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Assessing the Association between Depression and End Stage Kidney Disease for African American patients on dialysis.

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Bachelor of Science
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Thesis Committee Chair: Deborah A McFarland, PhD, MPH
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Abstract

Background: The prevalence of diabetic retinopathy is estimated to increase to 14 million from the current rate of 7 million Americans. Many researchers have demonstrated that depression and diabetic retinopathy are correlated and affect each other. African Americans are affected by diabetes more than any other racial group in the U.S. Diabetes is the main leading cause of diabetic retinopathy. The objective of this study is to assess the association between depression, diabetic retinopathy, and selected social determinants of health for 100 African Americans that have been diagnosed with end-stage kidney disease and that are on dialysis at the Emory dialysis centers.

Methods: We conducted a cross-sectional study of 100 African Americans with end-stage kidney disease on dialysis. We administrated 3 surveys, collecting information such as demographics, comorbidities, kidney burden of disease, and Impact of Vision Impairment. A visual acuity test was then administrated using the Rosenbaum pocket visual acuity test, followed by pictures to obtain eye images with the Optomed Aurora portable camera that were to be analyzed for diabetic retinopathy by an Emory Ophthalmologist and an AI software (AEYE in collaboration with Optomed Aurora portable camera) engineer.

Results: Of the ninety-eight participants who completed the surveys, the ratio of males to females was 1:1. On all the screened patients, only 55 images were successfully captured for analysis. The mean age for this population was 59.17 years old, with a standard deviation of ±12.178. Of the 55 participants who had sufficient images, the mean age and standard deviation were 59.26 ±12.20, respectively. The ratio of male to female was 26: 29 (n= 55). Out of the ninety-nine (n=99) participants who responded to the questionnaire, 11 (11.11%) have low food security. The average substance abuse score was 5.71, with a range of 1 to 11, suggesting a very high possibility of substance abuse in this population. The average depression score for this cohort was 6.02 with a standard deviation of ±5.20, suggesting a mild level of depression.

Discussion: From our findings, the correlation between a positive diagnosis of diabetic retinopathy and depression was not statistically significant (p=.830). The average value of depression was higher than the negative DR diagnosis, 5.91 vs 5.0. This probably affected the significance of the findings and therefore screening patients further is needed to conclude the impact of depression on diabetic retinopathy on African Americans. Based on the kidney burden of disease questionnaire, we found no statistically significant difference between participants assessed to have diabetic retinopathy and those who did not have diabetic retinopathy (p=.65). Based on the visual impact assessment, it was found that vision impacted a DR diagnosis, with most of the DR+ participants reporting a higher number of an impact than their DR- participants counterparts, with a significance level (P=.0329).

Conclusion: Depression is a disease correlated with diabetes and diabetic retinopathy. Diabetic retinopathy is a disease that is expected to rise by double its current number, therefore, increasing the burden of the disease on many communities, especially underserved communities.

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Table of Contents

Chapter 1: Introduction

1.1 Background

These past three years have proven to be unprecedented, with many factors that have affected the livelihood and health of individuals. Many people's lives have changed dramatically. Many are afraid and uncertain about the future after the Covid-19 pandemic. More and more healthcare professionals and others of different fields and backgrounds have started paying attention to mental health around the globe. Depression is one of the leading causes of death, and with the current pandemic, researchers have estimated that there is an increase of 25-27% in major depressive disorders across the globe[1] (U.S. Department of Health and Human Services (USDHHS), n.d). Depression exacerbates many diseases; however, there is a lack of research in this field mainly due to pervasive stigma (Latalova et al., 2014). Diabetes is on the rise and is one the leading cofactors leading to many other comorbidities such as diabetic retinopathy, end-stage kidney disease, heart failure, and many other diseases (Centers for Disease Control and Prevention CDC, 2022; Mayo, 2020). African Americans have the highest prevalence of diabetes and diabetic retinopathy and yet there is a lack of research focused on African Americans. This study was designed to assess the association between diabetic retinopathy and depression in the African American community. The research was conducted on 100 African Americans that had been diagnosed with end-stage kidney disease and that are on dialysis at the Emory dialysis centers.

Chapter 2: Literature Review

2.1 Depression

Depression, also known as major depressive disorder, is a common serious mood disorder that impacts an individual's ability to perform daily activities such as eating, sleeping, and performing other work-related activities (USDHHS, n.d.; (CDC), n.d.). Individuals can experience depression that is due to seasonal affective disorder, and this can cause further inability to handle underlying disease (USDHHS, n.d). Depression is one of the most common mental disorders on the globe. Many of its risk factors include biological, environmental, and genetic factors. It co-occurs with many diseases, including diabetes and heart disease. It affects children leading to high levels of anxiety among children and mid-life adults who tend to already have diseases that affect them due to their age. Depression isn't always detectable, early nor is it addressed by individuals due to the social stereotypes surrounding it and the inability to diagnose depression along with many behavioral and mental disorders (USDHHS, n.d.; (CDC), n.d.; Zhang et al., 2010). Depression can be classified into 5 different categories based on the symptoms. Major depression can be treated if it is caught early however, due to the stigma surrounding it, many individuals are not diagnosed on time, further complicating treatment (USDHHS, n.d.; (CDC), n.d.). Antidepressants can be used to treat depression; however, some patients affected by depression must go through several antidepressants to find the right medication for them, as all drugs do not treat the symptoms the same way across patients (USDHHS, n.d.; CDC, n.d.). Some anti-depressants may also inhibit the uptake of certain medicines making treatment harder for patients who have other diseases such as heart diseases, diabetes, and many more (USDHHS, n.d.; American Psychiatric Association (APA), 2021).

The CDC reports that at least 1 out of 6 people will go through a major depressive disorder at least once in their life (CDC, n.d.). However, the cause of depression does vary from person to person, making it harder to diagnose and treat all the millions of people that are affected by depression worldwide. The rate of depression in the United States is as high as 21% for women and 11% for men and is the major cause of suicide, which is in the top 10 major causes of death in the U.S. (USDHHS, n.d.). Those afflicted with depression are more likely to suffer from its comorbidities, such as a weakened immune system leading those afflicted more likely to be vulnerable to a wide array of diseases (Zhang et al., 2018). Research has also demonstrated that those who are afflicted by depression and suffer from another chronic disease are more like to aggravate their disease, shortening their lifespan (CDC, n.d.). Diseases, such as but not limited to diabetes, cancer, and heart failure, are also likely to lead to depression (USDHHS, n.d.). Those who are suffering from depression have a higher probability to develop diabetes and vice versa (Roy & Lloyd, 2012). Researchers have found that diabetes can lead to depression and vice versa. Depression can also lead to type 2 diabetes; however, the direct correlation has yet to be determined (CDC, n.d.). At the same time, depression can also lead to the onset of Type 1 diabetes (Wang et al., 2019). Treating depression helps diminish the effect of diabetes, and curing diabetes can also help in treating depression for many individuals. Treating depression is extremely costly to many families, especially those who are below the poverty line or suffering from poverty (APA, 2021). Depression leads to an economic burden in the country as it decreases the productivity of those who are afflicted with the disorder (APA, 2021).

The cost of treating depression in the U.S. alone was over 236 billion USD (APA, 2021). Depression not only cripples the finances of the people affected, but it also cripples the U.S. economy. The U.S. also loses its labor force and the money spent treating depression (APA, 2021; Greenberg et al., 2021). Depression coupled with Diabetes further affects the patient's quality of life.

2.2 Diabetes

Diabetes is a chronic disease that affects millions of Americans and affects how individuals turn food intake into energy (APA, 2021; CDC, n.d.). There are three types of diabetes according to the CDC, type I, which is due to an autoimmune response preventing the body from making its insulin, type II, which is when the body is unable to utilize the insulin it has and gestational diabetes, which is usually developed during pregnancy. Treatment for all three types has improved over the years, but people who are unable to afford healthcare can quickly develop depression affecting the severity of diabetes and decreasing their quality of life (APA, 2021; CDC, n.d.). Those unable to treat the disease in a timely manner are more likely to develop other infections and complications such as the need to be on lifelong dialysis due to end-stage kidney disease, amputations, and diabetic retinopathy (USDHHS, 2018). Regardless of current advancements in medicine, researchers continue to study diabetes as it is a lifelong disease that is very sensitive to many external factors such as food intake quality and stressors, whether environmental or those from daily life such as school or jobs. Diabetes is often correlated with obesity. Type II diabetic individuals are more likely to be obese, and those who are obese have a higher risk of being diabetic (Barrington et al., 2021; USDHHS, 2018).

To determine the risk factors that determine obesity and diabetes, researchers looked at biological risk factors such as body mass index, waist measurement, fasting glucose levels, lipids, blood pressure, and lung function (Barrington et al., 2021). Those factors are good indicators to determine the risk factors of the diseases in affected communities or racial groups. Obesity is the driving cause of type II diabetes. Researchers have found that socioeconomic factors, such as income and neighborhood play a significant role in the high rate of obesity in African Americans observed in the United States (Barrington et al., 2021). In 2018, the prevalence of obesity was found to be 38.3% for African Americans compared to that of the general U.S. population of 31.1%, a significant difference and indicating a massive disparity between African Americans and the general American population (Barrington et al., 2021; Mayo, 2020). This difference impacts African Americans by increasing the cost of living due to accrued expenses such as costs of medications (Proudfit et al., 2015) and decreasing the quality of life, thus contributing to an increase in diabetes and increasing the risk for African Americans being impacted by depression.

The prevalence of diabetes in the U.S. is estimated to be 10.2%, with 134.2 million Americans afflicted with diabetes (CDC,2022). This number does not include the rate of prediabetic patients, which amounts to an additional 94 million Americans. The prevalence of diabetes increases significantly by age, up to 26.5% for those >65 years of age (CDC,2022). Race also plays a significant role in the rate of diabetes cases, with African Americans having the highest prevalence of diabetes across the age groups with a total rate of 13.3%, which is 3.1% higher than the national average of diagnosed diabetes (CDC,2022; USDHHS, 2018). African Americans are twice as likely to develop diabetes as their white counterparts in the United States. This disparity has been increasing over the past 30 years and exacerbates the difference between

races (CDC,2022). Diabetic patients are very vulnerable to depression due to the burden of disease on the patient's daily lives (Roy & Lloyd, 2012). This leads to African Americans having a higher risk of depression due to diabetes. Researchers have discovered there was a high rate of depression among individuals that were diagnosed with diabetes (Roy & Lloyd, 2012).

