3). Individuals with data anomalies (n = 56); cases that were non-fasting (n = 4,321); individuals who self-reported use of insulin or oral glucose medications for glucose control (n = 4,315); individuals with no documented fasting glucose (n = 765) and cases that had blood glucose values ≥ 126 mg/dL (n = 893). Our final sample consisted of 4,768 participants with pre-diabetes, and 15,121 participants that were normoglycemic for a total analysis population of 19,889. The distribution of demographics and risk factor characteristics is provided in Table 1. Additional descriptive statistics for variables of interest are listed in Table 2.

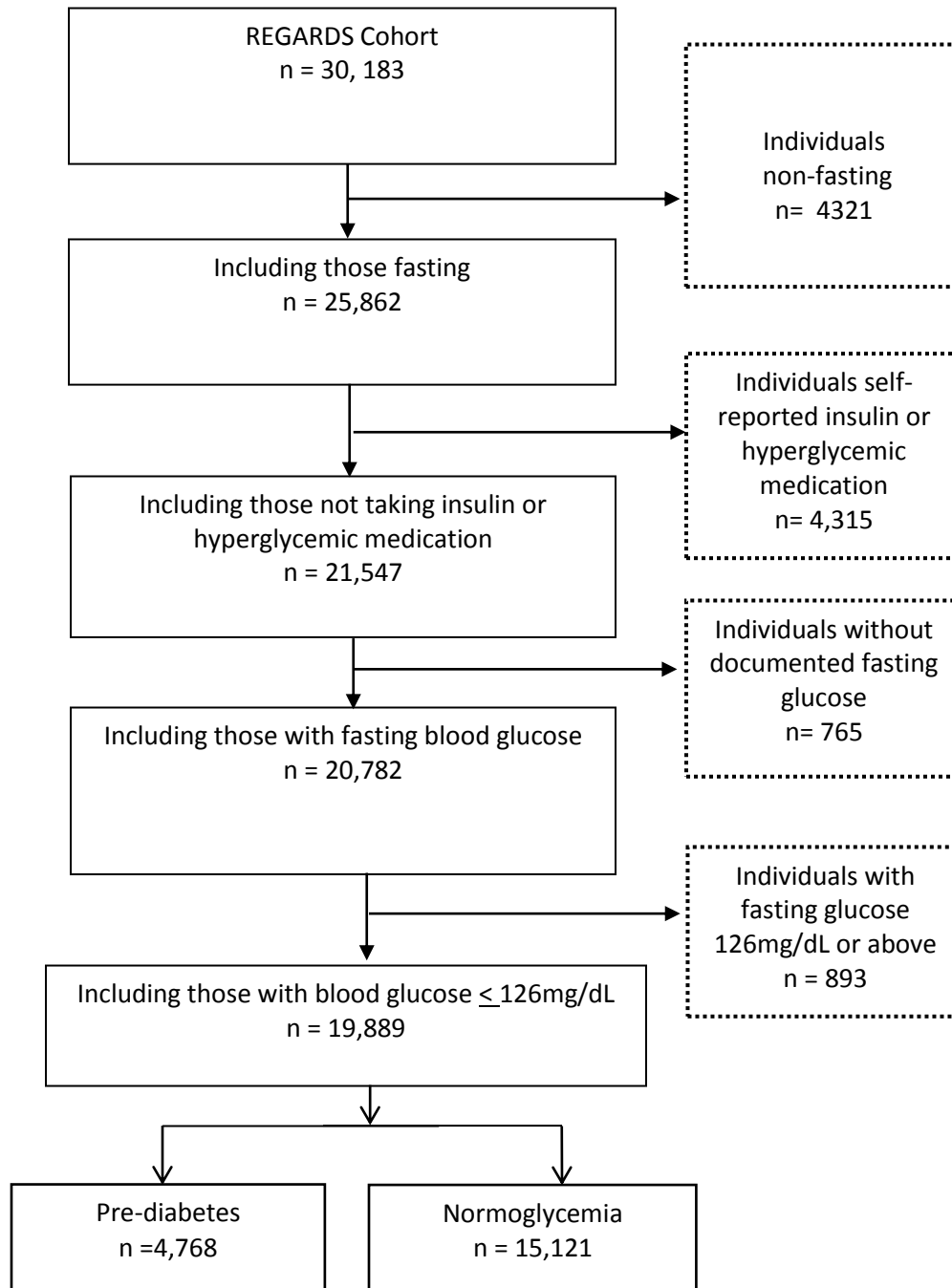


Figure 3. Exclusionary cascade for normoglycemia and prediabetes, excluding diabetes.

Note. Adapted from “Prehypertension, racial prevalence, and its association with risk factors: Analysis of Reasons for Geographic and Racial Differences in Stroke (REGARDS) study” by Glasser, S. P. and Judd, S., 2010, *American Journal of Hypertension*, 24, p. 195. Copyright 2010 by Nature Publishing Group. Adapted with permission.

Table 1

Descriptive Statistics with percentages and means.

			Race		Region	
			White	AA	SB	Not SB
			n= 12777	n= 7112		
Demo	Age mean		65 + 10	63 +10	64 + 9	65 +10
	Sex	Male	6139	2624	4601	4162
			48%	37%	42%	47%
		Female	6638	4488	6394	4732
			52%	63%	58%	53%
SES	Income	<\$20K	1359	1697	1836	1220
			11%	24%	17%	14%
		\$20K-\$34K	2779	1828	2549	2058
			22%	26%	23%	23%
		\$35K-\$74K	4235	1993	3388	2840
			33%	28%	31%	32%
		\$75K+	2854	739	1848	1745
			22%	10%	17%	20%
		Refused	1550	855	1374	1031
				12%	12%	13%
	education	<HS	803	1174	1211	766
			6%	17%	11%	9%
		HS Grad	3058	1981	2902	2137
			24%	28%	26%	24%
		Some College	3410	1937	2965	2382
		27%	27%	27%	27%	
		College Grad	5501	2014	3913	3602
			43%	28%	36%	41%
Lifestyle	Smk	Never	5869	3243	5108	4004
			46%	46%	47%	45%
		Past	5261	2543	4174	3630
			41%	36%	38%	41%
		Current	1605	1292	1671	1226
			13%	18%	15%	14%
	Alc	None	6674	4821	6853	4642
			53%	69%	63%	53%
		Mod	5198	1927	3492	3633
			41%	28%	32%	42%
	Heavy	722	199	482	439	
		6%	3%	5%	5%	
Phy Act	0	3798	2482	3426	2854	
		30%	36%	32%	33%	
	1-3	4638	2578	3979	3237	
		37%	37%	37%	37%	
	4+	4152	1940	3413	2679	
		33%	28%	32%	31%	
Illness Perception	S. R Health Status	Excellent	2927	860	2015	1772
			23%	12%	18%	20%
		Very good	4849	1934	3652	3131
			38%	27%	33%	35%
		Good	3735	2885	3730	2890
			29%	41%	34%	33%
		Fair	1022	1239	1322	939
	8%	18%	12%	11%		
	Poor	227	179	258	148	
		2%	3%	2%	2%	