Diabetes is the leading cause of diabetic retinopathy (DR), an eye disease that can lead to vision loss or blindness in individuals who have diabetes. It is also the highest leading cause of blindness globally an estimated 285 million afflicted with diabetes (Lee et al., 2015). Diabetic retinopathy may showcase itself with no symptoms; however, a diabetic patient needs to have regular checkups at least once a year to ensure that DR is detected early (Mayo, 2021; USDHHS, n.d.). The earlier diabetic retinopathy is detected, the easier it is to treat it (Mayo, 2021). In its early stages, individuals may not be able to see objects situated further from them, may have trouble reading, and note other minor changes in their vision (Lee et al., 2015; USDHHS, n.d.). However, in later stages, individuals would have popped blood vessels in their eyes, leading to scarring on the retina, making it harder to treat (Lee et al., 2015). Laser treatments are prevalent in treating diabetic retinopathy when the disease is caught in its early stages (Mayo, 2021).

Diabetic retinopathy can also lead to other severe issues such as diabetic macular edema, which is when blood vessels leak fluids into the macula; it affects 1 in 15 people with diabetes; neovascular glaucoma, when abnormal vessels grow out of the retina and block fluids from draining out of the eye; and retinal detachment, when scars form on the retina which can also lead to those scars pulling the retina away from the back of the eye (Mayo, 2021). Individuals who develop diabetic retinopathy risk lower quality of life, lower self-esteem, and a high risk of depression (Silverberg et al., 2021). The U.S. spends $500 million annually to treat diabetes-

related blindness (Zhang et al., 2010). DR leads to an economic burden on those it affects, their community, and the overall economy of the country (Silverberg et al., 2021).

Diabetic Retinopathy (DR) is the leading cause of blindness worldwide, with a prevalence of 2.5%, 7.7 million Americans, and there is no sign of this number going down anytime soon; rather, it is projected to double to a majority of 14.6 million between 2010-2050 (USDHHS, n.d.) Several studies suggest that DR is likely to cause lead to an increase in the prevalence of depression and vice versa. However, due to limitations, the association between depression and DR has yet to be investigated in an optimal setting (Chen & Lu, 2016). There aren't many studies that analyze diabetic retinopathy in the African American community. Most studies have examined DR in other racial groups. The lack of studies in African American communities leads to them being neglected and exacerbates the disparities observed in the United States.

End-stage kidney disease (ESKD) is when the kidney loses its ability to function normally (Wiznia et al., 2022). The kidney oversees the filtering of waste from the blood and ejecting it through urine. However, those afflicted with ESKD have an abnormal kidney that can no longer function normally, requiring either a kidney transplant or dialysis (USDHHS, 2018). Those who receive dialysis will stay on it for a lifetime and often must receive treatment 3 to 4 times a week for a minimum of three hours for each session (Goeree et al., 1995). Those who are diagnosed with End Stage Kidney Disease develop a few to several of the following symptoms - nausea, vomiting, loss of appetite, fatigue, and weakness, changes in how much one urinates, chest pain, fluid buildup around the lining of the heart, shortness of breath if there are fluids that build up in the lungs, swelling of feet and ankles, high blood pressure (hypertension) that's difficult to

control, headaches, difficulty sleeping, decreased mental sharpness, muscle twitches and cramps, persistent itching, and metallic taste (Barrington et al., 2021). Many of these symptoms also correlate with some of the signs that are also found in individuals that are diagnosed with depression (USDHHS, n.d.; CDC, n.d.).

Diabetes is the leading major cause of chronic kidney disease (CKD) and End Stage Kidney Disease (ESKD) (Silverberg et al., 2021). Diabetes is also a major leading cause of many other diseases such as hypertension, hyperlipidemia, vascular disease such as renal vein thrombosis, glomerular disease (primary or secondary), cystic kidney diseases, tubulointerstitial disease, urinary tract obstruction or dysfunction, recurrent kidney stone disease, congenital (birth) defects of the kidney or bladder, and unrecovered acute kidney injury (CDC, 2022). It can also inhibit the uptake of certain medications, such as non-steroidal anti-inflammatory drugs (NSAIDs), calcineurin inhibitors, and antiretrovirals (Barrington et al., 2021).

CKD and ESKD lead to disparities in different racial groups, the prevalence of the disease is 16%, almost double for African Americans compared to a rate of 9.6% for Caucasians in the U.S (Peterson Foundation, n.d.). Those who are afflicted with ESKD and CKD must depend on dialysis, which in 2022 is estimated to cost on average $88,585 for hospital hemodialysis, $55,593 for self-care hemodialysis, $44,790 for CAPD, and $32,570 for home hemodialysis annually (Goeree et al., 1995). The average American annual income in 2021 was $67,521, and African Americans have a lower annual income of $45,870 compared to their white counterparts at $74,912(Peterson Foundation, n.d.). African Americans face disparities due to many factors, such as wages and education, which affect their healthcare (Scott & Wilson, 2011). The difference

in income also exacerbates the rate of diabetes, which also affects the prevalence of depression observed by many researchers in their studies.

2.3. Social determinants of health

The World Health Organization describes Social Determinants of Health as non-health factors, such as neighborhood/ social structure, distribution of resources, power, and money, that impact an individual's health (World Health Organization (WHO), n.d.). To reduce the impact of the negative factors that influence an individual's health, the CDC suggests addressing factors such as low income, education, and food security in a community (CDC, 2021). Some researchers have indicated that the lack of capital, food, and inadequate healthcare communication has led to African Americans having the highest disparities when it comes to healthcare (Scott & Wilson, 2011). Discriminatory practices have led African Americans to face more disparities differences than any other race in America. The prevalence of food insecurity was 24% in 2020, making African Americans three times more likely to suffer from food insecurity than the whole nation (Feeding America, n.d.). The national poverty in 2022 is 11.4% for the government vs. 19.5% for African Americans (Feeding America, n.d.). These factors exacerbate the disease burden and depression in the African American community. Unless public health officials resolve this issue, African Americans will continually be afflicted by these disparities widening the gap between the African American community and the other racial groups and furthering the national disease burden.

2.4. Purpose Statement

The purpose of this study is to determine the association of depression using a patient Health Questionnaire (a depression screening diagnostic tool) for ESKD African American patients on dialysis that were found to have been diagnosed with diabetic retinopathy using the Optomed Aurora portable camera in collaboration with AEYE Camera from the three Emory Dialysis Clinics. Diabetic Retinopathy is a disease that continuously rampages the lives of many. Despite the increased research into the field, there is little to no information on the impact on the African American community. This prompted the study team to investigate the effect on African Americans. My study team and I analyzed the impact of depression and diabetic retinopathy on African Americans, one of the racial groups that are underrepresented in studies in the U.S. As the rate of diabetes and depression keeps increasing, public officials need to come together to develop intervention plans to aid vulnerable communities facing an array of disparities, holding down those communities throughout time (National HIV Curriculum, n.d.), which also cause the nation to undergo economic burdens.

[1] The study team consisted of 3 Emory Graduate students, 5 five postdocs in the Emory endocrinology department, one Emory ophthalmologist, and a professor of endocrinology in the Emory Medical School who served as the principal investigator. Exaucee Manishimwe, I, as the research assistant, oversaw submissions of the required materials to IRB. I developed the survey tools, recruited the patients, and performed 37 out of the 100 surveys.

Chapter 3: Methods

To conduct this prospective cross-sectional study, we piggybacked on a clinical trial study of 100 African American patients diagnosed with end-stage kidney disease (ESKD) and undergoing dialysis at one of the Emory dialysis centers.

3.1 Recruitment Process

Patients were recruited using power chart, an Emory record containing the personal information of each patient, from the three Emory Dialysis Centers – Decatur, Northside, and Candler. The requirements were that the patients had to be over 18, had the ability to consent, and must have been undergoing either hemodialysis or peritoneal dialysis for at least 6 months prior to recruitment. They had to be African American and Non-Hispanics to be eligible to participate in the study. The exclusion criteria included those under 18, or part of the vulnerable group as stated by Emory IRB (IRB# 00002826) no pregnant women, those with a mental deficit that prevents a patient to understand the scope of the study, prisoners, and neonates.

A participant that met all the above criteria was then briefed on the study scope by three Emory students in the Rollins School of Public Health or the School of Medicine, the researchers. Participants then were asked to sign the informed consent in the presence of one of the researchers and to participate in the study in the same visit as the signing of the consent form. Participants were given a copy of the signed Informed Consent.

I (Exaucee Manishimwe) started the study by retrieving a list of patients who were currently undergoing treatment in the dialysis center at one of the three Emory Dialysis centers.

The list was first broken down by race and only those who were African Americans were considered for participation in the study. The average age of the patients ranged from 27 years old and above. Each patient's file could be accessed on the Emory Power Chart which showed their MRN number which serves as an identification of the patient to ensure we had the right patient. I then received a schedule of the appointment time of each patient which helped in determining which patients could be approached for interview. The first 2 weeks of the study was spent in familiarizing the researcher/interviewer with the patients, nurses, and staffs in the dialysis center. As the dialysis centers are small, there was a community that was already built in the clinics and unfamiliar faces might lead to many patients and nurses not trusting us as the researcher experienced in the first week that I visited the clinics.

After familiarizing myself with the clinics and building rapport with staff and patients, I started my first round of recruitment by approaching patients 15-30 min after their arrival/appointment time. As patients need to be settled in their chairs and not disturbed in the process of treatment, we needed to allow for the extra time to settle in. We first started with a short 1 min introduction of the study as we did not want to coerce anyone into the study and make them feel as if they were part of an experiment. If the patient said yes, they would like to participate, we handed them the consent form and had it signed it with the researcher who went over it with them and we handed them a copy of the signed form and do the surveys on the same day (see Appendices). The research was designed to be completed in a one-time visit and participants were awarded a 20 dollars visa card as an appreciation for participating in the study.

3.2 Data Collection

Participants participated in a series of 3 surveys and 2 additional clinical assessments, a picture of the eye to determine presence of diabetic retinopathy, and a visual assessment to determine visual acuity. The test took place in the dialysis center. The participants answered a series of surveys and a list of questions focused on social determinants of healthcare such as education level, number of clinic-visits this year, etc. (see Appendices). Patients were guided through a test to examine their vison acuity and test their eyes for the presence of DR. For the acuity test the exam asked participants to identify numbers, letters, or symbols on a paper chart. Then, a picture of both eyes was taken with a special camera, while they sat int their chair. Due to the dialysis condition and the bright room, an eye drop (Phenylephrine 2.5%) was used to dilate participants' pupils to take a good photograph for those that the researcher had a hard time taking a successful picture of the retina.

The surveys were administered using two methods. The first method was the researcher going through the survey with the participants and marking the answers on the file which was identified by initials and participants number ranging from 001 to 100. The second method was to give the patients the survey file to complete on their own and comeback within an hour to complete the next steps. The next steps were to conduct the visual acuity test by standing arm's length from patient eyes. The last step was to take the photographs which required the researcher to set the cameras adjustments until the right settings were achieved to take an optimal picture. The camera determined whether there was presence of DR in each eye. When the data were collected then the data were entered into Redcap which was also set to record the paper version of the data collection. The photographs were sent to an ophthalmologist at the Emory University Eye Clinic who had IRB approval to be part of the study.

3.3 Data Storage and Confidentiality

Each file of the patients was stored in a cabinet that was only accessible to those who had permission from the IRB to participate on the study. The data was also stored on Redcap, an Emory tool that allows for collection of data. Emory requires both the collection of data to be stored electronically and physical copies to be stored in an Emory confidential cabinet. Only the study team had access to the physical files to ensure confidentially as promised in the signed informed consent forms. Each participant fille contained the original survey answers, the signed consent forms, and the results of the visual acuity test. The gift cards were also recorded with the same method of identifying each participant then kept in a checkbook that was also stored into the private research cabinet. The pictures were stored on a USB disk and the private research excel folders, with only the study patient number and R for the right eye and L for the left eye. The pictures were also stored on the AEYE website which is the site that helps determine whether the camera detected the presence of diabetic retinopathy in the photographs.

3.4 Phase 1 Survey

Participants completed the demographic survey with the aid of a researcher or on their own. The demographic variables collected were, race, age, sex, height, weight, BMI, and data about marital status, number of individuals in the household, employment status, personal and household Income, housing (whether they owned or rented their house), and educational level. Questions about whether they had insurance, and if yes, what type of insurance they had were also assessed and whether they were on disability. Participants were assessed on diabetes history. This part of the questionnaire included duration of diabetes in years, type of diabetes

(Type 1DM or Type 2DM), the type of treatments if any that the participants were undergoing (OAD, Insulin, or GLP1-RA), average HbA1C in the past year and FBG (recorded from their morning visit), type of dialysis (PD-peritoneal or HD-Hemodialysis), and the duration that participants had been undergoing dialysis in years. They were also assessed on whether they had any history of infection and which type of infection. History (Hx) of GI (Gastrointestinal) disease and type were also assessed in this phase of the survey. Family history was also assessed, and the information collected, included family Hx of diabetes, Family History of end stage kidney disease (ESKD), self-described vision, Hx of DR, the duration of known DR type of DR treatment (laser or injections) and the last visit to ophthalmology clinic during the past year if there were any visits. Data on comorbidities such as past diagnoses of coronary artery disease, heart failure, hypertension hyperlipidemia, Hx LE amputation and the number of admissions to the hospital in the past year. A 5-item food insecurity assessment was also conducted in this question (USDA, n.d.) as well as an 8 item questionnaire on substance abuse assessing abuse of alcohol, tobacco and other drugs. It also included a tool assessing depression called PHQ-2, in which patients rated the question about whether they had experienced a situation on daily basis or not at all (Not all:0, Several days:1 More than half the days:2, Nearly Every day:3) leading to total assessment score of 0-27 for severity of depression (Depression Severity: 0-4 none, 5-9 mild, 10-14 moderate, 15-19 moderately severe, 20-27 severe). The PHQ-2 is designated to assess the frequency of depressed mood and anhedonia over the past two weeks of the participants. Its purpose is to screen for depression in a “first-step” approach, however it does not determine whether someone is afflicted with a depressive disorder which can be further evaluated by assessing patients who screen positive for depression with the PHQ-2 using the PHQ-919 (Wiznia et al., 2022).

Participants were also assessed on social norms and attitudes, discrimination, and racism in the dialysis center and whether they believed that there were any biases that African Americans faced while getting treatment in the dialysis center.

3.5 Phase 2 Survey

This phase was conducted using the kidney disease and Quality of life Questionnaire (KDQOL-36^{TM}). The purpose of this survey is to assess participant's quality of life with kidney disease.

Participants either completed this survey with the aid of a researcher or on their own. This survey has 5 subtests - symptoms, burden of illness, social interaction, staff encouragement, and patient satisfaction. It was designed to assess the burden of kidney disease on patients that are receiving dialysis (About KDQOL, n.d.; Peipert et al., 2019).

3.6 Phase 3 Survey

This phase was conducted using an Assessment of the Impact of Vision Impairment questionnaire.

Participants completed this survey with the aid of a researcher or on their own.

This form contains 32 questions with the purpose to measure self-report of the impact of vision impairment on restriction of participants daily activities in five domains of functioning. This test allows clinicians to evaluate the effect of vision deficit on participants daily life which cannot be assessed through most clinical studies on the effect of visual impairment on daily life activities (Campayo et al., 2011).

3.7 Eyes Clinical Assessment

Visual Acuity was assessed using a Rosenbaum Pocket Vision Screener Chart. Participants were assessed under normal light conditions and were to do the test without using any correcting lenses. The participants were to sit straight. There was a lack of ruler to accurately measure the distance needed to perform the test therefore each researcher used their arm as reference for the 36cm distance required to perform the test. Fingers were pointed near the patient's eyes and extended to the researcher's shoulder where they stood. The patients were asked to read a series of numbers or letters (the smallest they could observe) or to point out the direction the smallest letter E was pointing on the chart. Visual acuity was accessed on the scale of 20/20 as perfect vision and 20/800 as the highest visual impairment.

Normal Visual acuity

- Snellen visual acuity = 20/20

Moderate Visual Impairment:

- Snellen visual acuity = 20/70 to 20/160

Severe Visual Impairment

- Snellen visual acuity = 20/200 to 20/400
- **OR** visual field of 20 degrees or less

Profound Visual Impairment:

- Snellen visual acuity = 20/500 to 20/1000
- **OR** visual field of 10 degrees or less

Blindness means central visual acuity

- Snellen visual acuity = 20/200 to 20/400 or less in the better eye with the use of a correcting lens.
- Total blindness is the complete lack of light perception and form perception, and is recorded as "NLP," an abbreviation for "no light perception."

3.8 Diabetic Retinopathy (DR) Imaging

To assess whether a patient had diabetic retinopathy a portable camera, Optomed Aurora portable camera, was used to take pictures of the eye. The Camera is associated with the AEYE Diagnostic System, which is an Artificial Intelligence modality that can detect retinopathy from an eye image within seconds. The AEYE Health has conducted few FDA approved trials mainly in Europe and has shown an accuracy of 91.9% sensitivity and 93.6% specificity.

3.9 Data Storage

The information collected was confidential, and each patient's file was coded using initials, MRN numbers which can be tracked only through Power Chart and a code 001 for the first participant to 100 for the last participant. Each File was stored in a confidential box where only the designated research group could access. Data was transferred to Redcap, Emory research that is only accessed by password and authorization from a designated Emory researcher on the study team, while maintaining the same levels of confidentiality and privacy. Only the research team can access the information. The Eye Images were stored in a folder by participants code numbers in OneDrive that is only accessible by researchers and the designated Emory Ophthalmologist for this study through their own Emory accounts.

3.10 Statistical analysis

Statistical Analysis was performed using SAS (version 9.2; SAS Institute, Cary, NC) and Excel (version 16.63.61). Most of the analyzed data were reported in averages, standard deviations, percentages, and counts. Each demographic characteristic was compared to

diagnosis of DR and depression. A linear regression and T test was run for the DR diagnosis, FI score and depression.

4. Results

4.1 Phase 1

A total of 100 participants were recruited and consented to participate in the study from all three Emory Dialysis centers. Among the 100 participants, ninety-eight (n:98) completed the survey, with two dropping out mid-study (missing n:2). Of the ninety-eight participants, the ratio was 1:1 male and female. The mean age for this population was 59.17 years old with a standard deviation of ±12.178. Of the 100 screened patients, only 55 images were successfully captured for analysis. The other 45 images came out as bad or had inadequate image for analysis. Out of the 55 images captured 47 participants (85%) screened positive for DR while the remaining 15% screened negative for DR. Of the 55 participants who had sufficient images, the mean age and standard deviation were 59.26 ±12.20 respectively. The ratio of man to women was 26: 29 (n= 55). Diagnosis was also confirmed with the use of EMR, an Emory medical record data storage which indicated whether a patient was previously diagnosed with DR. The medical record indicated that 54.7% of all participants in our study were diagnosed with DR by their ophthalmologist. The participants were diagnosed as mild to proliferate DR. The duration that one had diabetes also impacted the number of years one was diagnosed with DR, the average years 18.13 years and that of those diagnosed with DR 7 years. There is no significant association between DR status and duration of diabetes or type of diabetes ($p<.107$).

The average BMI score for patients that were successfully screened for DR (n=55) was 31.60 with a standard deviation of ±8.86. diabetes Duration for the sufficient images (n=55) was found to be 18.56 years. The prevalence of infection was 1 occurring in a participant that had a successful

image of DR+. 45 participants reported one or more of the comorbidities - coronary artery disease, heart failure, hyperlipidemia, and hypertension - with 87% of them screening for DR, (See Table1).

The average household income and standard deviation of income for this cohort was $39,585.61, ±$56,343.54 respectively. The household income in this cohort is lower than the national average by 41.3% and lower by 13.8% than the national African American household income in the US. The average education level for those who had sufficient DR images are high school and above 87.23%, and college and above, 27.27% compared to the national level of 87.9%, and 25.2% respectively (Figure 4). There isn't a significant difference between this cohort and the national average scores for African Americans. The distribution for employment status were employed were (n=6) with 5 DR+ and 1 DR-; out of work n=5, 4 DR+, disabled with 26 with DR+ diagnosis, (see Figure 2). The majority of respondents were renters (n=63) (see Figure 3). The average FI score was 1, with a standard deviation of ±1.6 suggesting low food insecurity. Out of the ninety-nine (n=99) participants who responded to the questionnaire 11 (11.11%) had low food security. The average Substance Abuse Score was 5.71 suggesting a very high possibility of substance abuse in this population. The average depression score for this cohort was 6.02 with a standard deviation of ±5.20 suggesting a mild level of depression. The prevalence of severe depression is 2% (n:2), 4.1% (n:4) for moderately severe, 16.3% (n:16) moderate, 33.7% (n:33) mild, 43.9% (n:33) minimal for the 98 participants who responded to this session, (see Table 3).