Table 2

Odds Ratios and 95% Confidence Intervals for pre-diabetes with race, region, demographic, socioeconomic status, lifestyle factors and illness perception

		Univar	R/R [†]	+Demo*	+SES [†]	+Lifestyle [‡]	+IP [€]
Race/	Stroke	1.18	1.20	1.24	1.22	1.23	1.22
Reg	Belt	1.10-1.26	1.13-1.28	1.16-1.32	1.15-1.31	1.15-1.32	1.14 -1.31
	Black	1.28	1.29	1.36	1.33	1.32	1.27
	Race	1.19-1.36	1.21-1.38	1.27-1.46	1.24-1.43	1.23-1.42	1.18- 1.37
Demo	Age	1.05		1.06	1.06	1.05	1.06
		1.02-1.09		1.03-1.10	1.03-1.10	1.01-1.09	1.02- 1.10
	Sex	1.32		1.37	1.38	1.37	1.37
		1.24-1.41		1.28-1.46	1.29-1.48	1.28-1.47	1.27- 1.47
SES	Income	<\$20k			1.00	1.00	1.00
		ref			ref	ref	ref
		\$20K-			0.90	0.90	0.92
		\$35K			0.81-1.00	0.81-1.01	0.82- 1.03
		\$35k-			1.00	0.1.00	1.04
		\$75K			0.90-1.12	0.89-1.12	0.93- 1.16
		\$75K+			0.99	0.97	1.03
		0.75-0.94			0.87-1.12	0.85-1.11	0.90- 1.18
		Refused			0.92	0.94	0.96
		0.75-0.96			0.81-1.05	0.82-1.07	0.84- 1.09
	Edu	<HS			1.00	1.00	1.00
		ref			ref	ref	ref
		HS			1.03	1.03	1.06
		Grad			0.91-1.16	0.91-1.17	0.93- 1.20
		Some			0.97	0.99	1.02
		College			0.86-1.10	0.87-1.12	0.90- 1.16
		College			0.85	0.88	0.92
		Grad			0.75-0.97	0.77-1.00	0.81- 1.05
Life style	Smk	Never				1.00	1.00
		ref				ref	ref
		Past				1.23	1.21
		1.22-1.41				1.14-1.32	1.12- 1.31
		Current				1.15	1.11
		1.13-1.37				1.03-1.27	1.00- 1.23
	Alc	None				1.00	1.00
		ref				ref	ref
		Mod				1.00	1.01
		0.91-1.05				0.93-1.08	0.94- 1.09
		Heavy				1.21	1.23
		1.03-1.39				1.03-1.42	1.05- 1.44
	Phy Act	0				1.00	1.00
		ref				ref	ref
		1-3				0.89	0.92
		0.81-0.95				0.82-0.97	0.85- 1.00
		4+				0.80	0.85
		0.76-0.90				0.74-0.87	0.78- 0.93

Table 2 (Continued)

			Univar	R/R [?]	+Demo [*]	+SES [†]	+Lifestyle [‡]	+IP [€]
Illness Perception	S.R. Health Status	Excellent	1.00					1.00
			ref					ref
		Very	1.30					1.28
		Good	1.18-1.44					1.15- 1.42
		Good	1.60					1.49
			1.45-1.77					1.35- 1.66
		Fair	1.67					1.50
			1.48-1.89					1.31- 1.71
Poor	1.94					1.72		
			1.55-2.43				1.36- 2.19	

Note. [?] Adjusts for race and region. ^{*} Adjusts for race, region plus demographics (age and gender). [†] Adjusts for race, region, demographics plus SES (education and income). [‡] Adjust for race, region, demographics, SES plus lifestyle (smoking, alcohol, physical activity). [€] Adjusts for race, region, demographics, SES, lifestyle plus illness perception.

The mean age of individuals with pre-diabetes living in or outside the stroke belt (64 years vs. 65 years; $p < .0001$), as well as mean ages among AAs and Whites (63 years vs. 65 years; $p < .0001$) while significantly different, were not clinically dissimilar. In this study there were fewer AA subjects, 7,112, (36%) overall, as compared to White subjects 12,777, (64%; $p < 0.0001$), and there were significantly fewer AA subjects (33%) as compared to White subjects (67%; $p < 0.0001$) living in the stroke belt. The study did not include any individuals with diabetes. The final analysis population was 37% AA males, 63% AA females, 48% White males, and 52% White females ($p < 0.0001$).

Statistically significant differences were found in measures of SES (education and income) between AAs and White subjects with pre-diabetes, and stroke belt and non-stroke belt residents. In general, AA pre-diabetes subjects were less educated than White subjects ($p < 0.0001$), and had lower income overall than White subjects ($p < 0.0001$). Additionally, stroke belt pre-diabetes subjects had significantly lower income than non-

stroke belt subjects ($p < 0.0001$), and were significantly less educated than subjects living outside the stroke belt region ($p < 0.0001$).

Significant differences were also observed in smoking history between AAs and White subjects with pre-diabetes ($p < 0.0001$), as well as subjects living in or outside the stroke belt ($p < 0.0001$), although these findings are not clearly clinically different.

Almost half of pre-diabetes subjects (AAs 46%; Whites 46%) denied smoking in the past, and less than 20% (AAs 18% and Whites 13%) were current smokers. Almost 50% of pre-diabetes subjects living inside (47%) and outside (45%) the stroke belt denied a smoking history .