4.2 Phase 2

For the five factors assessed in the KDQOL diagnostic tool, the mean and standard deviation respectively for each factor, symptom/problem list was 69.6, ±15.7; effects of kidney disease 59.72, ±13.11; burden of kidney disease, 41.67; ±26.52; SF-12 Physical Health Composite; 34.1, ±10.58 and the SF-12 Mental Health Composite 46.59, ±6.28(see Figure 1). There was no statistical significance difference between participants assessed to have diabetic retinopathy and those who did not have diabetic retinopathy (p=.65). Based on the visual impact assessment, it was found that vision impacted a DR diagnosis, with most of the DR+ participants reporting a higher number of impact than their DR- participants counterparts, with a P-value of (P=.0329).

4.3 Phase 3

For the visual acuity assessment, ninety-six participants (n:96) successfully completed this section. Out of the ninety-six participants, the prevalence of moderate and normal visual acuity was 60.4% (n:58), while the prevalence of severe visual impairment was 39.6%. (n:38) (see Table 4).

Chapter 5: Discussion, Conclusions, Limitations, and Recommendations

Previous data suggest that depression is likely to lead to worsening diabetic retinopathy. and inversely diabetic retinopathy patients were more likely to be depressed than the average person (Roy & Lloyd, 2012). From our findings, the correlation between positive diagnosis of diabetic retinopathy and depression was not statistically significant with a P-value (p= .830). However, there were differences between the two groups of this cohort; the average of those who had a successful positive clinical assessment of DR had a higher average of depression than those who were not diagnosed with DR. This cohort's average depression score shows that there those who were positive DR are more likely to be afflicted with Depression. It was not surprising, as many studies have demonstrated, that those who are diagnosed with diabetic retinopathy are more likely to be depressed and that depression can also accelerate DR (Roy & Lloyd, 2012; Campayo et al., 2011). Only 54% of the total population knew that they had DR. Therefore many may not have been depressed due to DR. The average of depression was also higher than the negative DR diagnosis, 5.91 vs 5.0. This probably affected the significance of the findings. Screening patients further is needed to conclude the impact of depression on diabetic retinopathy on African Americans.

Depression doesn't manifest in individuals the same way. The questionaries that were used in this study demonstrated a moderate level of depression across the cohort. However, the setting of this study prevents us from accurately diagnosing depression in an accurate manner. Questionnaires have their own limitations. This was a long questionnaire that took an average of an hour and half per patient and during the interview people seem to lose interest in the study

after the first few questions. Therefore, there could have been some response bias from the participants. Depression can showcase abnormalities in brain ERP data which was not done in this study (Proudfit et al., 2015). The depression measures in in this study were self-reported which could explain the lower rate of depression compared to that of national levels. Another factor that could've led to the non-significance levels could've been that the patients that were studied were all diabetic and had end-stage kidney disease for years and therefore, there would be no significant differences between the patients. This study had no comparison group due to nature of the study; the interest of the team was to assess the function and use of the camera for potential future use at the Emory eye clinics.

Current research suggests that the prevalence of diabetic retinopathy for Americans is 20.2% (Duffin, 2021) and declining but in this cohort the prevalence was as high as 85% for the overall population. However, the lack of photo images for 45% of the participants, (Missing=45) is more likely to affect the level of discrepancy observed in the data. The research in the field of diabetic retinopathy (Feller, 2020) is very limited in the African American community and this study was the first of its kind. The Optomed Camera was invented in Finland and the developers of the camera conducted their research solely using a white cohort therefore, the development of the camera had a hard time capturing images for a black cohort. The retina is brighter in European descendants than in African American descendants (Luo et al., 2019). This is an issue that is also observed in ophthalmology clinics in the United States as most apparatus was developed mainly by experimenting using a white cohort rather than a diverse cohort (Luo et al., 2019). There is a need to increase the research in African American cohorts to allow for better and more accurate results. This will ensure that African Americans receive appropriate treatment

and decrease the gap that is being observed between the African American communities and the general U.S. population.

Many other factors could have also affected these differences such as the level of income. This cohort's income was $39585 which is 13.8% lower than that of the national average income for African Americans across the U.S (Peterson Foundation, n.d.). Some studies have found that age is correlated with DR positive diagnosis, those who are commonly affected are between the ages of 45-64 (Duffin, 2021). The average of this cohort age group of those diagnosed with DR is 59.26 ±12.20, making this cohort in accord with that of what other studies have observed in their analysis (Duffin, 2021). The number of years that one is diagnosed is likely to affect the probability of an individual being diagnosed with DR. The probability of DR increases with the duration one is diagnosed with diabetes (Lee et al., 2015). The average age for positive DR in this cohort is 18 years, while that of those without DR is 18.74 years, and contrary to what other studies show, there was no association between getting diagnosed with DR positive and DR negative as the association between diabetes duration and diabetic retinopathy is not statistically significant, P-Value(P=.107).

Many studies have shown that DR affects the quality of life (Luo et al., 2019; Cohen et al., 2019). There are many issues that one must face when suffering from DR, such as comorbidities, the impact of complete or partial vision loss, and the need to be on dialysis due to end-stage kidney disease. There were no statistical differences observed in the two DR groups with a P-value (P>.001) for this cohort's burden of disease on their life. However, there were differences; the average for the burden of disease was 41.67 for DR positive and 62.5 for DR- while the Mental

Health Composite was similar for each group with an average of 46.59 for DR+ and 49.41 for DR-. The patients who screened negative for DR had a higher burden of disease and a higher mental health score. The results of the KDQOL are different than what we were expecting as we hypothesized that those who were diagnosed with DR+ would have more worries as they had to add one more issue and a higher living cost on top of dialysis and diabetes related costs.

Other SES factors that can affect depression and DR score are food security and education levels. The average education level for this cohort - high school and above 87.23%, and college and above at 27.27% - is better than the 2022 national average for African Americans which is at 87.2% and 25.2 % but is still lower for all Americans which is at 89.8% for high school degree and above and 35% for college education (Duffin, 2021). There are no significant differences between the average African American cohort to suggest that the depression rate seen in this cohort is due to the level of education. The food insecurity scores for both groups are the same showing that there was no statistical difference both DR groups.

5.1 Conclusion

Depression is a disease correlated with diabetes and diabetic retinopathy. Diabetic Retinopathy is a disease that is expected to triple in the next 30 years increasing the burden of disease on many communities, especially underserved communities (Zhang et al., 2010). African Americans are severely impacted by many social determinants of health and cannot carry an increase in the

burden of disease that depression and diabetic retinopathy will bring on the community in the next 30 years.

As observed during this study the camera wasn't developed to assess the presence of diabetic retinopathy in African Americans. We have determined in the study that the lack of research in these diseases makes it harder to assess the real impact of disease in African American communities. This showcases the disparities and socioeconomic gaps that are observed between African Americans and the general U.S. population. Although we concluded that there was a presence of moderate depression present in the study population the results were not significant. I was unable to determine that the results were due to the inadequacy capturing retina images or other factors. and public officials need to come up with rigorous programs to tackle the root causes of these health issues especially in underserved communities.

5.2 Limitations

This research was conducted during the pandemic which affected data collection as much of the data wasn't successfully completed. We were unable to collect adequate pictures to analyze the presence of diabetic retinopathy. Ideally, the Finish team who developed the camera would have been present on site to train and adjust the settings of the camera for its optimal use. Another limitation that was faced was the lack of perfect environment to collect data. The perfect environment to use the Optomed Aurora portable camera is a dark room, however the clinics were too brightly lit which impacted the collection of eye images which were needed for analysis to determine DR prognosis. This was one of the first studies that utilized the Optomed

Aurora Camera in the African American communities, and this camera wasn't developed to cater for darker retinas further impeding the data collection and the inability to evaluate the true incidence rate of diabetic Retinopathy.

Another limitation that was encountered is that there were no psychologist or neuroscientist that gave input on the diagnosing for depression. We evaluated depression, and after looking at the available depression surveys available on the Web, picked the best to assess depression and the results were self-reported, which could induce response bias in the data collected. The last limitation was that most surveys were collected in the same clinic, and the people attending those clinics live in the same neighborhood, and this prevents a general overview of the association between depression and diabetic Retinopathy in the African American community.

5.3 Recommendations

Future surveys should expand research in different communities and ensure similar distribution of participants in each clinic. To provide accurate assessment of depression, the research team should find a tool that can accurately diagnose depression and diminish response bias. Diversifying the team by adding an expert in the behavioral field would ensure proper assessment of depression. Providing the use of an optimal environment will enhance the usefulness and accuracy of the Optomed Aurora cameras for better images.

References:

About KDQOL complete. KDQOL Complete. (n.d.). Retrieved February 13, 2022, from https://www.kdqol-complete.org/about/kdqol

Barrington, D. S., James, S. A., & Williams, D. R. (2021). Socioeconomic Correlates of Obesity in African-American and Caribbean-Black Men and Women. *Journal of racial and ethnic health disparities*, *8*(2), 422–432. https://doi.org/10.1007/s40615-020-00798-4

Beurel, E., Toups, M., & Nemeroff, C. B. (2020). The Bidirectional Relationship of Depression and Inflammation: Double Trouble. Neuron, 107(2), 234–256. https://doi.org/10.1016/j.neuron.2020.06.002

Campayo, A., Gómez-Biel, C. H., & Lobo, A. (2011). Diabetes and depression. *Current psychiatry reports*, *13*(1), 26–30. https://doi.org/10.1007/s11920-010-0165-z

Centers for Disease Control and Prevention. (2021, March 10). *About Social Determinants of Health (SDOH)*. Centers for Disease Control and Prevention. Retrieved April 1, 2022, from https://www.cdc.gov/socialdeterminants/about.html

Centers for Disease Control and Prevention. (July 7, 2022). *What is diabetes?* Centers for Disease Control and Prevention. Retrieved July 28, 2022 from https://www.cdc.gov/diabetes/basics/diabetes.html

Centers for Disease Control and Prevention. *Mental health conditions: Depression and anxiety*. Centers for Disease Control and Prevention. Retrieved July 28, 2022 from https://www.cdc.gov/tobacco/campaign/tips/diseases/depression-anxiety.html

Chen, X., & Lu, L. (2016). Depression in Diabetic Retinopathy: A Review and Recommendation for Psychiatric Management. *Psychosomatics*, *57*(5), 465–471. https://doi.org/10.1016/j.psym.2016.04.003

Cohen, D. E., Lee, A., Sibbel, S., Benner, D., Brunelli, S. M., & Tentori, F. *Use of the KDQOL-36™ for assessment of health-related quality of life among dialysis patients in the United States*. BMC nephrology, 2019. 20(1), 1-9.

Daly, M., & Robinson, E. (2022). Depression and anxiety during COVID-19. The Lancet, 399(10324), 518. doi:10.1016/S0140-6736(22)00187-8

Feller, M. (2020, June 17). *Black people are often unfairly blamed for health disparities-which ignores everything we know about being well*. Well+Good. Retrieved April 2,2022, from https://www.wellandgood.com/social-determinants-health/

Goeree, R., Manalich, J., Grootendorst, P., Beecroft, M. L., & Churchill, D. N. (1995). Cost analysis of dialysis treatments for end-stage renal disease (ESRD). *Clinical and investigative medicine. Medecine clinique et experimentale*, *18*(6), 455–464.

Greenberg, P. E., Fournier, A.-A., Sisitsky, T., Pike, C. T., & Kessler, R. C. (2021, April 22). *The economic burden of adults with major depressive disorder in the United States (2005 and 2010)*. Psychiatrist.com. Retrieved July 31, 2022, from https://www.psychiatrist.com/jcp/delivery/economic-burden-adults-major-depressive-disorder-united/

Hunger hits black communities harder. Feeding America. (n.d.). Retrieved April 1, 2022, from https://www.feedingamerica.org/hunger-in-america/african-american

Income and wealth in the United States: An overview of the latest data. Peter G. Peterson Foundation. (n.d.). Retrieved April 1, 2022, from https://www.pgpf.org/blog/2021/11/income-and-wealth-in-the-united-states-an-overview-of-data

Latalova, K., Kamaradova, D., & Prasko, J. (2014). Perspectives on perceived stigma and self-stigma in adult male patients with depression. *Neuropsychiatric disease and treatment*, *10*, 1399–1405. https://doi.org/10.2147/NDT.S54081

Lee, R., Wong, T. Y., & Sabanayagam, C. (2015). Epidemiology of diabetic retinopathy, diabetic macular edema and related vision loss. *Eye and vision (London, England)*, *2*, 17. https://doi.org/10.1186/s40662-015-0026-2

Luo, H., Bell, R. A., Garg, S., Cummings, D. M., Patil, S. P., & Jones, K. (2019). Trends and Racial/Ethnic Disparities in Diabetic Retinopathy Among Adults with Diagnosed Diabetes in North Carolina, 2000-2015. *North Carolina medical journal*, *80*(2), 76–82. https://doi.org/10.18043/ncm.80.2.76

Mayo Foundation for Medical Education and Research. (2020, September 3). *Diabetes and depression: Coping with the two conditions*. Mayo Clinic. Retrieved July 28, 2022 from https://www.mayoclinic.org/diseases-conditions/diabetes/expert-answers/diabetes-and-depression/faq-20057904

Mayo Foundation for Medical Education and Research. (2021, October 12). *End-stage renal disease*. Mayo Clinic. Retrieved July 28, 2022 from https://www.mayoclinic.org/diseases-conditions/end-stage-renal-disease/symptoms-causes/syc-20354532

National diabetes report - centers for disease control and ... (n.d.). Retrieved April 1, 2022, from https://www.cdc.gov/diabetes/pubs/statsreport14/national-diabetes-report-web.pdf

Patient health questionnaire-2 (PHQ-2). National HIV Curriculum. (n.d.). Retrieved February 25, 2022, from https://www.hiv.uw.edu/page/mental-health-screening/phq-2

Peipert, J. D., Nair, D., Klicko, K., Schatell, D. R., & Hays, R. D. (2019). Kidney Disease Quality of Life 36-Item Short Form Survey (KDQOL-36) Normative Values for the United States Dialysis Population and New Single Summary Score. *Journal of the American Society of Nephrology : JASN*, *30*(4), 654–663. https://doi.org/10.1681/ASN.2018100994

Proudfit, G. H., Bress, J. N., Foti, D., Kujawa, A., & Klein, D. N. (2015). Depression and Event-related Potentials: Emotional disengagement and reward insensitivity. *Current opinion in psychology*, *4*, 110–113. https://doi.org/10.1016/j.copsyc.2014.12.018

Published by Erin Duffin, & 11, M. (2021, March 11). *U.S.: Educational attainment, by ethnicity 2018*. Statista. Retrieved April 2, 2022, from https://www.statista.com/statistics/184264/educational-attainment-by-enthnicity/

Roy, T., & Lloyd, C. E. (2012). Epidemiology of depression and diabetes: a systematic review. *Journal of affective disorders*, *142 Suppl*, S8–S21. https://doi.org/10.1016/S0165-0327(12)70004-6

Scott, A. J., & Wilson, R. F. (2011). Social determinants of health among African Americans in a rural community in the Deep South: an ecological exploration. *Rural and remote health*, *11*(1), 1634.

Silverberg, E. L., Sterling, T. W., Williams, T. H., Castro, G., Rodriguez de la Vega, P., & Barengo, N. C. (2021). The Association between Social Determinants of Health and Self-Reported Diabetic Retinopathy: An Exploratory Analysis. *International journal of environmental research and public health*, *18*(2), 792. https://doi.org/10.3390/ijerph18020792

Six-Item Short form food security survey module - USDA ERS. (n.d.). Retrieved February 19, 2022, from https://www.ers.usda.gov/media/8282/short2012.pdf

The economic cost of depression is increasing; direct costs are only a small part. Psychiatry.org - The Economic Cost of Depression is Increasing; Direct Costs are Only a Small Part. (May 27, 2021). Retrieved July 28, 2022from https://www.psychiatry.org/News-room/APA-Blogs/The-Economic-Cost-of-Depression-is-Increasing

U.S. Department of Health and Human Services. (2018, January 23). *Factors contributing to higher incidence of diabetes for Black Americans*. National Institutes of Health. Retrieved Retrieved July 28, 2022 from https://www.nih.gov/news-events/nih-research-matters/factors-contributing-higher-incidence-diabetes-black-americans

U.S. Department of Health and Human Services. (n.d.). *Depression*. National Institute of Mental Health. Retrieved July 17, 2022 from https://www.nimh.nih.gov/health/topics/depression#part_2254

U.S. Department of Health and Human Services. (n.d.). *Diabetic retinopathy*. National Eye Institute. Retrieved July 28, 2022 from https://www.nei.nih.gov/learn-about-eye-health/eye-conditions-and-diseases/diabetic-retinopathy

U.S. Department of Health and Human Services. (n.d.). *Diabetic retinopathy data and statistics*. National Eye Institute. Retrieved April 1, 2022, from https://www.nei.nih.gov/learn-about-eye-health/outreach-campaigns-and-resources/eye-health-data-and-statistics/diabetic-retinopathy-data-and-statistics

U.S. National Library of Medicine. (n.d.). *Home - books - NCBI*. National Center for Biotechnology Information. Retrieved July 28, 2022, from https://www.ncbi.nlm.nih.go8v/books

Wang, K., Li, F., Cui, Y., Cui, C., Cao, Z., Xu, K., Han, S., Zhu, P., & Sun, Y. (2019). The Association between Depression and Type 1 Diabetes Mellitus: Inflammatory Cytokines as Ferrymen in between?. *Mediators of inflammation*, *2019*, 2987901. https://doi.org/10.1155/2019/2987901

Wiznia, D. H., Nelson, C. L., & Harrington, M. (2022). Movement is Life - Optimizing Patient Access to Total Joint Arthroplasty: Chronic Kidney Disease Disparities. *The Journal of the American Academy of Orthopaedic Surgeons*, 10.5435/JAAOS-D-21-00919. Advance online publication. https://doi.org/10.5435/JAAOS-D-21-00919

World Health Organization. (n.d.). *Social Determinants of Health*. World Health Organization. Retrieved April 1, 2022, from https://www.who.int/teams/social-determinants-of-health

Zhang, X., Saaddine, J. B., Chou, C. F., Cotch, M. F., Cheng, Y. J., Geiss, L. S., Gregg, E. W., Albright, A. L., Klein, B. E., & Klein, R. (2010). Prevalence of diabetic retinopathy in the United States, 2005-2008. *JAMA*, *304*(6), 649–656. https://doi.org/10.1001/jama.2010.1111

Zhang, Y., Chen, Y., & Ma, L. (2018). Depression and cardiovascular disease in elderly: Current understanding. *Journal of clinical neuroscience : official journal of the Neurosurgical Society of Australasia*, *47*, 1–5. https://doi.org/10.1016/j.jocn.2017.09.022

Tables and Figures

Table1 : Data Summary of demographics of African American dialysis patients.

	DR+	DR-	ALL
N	47(85%)	8(15%)	55(100%)
Age	59.26 ±12.20	58.63 ±12.38	59.26 ±12.20
Sex(Female)	22(85%)	4(15%)	26(100%)
Sex(Male	25(86%)	4(14%)	29(100%)
BMI	31.7 ±8.89	31.01 ±8.68	31.60 ±8.86
Household Income (below $45,870)	27151.7 ±34994.11	53966.67 ±57925.53	39585.61 ±56343.54
Employment (+)	14(78%)	4(22%)	18(100%)
Diabetes Duration(years)*	18.00	18.74	18.56
FI Score*	1.01	1.01	1.01
Depression*	6.07	6.47	6.07
Substance Abuse*	5.72	5.99	5.73
Hx of infection (+)	1(100%)	0(0%)	1(100%)
Comorbidities (+)	39(87%)	6(13%)	45(100%

Table2: Descriptive Summary of KDQOL of African American dialysis patients.

	Mean	STD	SE	Mean	STD	SE	T-test (p-value)
Symptom/problem list (12)	69.68	15.7	5.23	69.81	18.32	6.11	0.986
Effects of kidney disease (8)	59.72	13.11	4.37	73.83	16.28	5.76	0.067
Burden of kidney disease (4)	41.67	26.52	8.84	62.5	37.24	12.41	0.19
SF-12 Physical Health Composite	34.19	10.58	3.53	37.44	11.19	3.73	0.535
SF-12 Mental Health Composite	46.59	6.28	2.09	49.41	11.65	3.88	0.662

Table3: Descriptive analysis showcasing the association of depression and diagnosis of Diabetic Retinopathy.