African American pre-diabetes subjects consumed significantly lower amounts of alcohol compared to Whites ($p < 0.0001$), while participants residing in the stroke belt consumed significantly less alcohol than non-stroke belt residents ($p < 0.0001$). Based on self-report, a substantial majority of pre-diabetes AA (69%) and White (53%) subjects reported no alcohol use at all, as did a majority of pre-diabetes participants living inside (63%) and outside (53%) the stroke belt.

White subjects with pre-diabetes were significantly more likely to be physically active than AA pre-diabetes subjects ($p < 0.0001$), while no difference was found between degree of physical activity among stroke belt and non-stroke belt participants. A minority of pre-diabetes participants (AAs 28%, Whites 33%) reported intense physical activity four or more times/week.

Illness perception as self-reported health status demonstrated significantly higher levels of health status among White subjects with pre-diabetes as compared to AA subjects with pre-diabetes ($p < 0.0001$), as well as significantly higher levels of health

status among non-stroke belt pre-diabetes residents as compared to stroke belt residents ($p < 0.0001$). White subjects with pre-diabetes were more likely to report their health status as “excellent” or “very good” as compared to AA subjects with pre-diabetes.

Statistically significant ($p < 0.05$) univariate differences in pre-diabetes rates existed in all the characteristics in Table 2 with the exception of:

- income categories (\$20 – 35 thousand dollars/year [$p = 0.3747$]);
- \$35-75 thousand dollars/year ($p = 0.3219$);
- \$75 thousand dollars and above/year ($p = 0.0703$);
- Refused report of income ($p = 0.2156$);
- education categories (high school graduate ($p = 0.1244$);
- some college ($p = 0.5759$);
- exercise categories 1-3 times/week ($p = 0.3736$); and,
- smoking category current ($p = 0.0684$).

Factors that had the largest impact ($p < 0.0001$) on likelihood of pre-diabetes were region, race, gender, education category “college graduate,” and smoking category “past.”

In the following section, each research question is identified, and the results are presented. We used multivariable logistic regression to describe the association of risk factors for pre-diabetes.

Research Question 1

The first research question dealt with effect of regionality on odds of pre-diabetes: Is there a difference in the odds of pre-diabetes in people living in the stroke belt compared to people living outside the stroke belt?

Multivariable modeling adjusted for region revealed residency in the stroke belt (OR 1.20; 95% CI; 1.13, 1.28) was associated with increased odds of pre-diabetes when compared to residency in the remainder of the United States (Table 2). People living in the stroke belt were more likely to have pre-diabetes across all adjusted models (demographic, SES, lifestyle and illness perception adjusted models).

Research Question 2

The second research question dealt with whether race (AA) increased the odds of pre-diabetes after controlling for covariates of interest: Does race (AA) increase the odds of pre-diabetes after controlling for selected independent variables such as age, sex, regionality, SES (income level, education level), cigarette smoking, alcohol use, intense physical activity and illness perception in the REGARDS study cohort?

African American race (OR 1.28; 95% CI; 1.19, 1.36) was associated with higher odds of pre-diabetes compared to Whites in crude modeling. In the adjusted models AAs were associated with even greater odds of pre-diabetes, except in the illness perception fully adjusted model (OR 1.27; 95% CI; 1.18, 1.37).

Research Question 3

The third research question dealt with whether physiologic factors (older age and gender [male]) increased the odds of pre-diabetes: Do older age and gender (male) increase the odds of pre-diabetes in the REGARDS study cohort?

A ten-year increment in age was nominally associated with increased odds for pre-diabetes across all adjusted models:

- demographic and SES (OR 1.06; 95% CI; 1.03, 1.10);
- lifestyle (OR 1.05; 95% CI; 1.01, 1.09);
- illness perception (OR 1.06; 95% CI; 1.02, 1.10).

However, gender (male) was associated with increased odds of pre-diabetes after adjusting for other covariates including demographics (OR 1.37; 95% CI; 1.28, 1.46), SES (OR 1.38; 95% CI; 1.29, 1.48), lifestyle (OR 1.37; 95% CI; 1.28, 1.47), and illness perception (OR 1.37, 95% CI; 1.27, 1.47).

Research Question 4

The fourth research question dealt with whether SES increased the odds of pre-diabetes: Does lower SES increase the odds of pre-diabetes after controlling for covariates such as lifestyle choices and illness perception?

Multivariable modeling revealed that all ranges of income did not increase the odds of pre-diabetes after controlling for lifestyle choices and illness perception. In crude adjusted models some income ranges were protective for pre-diabetes (95% CI; \$20-\$35 thousand dollars/year [OR 0.87; 0.78, 0.96], \$35-\$75 thousand dollars/year [OR 0.92; 0.83, 1.01], \$75 thousand dollar/year and above [OR 0.84; 0.75, 0.94], and refused [OR 0.85; 0.75, 0.96]). Income also remained protective for pre-diabetes across most adjusted models.

- SES adjusted model (95% CI; \$20K- \$35K/year [OR 0.90; 0.81, 1.00]), \$75k and above/year [OR 0.99; 0.87, 1.12], refused [OR 0.92; 0.81, 1.05]);
- lifestyle adjusted model (95% CI; \$20- \$35K/year [OR 0.90; 0.81, 1.01], \$75k and above/year [OR 0.97; 0.85, 1.11], refused [OR 0.94; 0.82, 1.07]); and,

- illness perception adjusted model (95% CI; \$20-\$35k/year [OR 0.92; 0.82, 1.03], refused [OR 0.96; 0.84, 1.09]).

The educational attainment category “college graduate” was protective for pre-diabetes compared to the referent, less than high school, across all adjusted models (95% CI, SES adjusted model [OR 0.85; 0.75, 0.97], lifestyle adjusted model [OR 0.88; 0.77, 1.00], illness perception adjusted model [OR 0.92; 0.81, 1.05]). There was no association between educational attainment category, high school and pre-diabetes and with the educational attainment category, “some college” in the illness perception adjusted model.

Research Question 5

The last research question dealt with the effect of lifestyle choices and illness perception on pre-diabetes: Do lifestyle choices (smoking, intense physical activity and alcohol intake) along with illness perception increase the odds of pre-diabetes in the REGARDS study cohort?