AEYE DR Status	Depression Score	STD	SE	F Score	STD	SE
DR +	5.898477157	4.151450167	0.525241	1.01	1.396502	0.297735
DR -	5	4.358899	1.125463	1.01	1.75119	0.452155
insufficient image	5.912398537	6.351351	1.01703	1.0263	1.026316	0.164342
TTEST DR+ vs. D- depression score		0.124347				
TTEST DR+ vs. D- Food insecruity score		0.830021				

Table 4: Association between reported visual assessment and Visual Acuity.

	Means				undefined
	Symptom/ problem list	Effects of kidney disease	Burden of kidney disease	SF-12 Physical Composite	SF-12 Mental Composite
Normal Visual Acuity	72.76	67.67	56.01	36.35	46.28
Moderate Visual Impairment	64.73	60.65	48.64	33.52	49.81
Severe Visual Impairment	66.22	56.47	47.77	30.95	49.66
Profound Visual Impairment	61.46	69.53	48.44	47.55	40.41
	Standard Errors				undefined
	Symptom/ problem list	Effects of kidney disease	Burden of kidney disease	SF-12 Physical Composite	SF-12 Mental Composite
Normal Visual Acuity	3.88	5.86	7.3	7.45	2.31
Moderate Visual Impairment	4.5	5.6	7.01	2.09	2.09
Severe Visual Impairment	5.56	7.7	6.86	2.78	2.57
Profound Visual Impairment	4.62	12.59	3.93	5.56	8.25

Figure1: Summary of the association between DR presence and KDQOL scores

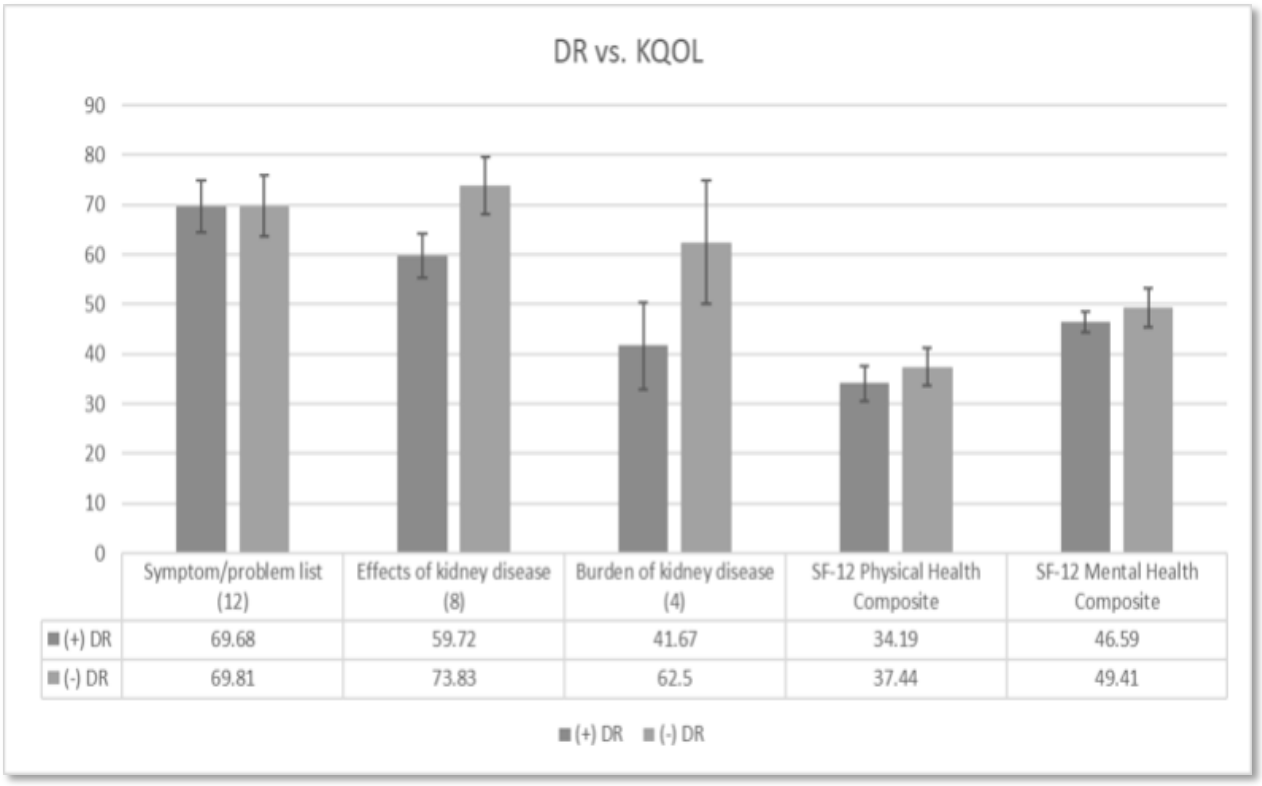


Figure 2: Association between DR presence and Employment Status

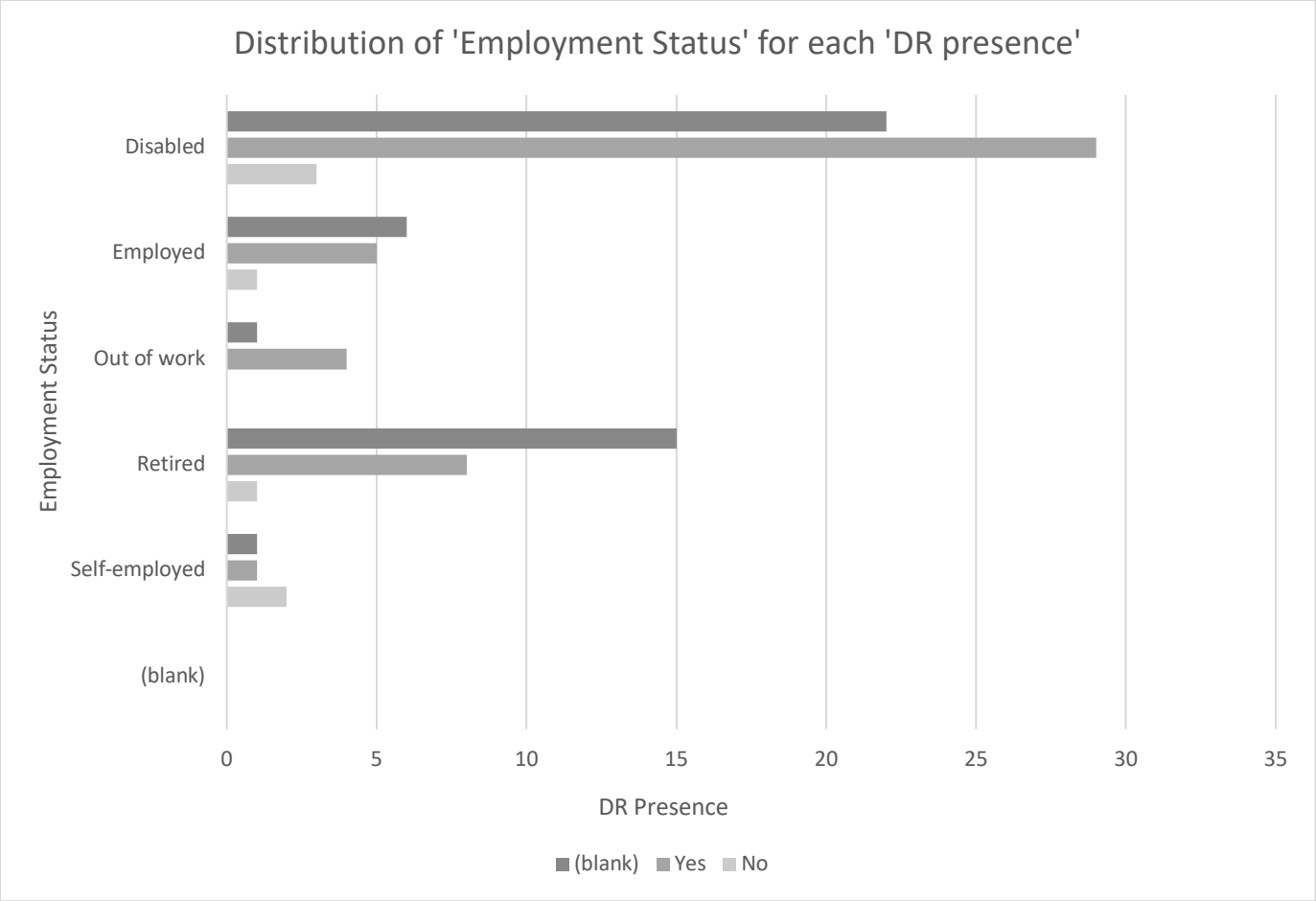


Figure3: Association between DR presence and Housing.

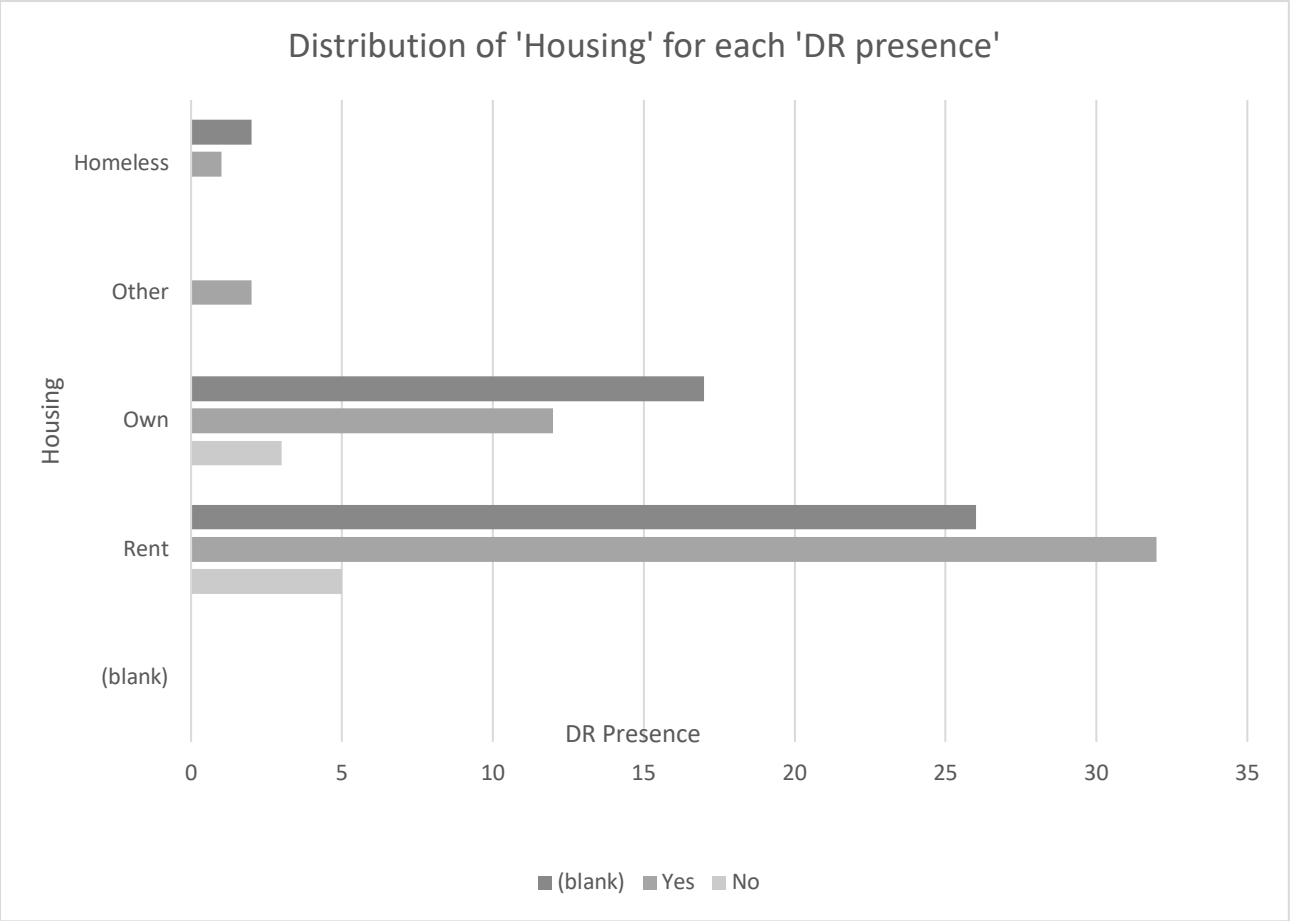
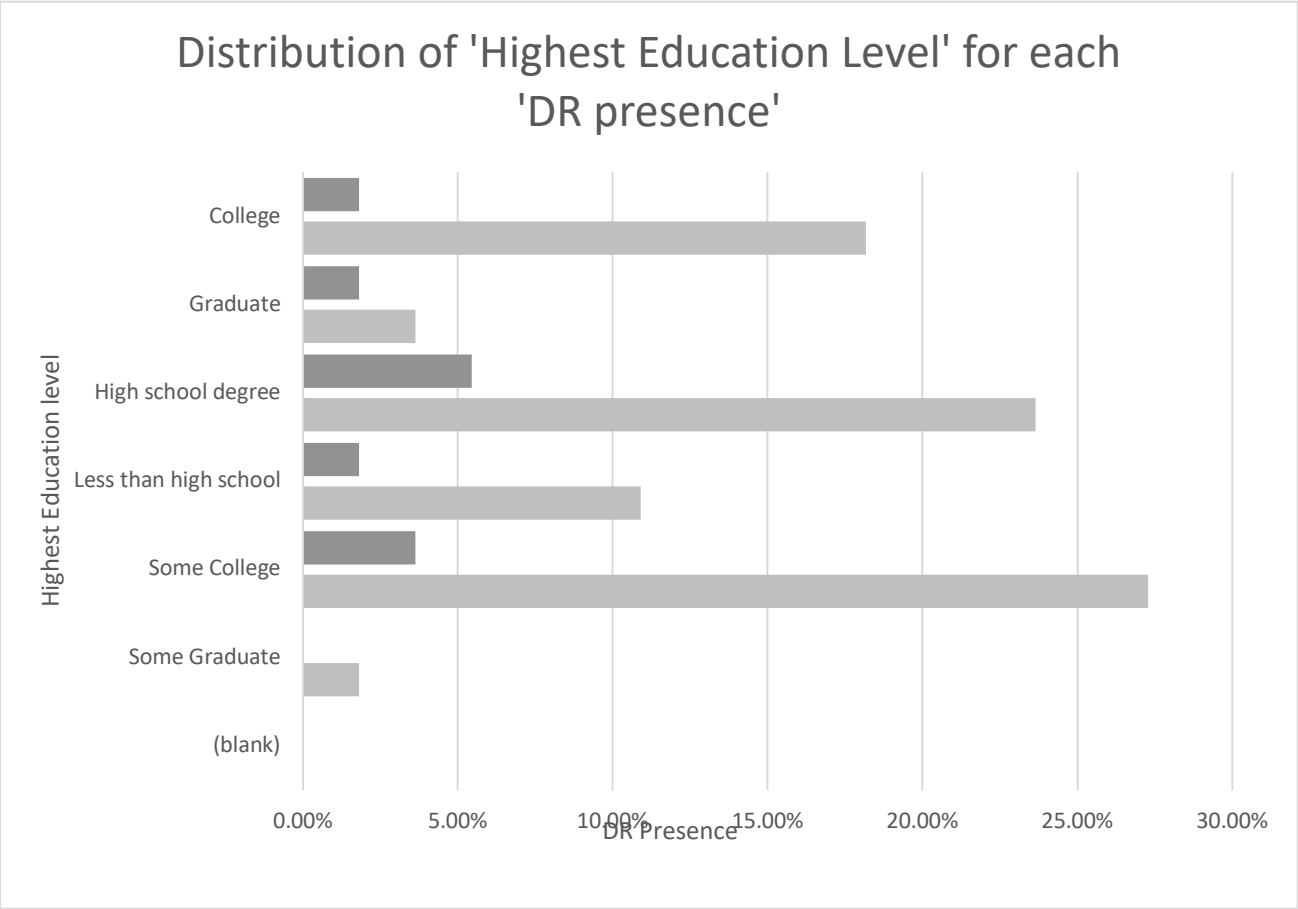


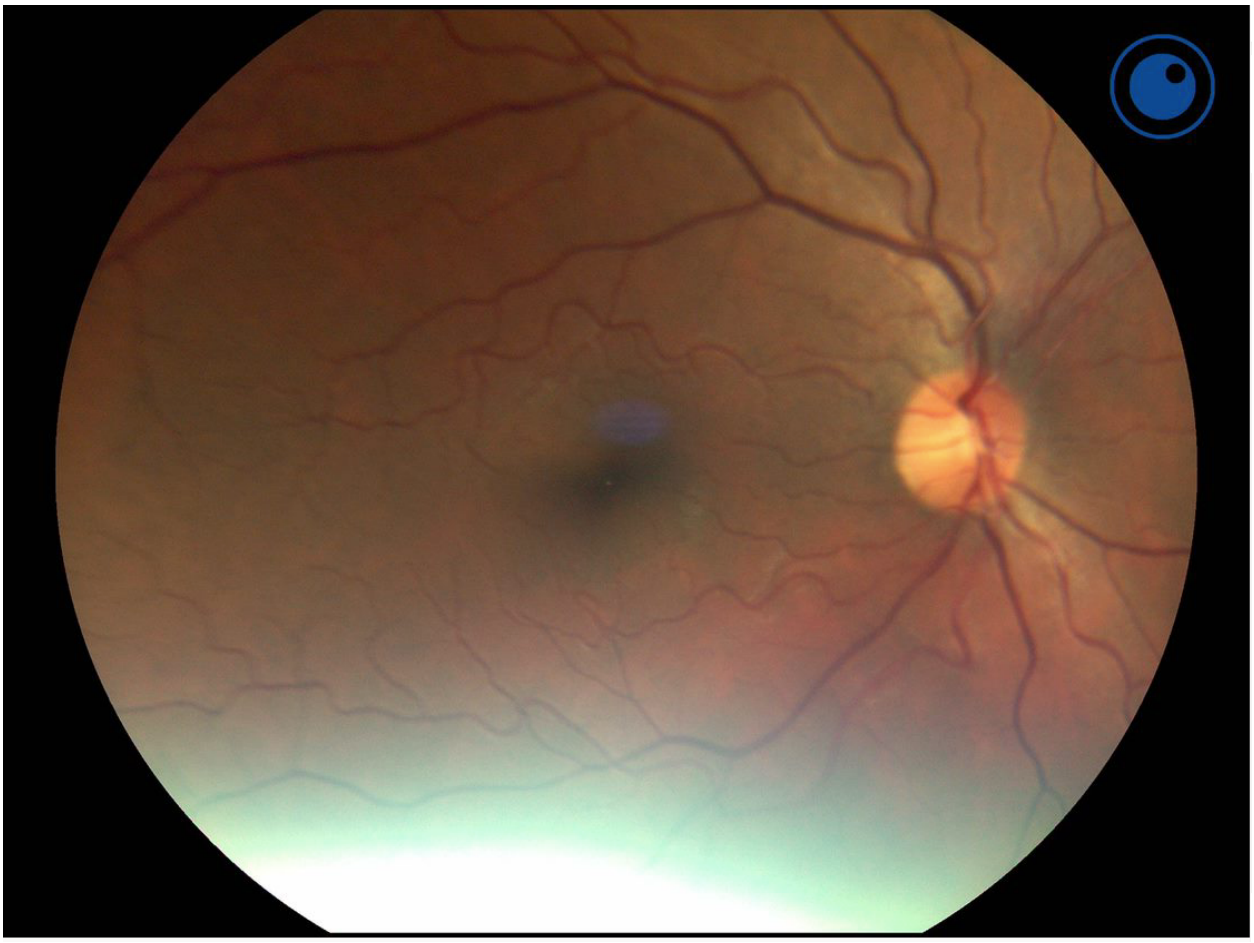
Figure 4: Association between Education level and DR Status