Smoking was associated with an increased odds of pre-diabetes in crude modeling for “past smoking” (OR 1.31; 95% CI; 1.22, 1.41), and “current smoking” (OR 1.25; 95% CI; 1.13, 1.37). Smoking was also associated with increased odds of pre-diabetes across the lifestyle “past smoking” (OR 1.23; 95% CI; 1.14, 1.32), “current smoking” (OR 1.15; 95% CI; 1.03, 1.27) and illness perception “past smoking” (OR 1.21; 95% CI; 1.12, 1.32), “current smoking” (OR 1.11; 95% CI; 1.00, 1.23) adjusted models.

Heavy alcohol consumption was associated with increased odds of pre-diabetes compared to the referent no alcohol consumption after adjustment for lifestyle (OR 1.21; 95% CI; 1.03, 1.42) and illness perception covariates (OR 1.23; 95% CI; 1.05, 1.44). In crude

modeling moderate alcohol intake (OR 0.98; 95% CI; 0.91, 1.05) had a protective effect for pre-diabetes. Physical activity had a protective effect for pre-diabetes across crude modeling “one to three times a week” (OR 0.88; 95% CI; 0.81, 0.95), and “four or more times a week” (OR 0.83; 95% CI; 0.76, 0.90). A protective effect was found for adjusted models lifestyle (“one to three times a week” [OR 0.89; 95% CI; 0.82, 0.97], “four or more times a week [OR 0.80; 95% CI; 0.74, 0.87]) and illness perception (“one to three times a week” [OR 0.92; 95% CI; 0.85, 1.00], “four or more times a week” [OR 0.85 95% CI; 0.78, 0.93]).

Illness perception, self-reported health status was associated with increased odds of pre-diabetes in both crude modeling and fully adjusted models. Self-reported health status of “poor” (OR 1.94; 95% CI; 1.55, 2.43) compared to the referent “excellent” had a higher odds of pre-diabetes than the other categories of “fair” (OR 1.67; 95% CI; 1.48, 1.89), “good” (OR 1.60; 95% CI; 1.48, 1.89) and “very good” (OR 1.30; 95% CI; 1.18, 1.44) compared to the referent “excellent” in crude modeling and fully adjusted models (“poor” [OR 1.72, 95% CI; 1.36, 2.19], “fair” [OR 1.50; 95% CI; 1.31, 1.71], “good” [OR 1.49; 95% CI; 1.35, 1.66], “very good” [OR 1.28; 95% CI; 1.15, 1.42]).

Summary

The purpose of this study was to explore factors associated with pre-diabetes in the REGARDS study cohort. Several factors were associated with risk for pre-diabetes. Chapter 5 will detail how study findings relate to results reported in the literature, and draw conclusions from this work, as well as implications for practice.

CHAPTER 5

DISCUSSION

A secondary data analysis was conducted to explore the factors associated with pre-diabetes in the REGARDS study cohort. The Expanded Biobehavioral Interactive Model, developed by Kang, Rice, Park, Turner-Henson, and Downs (2009) was used as a conceptual framework to guide the study. Data were analyzed using descriptive statistics, chi-square, and multiple logistic regression analysis. This chapter includes a discussion of findings as related to the five research questions; their relationship to the conceptual framework; and a discussion of the conclusions, implications for practice and recommendations.

Discussion Related to Findings

In this cohort study, the overall rate of pre-diabetes was 24% as diagnosed by fasting blood glucose. In 2005 to 2008, 35 % of adults 20 years old and above had pre-diabetes and 50% of adults 65 years old and above had pre-diabetes in the United States as diagnosed by IFG or hemoglobin A1C (USDHHS, 2011). This cohort population with pre-diabetes defined by fasting blood sugar is representative of these national statistics although our cohort population was 45 years old and above. These alarming rates justify the need for this study.

Research Question 1

Research Question 1 asked, is there a difference in the odds of pre-diabetes in people living in the stroke, belt compared to people living outside the stroke belt?

Univariate modeling revealed that residency in the stroke belt (OR 1.18; 95% CI; 1.10, 1.26) was associated with higher odds of pre-diabetes compared to residency outside the stroke belt. Across all adjusted models the odds of pre-diabetes were slightly increased for people living in the stroke belt compared to people living outside the stroke belt. The slight increase in odds of pre-diabetes across race and region (OR 1.20; 95%CI; 1.13, 1.28), demographic (OR 1.24; 95%CI; 1.16, 1.32), SES (OR 1.22; 95%CI; 1.15, 1.31), lifestyle (OR 1.23; 95%CI; 1.15, 1.32), and illness perception (OR 1.22; 95%CI; 1.14, 1.31) models suggest an association with increased odds of pre-diabetes and living in the stroke belt that is not explained by the covariates of interest alone. The fact that people living in the Stroke Belt were more likely to have pre-diabetes compared to people not living in the Stroke Belt suggests that living in the Stroke Belt region is a risk factor for pre-diabetes. This risk factor may be present due to environmental conditions, acculturation, or other unknown factors.

There are limited studies that exam the relationship between the Southeast region of the US or the Stroke Belt and diabetes or pre-diabetes. However, our results are congruent with the paucity of literature available. The CDC (2009) identified several southeastern states for high prevalence of diabetes. Most of the states identified are within the stroke belt region. Limited studies provide support for regionality as a modifiable risk factor for diabetes (Pearson et al, 2010; Voeks et al, 2008). Voeks et al.

(2008), using data from the REGARDS study, found that the odds of diabetes in AAs and Whites were significantly increased by living in the stroke belt in their study sample of 20,906 participants. The study's findings support those of Voeks et al. (2010) and Barker et al. (2011).

Pearson et al. (2010) examined regionality from a slightly different perspective but the findings were consistent with the current study. Pearson et al. (2010) analyzed data using multivariate regression techniques with adjustment for race, obesity, exercise, geographic latitude, and population density, finding a strong and consistent relationship between states with high particulate concentration and diabetes. Previous EPA data revealed that states with the highest particulate pollution were southern States (Person et al., 2010) with many being in the stroke belt region. A group of researchers from the CDC has pinpointed 644 counties in Alabama, Arkansas, Florida, Georgia, Kentucky, Louisiana, North Carolina, Ohio, Pennsylvania, South Carolina, Tennessee, Texas, West Virginia, Virginia, and Mississippi as areas of the US where rates of diabetes are greater than or equal to 11% of the population (Barker, Kirtland, Gregg, Geiss, & Thompson, 2011). The majority of states in the Stroke Belt region have a diabetes population greater than or equal to 11percent. Barker et al. (2011) have identified the "claw-shaped" region as the Diabetes Belt. This study supports the Diabetes Belt research reported by these researchers. While this study didn't examine particulate matter pollution directly, the study by Pearson et al. (2010) may offer some explanation for the study's findings in the same region of the US.

Research Question 2

Research Question 2 asked, does race (AA) increase the odds of pre-diabetes after controlling for selected independent variables such as age, sex, regionality, income level, education level, cigarette smoking, alcohol use, intense physical activity and illness perception in the REGARDS study cohort?

The “thrifty gene” theory has long been abandoned as a theory that explains the racial disparity of diabetes and pre-diabetes among AAs compared to Whites. However, our study found that AAs did have higher odds of having pre-diabetes compared to Whites in univariate analysis (OR 1.28; 95% CI; 1.19, 1.36). Some experts believe that genetic factors such as race may increase the risk of having diabetes (Konen, Summerson, Bell & Curtis, 1999) and pre-diabetes (Ping et al, 2005). Konen et al. (1999) conducted a cross sectional analysis of 304 adults with type 2 diabetes. The sample included 142 AAs. The researchers found that AA males and females had poorer metabolic control after adjustment for diabetes duration, and glycosylated hemoglobin compared to their White counterparts.

Researchers in the Atherosclerosis Risk in Communities Study examined fasting insulin levels as a predictor of diabetes between AAs and Whites. The study was conducted over a 11-year period, from 1987 to 1998. Researchers hypothesized that fasting serum insulin is higher in non-obese AAs compared to Whites, and that high fasting insulin predicts diabetes (Carnethon, Palaniappan, Burchfiel, Brancati & Fortmann, 2002). Study participants were examined for diabetes at year three, seven and nine of the study. The researchers found that fasting insulin levels were higher in AA women compared to White women, however there were no differences among men.

They also found that on average at 8.7 years of follow-up 10% of women and 12% of men were diagnosed with diabetes. The researchers concluded that non-obese AA women have a higher fasting insulin compared to non-obese White women, and that fasting insulin is a strong predictor of diabetes in AAs and Whites. These decade old findings guide our research today. Study findings of this current study support increased odds of pre-diabetes in AAs. Much of the research mentioned above may provide an explanation for our findings of increased odds among AAs.

Most of the studies that focus on race and type 2 diabetes do not identify race alone as a risk factor for diabetes, but identify genetic factors such as race and covariates as risk factors for diabetes (Shacter, Shea, Akhabue, Sablani, & Long, 2009). Shacter et al. (2009) conducted a qualitative study among 54 veterans to exam barriers to glucose control that were specific to AAs compared to Whites. The participants were 60% AAs and 40% White. Among well-controlled glucose groups, self-care, health care, and psychosocial factors including exercise and SES were reported by participants as important factors in the control of their diabetes. Poorly controlled AAs and Whites reported self-care practices as important in glucose control, but expressed difficulty following self-care practices. Both poorly controlled groups also reported difficulties with psychosocial factors that are important in glucose control. AAs expressed more difficulty with self-care practices and psychosocial factors compared to Whites. The researchers concluded that poorly controlled AAs endorsed positive self-care practices but found it difficult to follow through resulting in poorer glycemic control. The findings from the current study revealed poor compliance with participation in intense physical activity on a regular basis. It is possible that the poor compliance relates to the inability

to follow through with important self-care practices as mentioned in the previous study. Other researchers have found increased odds of diabetes in AAs in the presences of covariates such as low SES and low health literacy (Osborn et al, 2011; Sudano & Baker, 2006) A comparison of these study findings and our findings will be explored later in this paper.

In the current study in adjusted models for age, male gender, regionality, income level, education level, cigarette smoking, alcohol use and intense physical activity the magnitude of the risk of pre-diabetes in AAs increased compared to the risk of pre-diabetes in AAs in crude modeling. These study findings provide support for previous research conducted that race (AA) and covariates increase the odds of pre-diabetes. The findings also suggest that the presence of covariates such as the aforementioned do not independently explain the relationship with race and the increased odds of pre-diabetes in AAs. The addition of illness perception did not increase the magnitude of association of risk of pre-diabetes in the presence of race and other covariates. In summary race (AA) does increase the odds of pre-diabetes in the presence of selected covariates, however the increased odds of pre-diabetes in AAs are likely not contributed to race alone but contributed to race with the presence of covariates.

Research Question 3

The third research question asked, does older age and gender (male) increase the odds of pre-diabetes in the REGARDS study cohort?

This study examined age in 10-year increments as a predictor variable. Findings of this study revealed that age alone had a modest affect (OR 1.05; 95% CI; 1.02, 1.09) on

the odds of pre-diabetes in AAs. Gender (male) alone increased the odds of pre-diabetes (OR 1.32; 95% CI; 1.24, 1.41). In multivariate modeling age was adjusted for other demographic factors, SES, lifestyle choices, and illness perception however the odds of pre-diabetes did not increase. Yet when gender (male) was adjusted for the same covariates the magnitude of association of pre-diabetes and gender slightly increased (demographics [OR 1.37; 95% CI; 1.28, 1.46], SES [OR 1.38; 95% CI; 1.29, 1.48], lifestyle [OR 1.37; 95% CI; 1.28, 1.47], illness perception [OR 1.37; 95% CI; 1.27, 1.47]). The findings suggest that the impact of age and gender (male) on increased odds of pre-diabetes in AAs is more attributable to gender, then age.

Early research findings have shown that the risk for diabetes increases with age. A cross sectional population based survey conducted in Finland from 2004 to 2005 reported an increased risk of diabetes for older study participants. This study, known as The Finnish Trial examined a random sample of 4500 subjects, aged 45 to 74 years old. The sample was stratified according to sex and 10-year age groups. The age groups were 45 to 54 years, 55 to 64 years old and 65 to 74 years old. The prevalence of abnormal glucose tolerance was found to increase steadily with age in the presence of covariates such as obesity. This finding was not the same for individuals with IFG which was more common in males (Saaristo, 2008). The current study's findings did not support this increase. Perhaps the lack of support relates to cultural differences in the study populations or the assessment tool used to collect the data. Another possibility is that our study did not include obesity as a covariate of study.

Few research studies have focused on gender and pre-diabetes but have focused on IGT and or IFG and gender (Williams et al., 2003; Unwin, Shaw, & Albert, 2002; Qiau,

Hu, Tuomilehto, Balkau, & Bord-Johnsen, 2002). Most study findings are that IFG is more common in males compared to females after controlling for some covariance.

Findings from our study support that both age and gender (male) have an impact on increased odds of pre-diabetes, with a greater impact being seen with gender (male).

Research Question 4

The fourth research question was, does lower SES increase the odds of pre-diabetes after controlling for covariates such as lifestyle choices and illness perception?

Multivariate analysis was used to examine this question. This study examined each income level compared to the referent income level of less than \$20,000 annual income. The findings revealed that lower income levels did not increase the odds of pre-diabetes in AAs compared to Whites when other covariates such as smoking history, intensity physical activity, alcohol intake and illness perception were considered. In AAs with annual income levels at \$35,000.00 to \$75,000.00 (OR 1.0; 95% CI) the odds of pre-diabetes were equal to the odds of pre-diabetes in Whites across all adjusted models. In crude modeling AAs with income levels above \$75,000.00 annually (OR 0.84; 95% CI; 0.75, 0.94) were more protected from increased odds of pre-diabetes compared to income levels below \$75,000.00 annually. The protective effect may be attributed to increase access to care or increase use of health care services among individuals with an income level above \$75,000.00 annually. Additionally, education levels were found to be protective for increased odds of pre-diabetes. College graduates were more protected from increased odds of pre-diabetes compared to the referent group less than high school education when covariates were considered.

Many researchers believe income level and education are closely associated with SES (Tang et al, 2003) and that higher SES is protective for health (Deaton, 2003). Researchers also suggest that people with lower SES score lower on most health evaluation tools (Bravata et al, 2005; Liu & Nunez, 2010). Sudano and Baker (2006) conducted a prospective cohort study to examine the effect of SES, health behaviors and health insurance on racial and ethnic disparities in mortality and health decline. The researchers used data from the 1992 and 1998 Health and Retirement Study (HRS). This study was a longitudinal, nationally representative sample of 8,400 US households. Socioeconomic status was measured by education level and income level. The investigators found that AAs and Hispanics were more SES disadvantaged compared to Whites. AAs were more likely to be current smokers compared to Hispanics and Whites, and AAs and Hispanics were more likely to have histories of past drinking problems. Both minority groups were more likely to be overweight compared to Whites. AAs had an unadjusted relative risk of death or major health decline two times that of Whites. Of interest to our study was the finding that SES was one factor that affected health outcomes and mortality rates.

Osborn et al. (2011) hypothesized that AAs had poor medication compliance compared to Whites, suggesting that poor compliance was related to low health literacy, and diabetes- related numeracy. Because there is research support for health literacy as a valid indicator of SES, these investigators analyzed data from their previously published data sets to assess whether AA race was associated with medication adherence, and whether health literacy, diabetes-related numeracy or general numeracy explained this relationship. Among the many findings from their study of 398 participants were

that AA study participants were more likely to be female, report annual incomes of less than \$20,000.00, have less education, have public health insurance, higher BMIs, be less adherent to diabetes medications and have poor glycemic control. AAs were also more likely to have lower health literacy compared to Whites. These findings directly challenged their earlier work which suggested that health literacy was not related to glycemic control, but they do support the hypothesis that AA race is associated with less adherence to diabetic medication regimens after adjustment for demographic and SES covariates. Additionally, these findings also lend support to their hypothesis that low health literacy is associated with lower diabetes medication compliance.

This study finding provides support for much of the research previously mentioned related to the relationship between SES and diabetes or pre-diabetes. Forty-three percent of the White study participants were college graduates compared to 28% of AAs. The lower educational level of AAs is congruent with decreased health literacy which may influence compliance and ultimately health outcomes. Income especially above \$75,000.00 annually and education at college level and above, were found to be protective for pre-diabetes after adjusting for covariates of interest.

Research Question 5

The final research question was, do lifestyle choices (smoking, intense physical activity and alcohol intake) along with illness perception increase the odds of pre-diabetes in the REGARDS study cohort?

The study findings showed that past and current smoking was associated with increased odds of pre-diabetes (“past” OR 1.31; 95% CI; 1.22, 1.41) and (“current” OR

1.25; 95% CI; 1.13, 1.37) in AAs compared to Whites. Moderate alcohol intake was protective for pre-diabetes (OR 0.98; 95% CI; 0.91, 1.05) while heavy alcohol intake increased the odds of pre-diabetes (OR 1.19; 95% CI; 1.03, 1.39). Intense physical activity was also found to be protective for pre-diabetes in univariate analysis (“one to three times a week” OR 0.88; 95%CI; 0.81, 0.95, “more than four times a week” OR 0.83; 95% CI.; 0.76, 0.90) and multivariate analysis lifestyle (“one to three times a week” [OR 0.89; 95%CI; 0.82, 0.97], “more than four times a week” [OR 0.80; 95%CI; 0.74, 0.87]) and illness perception (“one to three times a week” [OR 0.92; 95%CI; 0.85, 1.00], “more than four times a week [OR 0.85; 95%CI; 0.78, 0.93]). These findings are congruent with the literature, in that there is clear evidence supporting participation in moderate to intense physical activity most days of the week, as a method to prevent diabetes. Participation in moderate physical activity 150 minutes per week in combination with 5% to 10 % weight loss will prevent or delay the development of diabetes and help maintain weight loss in pre-diabetes (ADA, 2010; Taylor et al. 2010; Hamman et al, 2006; Diabetes Prevention Program Research Group, 2002; Lindstorm et al, 2003; “Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin”, 2002; Pan, 1997).

The benefits of moderate alcohol intake is commonly reported in the literature (Koppes, Dekker, Hendriks, Bouter, & Heine, 2005; Meigs, Hu, Rafai, & Manson, 2004; Hu, Meigs, Li, Rafai, & Manson, 2004; Beulens et al, 2008). Cigarette smoking has also been linked to diabetes, and significantly increases the risk of this disease (Zie, Liu, Wu, and Waku, 2009; Willi, Bodenmann, Ghali, Faris, and Cornuz, 2007). Men who smoke more than 25 cigarettes a day have increased risk of diabetes (Rimm et al., 1995).

Similar results were found in another study conducted by Wannamethee, Shaper, and Perry (2001), who found a reduction in risk of diabetes related to smoking cessation at year five during a 17-year cohort study. These results have been replicated in other smoking cessation studies (Manson et al., 2001; Ko et al., 2001). Evidence supports use of illness perception as an acceptable measure of self-reported health status (Kartal, & Inci, 2011; Petricek et al., 2009; Frostholm et al., 2006). Findings from the cross sectional study conducted by Petricek et al. (2009) revealed that subjects perception of control over their illness, and subject concern about illness were predictors of fasting blood glucose. The current study revealed that people who self-report poor perception of health had increased odds of pre-diabetes (OR 1.94; 95% CI; 1.55, 2.43) compared to people who self-reported illness perception as “excellent” (OR 1.00; 95% CI). After adjustment for covariates OR decreased slightly but were still significantly increased for the odds of pre-diabetes. Our findings are congruent with the literature, suggesting that illness perception or self-reported health status are valid predictors of health outcomes such as pre-diabetes.

The findings from this study add to the limited research available related to pre-diabetes and possible risk factors. In summary, study findings reveal both race and regionality may increase the odds of pre-diabetes, and these increased odds are even more astounding when controlling for covariates of SES, lifestyle factors, and illness perception.

Relevance of Findings to Conceptual Framework

The conceptual framework for this study was based on the Expanded Biobehavioral Interactive Model developed by Kang et al. (2009). Pre-diabetes is defined as blood glucose above the level of normal blood glucose but below the level of diabetes. Physiologically it is defined as blood glucose level above 100mg/dL and below 126mg/dL. Pre-diabetes is a multidimensional physiological process possessing both physiological and behavioral factors that affect the clinical presentation of the disease. The interactive model designed by Kang et al consists of both biological and behavioral domains making it a useful framework for this study.

Kang et al described five bio-behavioral domains. The first domain was the Individual domain. In the current study the Individual domain included age, SES, and race. The second domain is the Environmental domain, and pertinent to our study was the concept of regionality. The third domain is the psychosocial domain that was represented by illness perception for our study. The fourth domain is the Behavioral domain that included lifestyle choices such as smoking, alcohol intake and intense physical activity in our study. The final domain included is the biological domain, which was represented in our study by disordered blood glucose metabolism, resulting in the outcome variable, pre-diabetes.

The Interactive model was modified to fit our study. In the modified and un-modified model, each of the domains had some factor that could contribute to the outcome variable, pre-diabetes and each domain had the potential to be modified by race. In the un-modified model, all of the domains interacted with each other by correlational, bidirectional or unidirectional relationships. The modified model only used the

unidirectional relationships to depict the direct progression from bio-behavioral interactions to the outcome variable, pre-diabetes and is a more accurate reflection of the dimensions affecting disease occurrence in our study.

Conclusions

Based on the findings of this study, we conclude the following:

1. There is disparity in pre-diabetes between AAs and Whites that is independent of SES, lifestyle, or illness perceptions. While these factors also increase the risk of pre-diabetes, occurrence of pre-diabetes in AAs cannot be explained by these factors alone or in combination.
2. Living in the stroke belt increases the odds of pre-diabetes.
3. Age does not explain the disparity of pre-diabetes in AAs compared to Whites. Given the prevalent view that older age is a major factor in diabetes and pre-diabetes, this finding is important.
4. Gender (male) is a significant risk factor for pre-diabetes.
5. Low income (income below \$20,000.00 annually) alone is not a risk factor for prediabetes. As income rises above the level of \$20,000.00 annually, individuals are protected for pre-diabetes. Individuals with incomes above \$75,000.00 annually receive the most protective effect before and after controlling for covariates.

Limitations

The following is a discussion of several limitations of the present study.

1. A cross-sectional design was used, with data collection occurring at only one point in time. Thus, we did not evaluate test-retest reliability. This would have provided information as to the consistency of self-reported measures over time. Additionally, our non-experimental methods prevent us from identifying causal relationships between the independent variables and the dependent variable, pre-diabetes.
2. The use of self-report items might have increased the possibility for socially desirable responses on certain items, such as alcohol intake, smoking history, and intense physical activity participation.
3. Our limitations extend to the methods used for the REGARDS study: A) Because the highly rural Stroke Belt region carries high rates of poverty among AAs, and these individuals may lack telephones, we are unclear whether our findings are representative of this group since these subjects were excluded from the REGARDS study; B) participant blood glucose was measured on a single occasion notwithstanding standard protocol; C) our study lacked a good indicator for access to care. Some factors may have been affected by the lack of access to care, thus increasing the odds of pre-diabetes; D) Our study lacked covariates, body mass index (BMI), dyslipidemia, hypertension, heart disease and stroke. The presence of these comorbidities may have skewed the odds of pre-diabetes.
4. Our study utilized data from a study that was collected for other purposes. The precision with which the variables used in this study accurately measured our variables of interest cannot be guaranteed; nor can we verify the results of this study because of the restrictions of our design.

Implications

The results of this study have implications for the Stroke Belt Region of the US and both nursing and advanced nursing practice, education and research. Those implications are presented in the following sections.

Implications for the Stroke Belt Region of the US

Study findings revealed that there was an increase in the odds of pre-diabetes in people living in the stroke belt compared to people living outside the stroke belt. Voeks et al. (2008) suggest that the increased prevalence of diabetes in the Southeast region of the US is attributable to increase stroke mortality in the region. Therefore it is theoretically sound to conclude that pre-diabetes is a risk factor for stroke and may contribute to the increase stroke mortality in the region. The finding support the need to decrease the geographic disparity of pre-diabetes in order to decrease the stroke mortality in the Stroke Belt.

Finally, AA are at increased risk of pre-diabetes compared to Whites. Previous research findings support the increased AA population in the southern US compared to other regions of the US. The increased AA population in the southern region of the US is congruent with increased pre-diabetes in the Stroke Belt Region. These finding support the need to decrease the racial disparity of pre-diabetes in AAs in the Stroke Belt in order to decrease stroke mortality in the region.

Implications for Nursing Practice

African Americans are at increased risk for pre-diabetes even after controlling for potential confounders such as SES, lifestyle choices and illness perception. These findings suggest that factors over and above race and region may be at work. One potential explanation for the continued disparity derives from the observation that AAs who smoked in the past and currently smoke, and individuals who consume alcohol heavily, are at increased risk for pre-diabetes. These findings indicate that practitioners might need to be more aggressive in connecting patients with smoking cessation programs. In addition, nurses might need to approach cessation of alcohol consumption from a more realistic point of view and address cessation programs and patient education in heavy drinkers.

Income ranges from \$35,000.00 to \$75,000.00 annually did not increase the odds of pre-diabetes. However, the protective effect was not seen as compared to incomes above \$75,000.00. Therefore consideration of cost should be given when establishing a treatment plan for individuals in the \$35,000.00 to \$75,000.00 annually income range, in an effort to increase compliance. For example health care providers can allow generic substitution when available instead of brand medications, limit referrals to specialists unless clear indications for specialty care and follow-up are present and evaluate options for low cost monitoring blood glucose in the home to prevent the need of office visits.

Implications for Nursing Education

The implications mentioned above should be incorporated into baccalaureate and advance practice nursing programs. Students should be educated on racial disparities in

pre-diabetes as well as diabetes. In terms of providing care, the nursing process should be focused on assessment, planning, implementation and evaluation of interventions in relation to factors that are in line with the risk for pre-diabetes, particularly in AA patients and their family members. Encouraging patients with pre-diabetes to exercise regularly, stop smoking and limit alcohol intake should be included as part of an overall plan to control pre-diabetes. Students should be aware of “non-compliance” in AAs but also factors that affect compliance, some of which patients may or may not have control over.

Nurse educators should also address the disparities in education that may potentially affect optimal compliance. Nurse educators should instruct students on assessment of other measures of SES beyond income. Students should be educated that income is not the primary disparity in SES but rather education levels. Nurse educators should also address the potential impact of financial barriers to glycemic control. Educators should include in the nursing curriculum effective strategies for monitoring blood glucose without increasing cost to median and low-income individuals.

Implications for Nursing Research

The information from this study suggests that some of the disparity in pre-diabetes can be eliminated or reduced. A paucity of literature exists that examines disparities in pre-diabetes. We have used cross-sectional associations of pre-diabetes with a number of lifestyle, SES, demographic, and illness perception factors in order to increase understanding of the epidemiology of pre-diabetes, the pre-cursor for diabetes. Longitudinal research that aims to identify the effect of a variety of interventions on the

development of pre-diabetes should be pursued. Nursing research is also needed to identify factors that may contribute to lifestyle choices and illness perception in patients with pre-diabetes.

Recommendations for Future Research

Recommendations for future research are as follows:

1. We have identified several risk factors for increased odds of pre-diabetes. Interventional studies are needed to focus on elimination of risk factors and reduction of disparity in pre-diabetes and diabetes.
2. Future studies are also needed to explain the disparities in pre-diabetes between AAs and Whites. These would include additional covariates such as provider perception of patient health status, access to care, and important co-morbidities that are theoretically in-line with the development of prediabetes (obesity, hypertension, stroke, dyslipidemia).
3. We modified the framework used in this study to reflect a unidirectional relationship between the domains representing variables in our study and the study outcome. Further studies are needed to evaluate the relationships between the domains of the Expanded Biobehavioral Interactive Model developed by Kang et al. (2009), as they relate to pre-diabetes. Whether there truly is a valid reciprocal relationship among variable domains as originally proposed by this model was beyond the scope of this study, but the theoretical soundness of the model should be considered, as well as its viability as a model to guide research design.

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APPENDIX A

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APPENDIX C

INSTITUTIONAL REVIEW BOARD APPROVAL

Form 4: IRB Approval Form
Identification and Certification of Research
Projects Involving Human Subjects

UAB's Institutional Review Boards for Human Use (IRBs) have an approved Federalwide Assurance with the Office for Human Research Protections (OHRP). The Assurance number is FWA00005960 and it expires on September 29, 2013. The UAB IRBs are also in compliance with 21 CFR Parts 50 and 56.

Principal Investigator: LEE, LORETTA TAYLOR

Co-Investigator(s):

Protocol Number: **E110825001**

Protocol Title: *An Exploration of Factors Associated with Pre-Diabetes in the REGARDS Study Cohort*

The above project was reviewed on 8/26/11. The review was conducted in accordance with UAB's Assurance of Compliance approved by the Department of Health and Human Services. This project qualifies as an exemption as defined in 45CFR46.101, paragraph 4.

This project received EXEMPT review.

IRB Approval Date: 8-26-11

Date IRB Approval Issued: 8/26/11



Marilyn Doss, M.A.
Vice Chair of the Institutional Review
Board for Human Use (IRB)

Investigators please note:

IRB approval is given for one year unless otherwise noted. For projects subject to annual review research activities may not continue past the one year anniversary of the IRB approval date.

Any modifications in the study methodology, protocol and/or consent form must be submitted for review and approval to the IRB prior to implementation.

Adverse Events and/or unanticipated risks to subjects or others at UAB or other participating institutions must be reported promptly to the IRB.

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APPENDIX D

APPROVAL FOR SECONDARY DATA ANALYSIS OF REGARDS STUDY
COHORT

Department of Biostatistics

August 1, 2011

Loretta T. Lee, MSN, CRNP

School of Nursing

UAB

NB 542 1530 3rd Ave South

Birmingham, AL 35294-1210

Dear Loretta:

This letter serves to confirm that you have received approval from the REGARDS Executive Committee to conduct the work described in your manuscript proposal entitled: An exploration of factors associated with pre-diabetes in the REGARDS study cohort (2011-P168).

The dataset provided to you will have no personal identifiers and you will not be able to ascertain the identity of individuals in the dataset because the data are coded and the key will not be released to you. You will be assigned a REGARDS statistician to provide assistance to you in the analysis.

We are pleased that you have chosen to use the REGARDS dataset as part of your dissertation work and we wish you success at completing this work.

Please do feel invited to contact me if there is any additional information that we can provide to support your exciting work.

Sincerely

George Howard, DrPH

REGARDS Principal Investigator

Professor and Chair