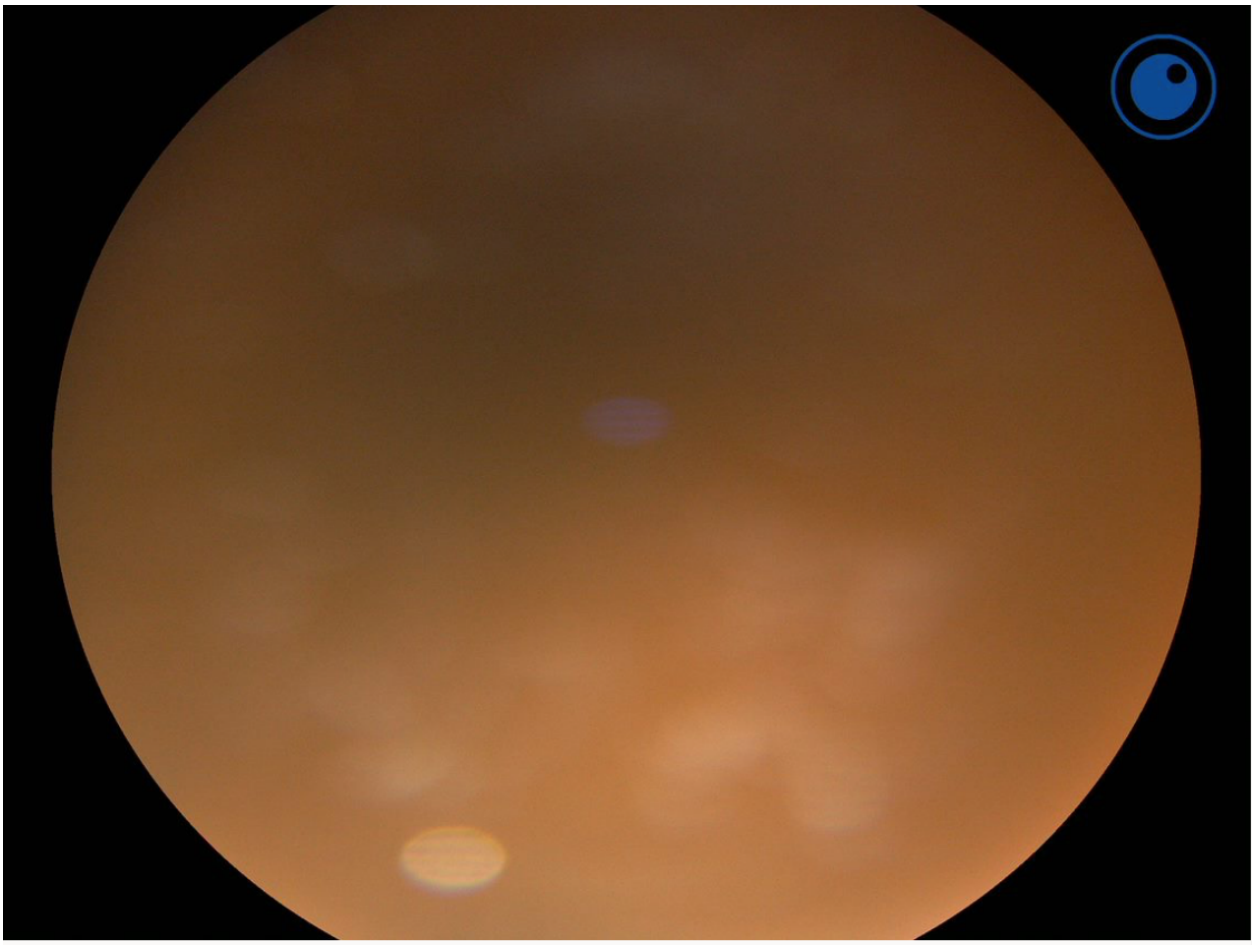
Appendices

Eye Images taken from patients

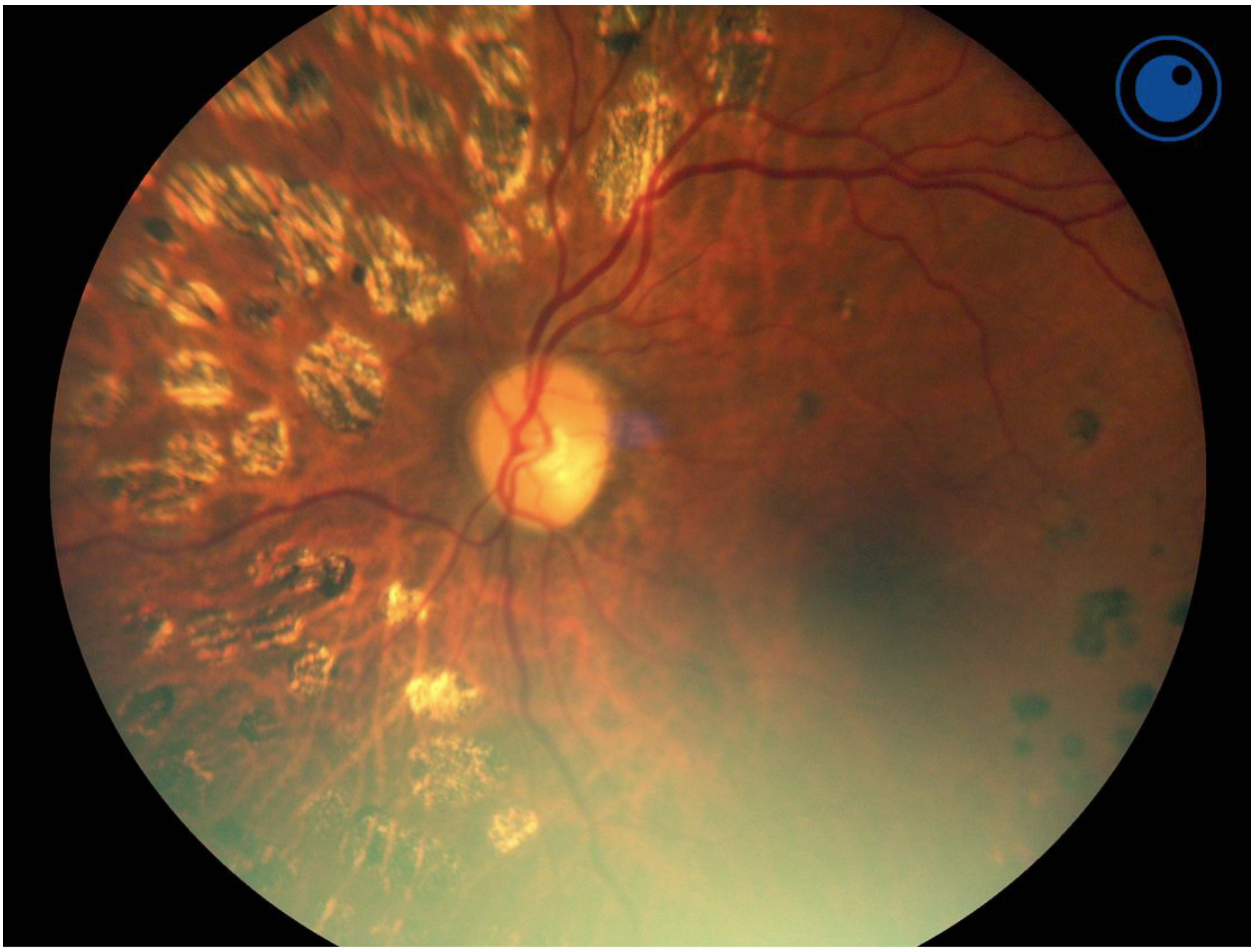
Successful picture and No DR presence (DR-)



Unsuccessful picture



Successful photograph/DR presence (DR+)



Study Questionnaire

Phase 1

Date: / / (m/d/y)
ðEmory Dialysis at Candler ðEmory Dialysis at Greenbriar
ðEmory Dialysis at Northside

Name: MRN:
Consent date: / / (m/d/y)

INCLUSION / EXCLUSION

Subjects eligible for this clinical study must fulfill all of the following criteria:

Inclusion Criteria	**YES**	**NO**
1. Ability to understand the purposes and risks of the study and willingly give written informed consent		
2. Male and female Black individuals ≥ 18 years with diabetes (type 1 or type 2) on dialysis treatment.		
3. Duration of dialysis > 6 months		

Subjects are not eligible if any of the following criteria is met:

Exclusion Criteria	**YES**	**NO**
1. Mental deficit that will make the subject unable to understand the study.		
2. Inclusion of children: No patients under the age of 18 will be recruited in this study.		
3. Prisoners, pregnant women, neonates, and people unable to consent will not be included in the study.		

CONTACT INFORMATION

Address:
Contact Information: (Contact by: phone email both)
Email:
Phone #:

Demographics

Date of birth:___/___/___(m/d/y) Age :____years old
Sex: M__F__ Race: American Indian/Alaska Native__ Asian__ Native Hawaiian or Other Pacific Islander__ Black or African American__ White__ Unknown
Ethnicity: Hispanic or Latino__ Not Hispanic or Latino__ Unknown__
Height (ft, in): Weight (lbs): BMI:

Marital status: Married___ Divorced___ Separated___ Never married___
People in household: 1___ 2___ 3-6___ 7 or more___
Employment Status: Employed__ Self-employed___ Out of work___ Disabled___ Retired___ Home maker___ Student___
Personal income(yearly) $_____
Household Income(yearly) $_____
Housing: Own___ Rent___ Homeless___ Other_____
Highest Education level: Less than High School___ High school degree___ Some College___ College___ Some Graduate___ Graduate___

Insurance

Type of Insurance: Commercial___ Government (Medicare/Medicaid)___No insurance___
Disability: Y__ N__

Diabetes History

Duration of Diabetes___ (years)
Diabetes type: type 1DM ____ Type 2DM
Treatment: OAD___ Insulin___ GLP1-RA___
Average HbA1c during the past_____
Average FBG during the past year_____
Type of dialysis: PD(peritoneal)____ HD(Hemo)____
Duration of dialysis_____ (years)
Hx of infection: Y___ N___
Type of infection_____
Hx of GI: Y___ N___
GI specify:

Family History

Family Hx diabetes _____
Family Hx Diabetic Retinopathy DR _____
Family History of End Stage Kidney Disease (ESKD)_____
Self-described vision: Excellent____ good____ poor____ bad____ blind ____
Hx of DR: Y___ N___ Duration of known DR _____

Type of DR treatment: laser___ injections___
When was the last visit to ophthalmology clinic during the past year
__/__/__(m/d/y) Eye Clinic Visit

Comorbidities

Coronary artery disease : Y__ N__
Heart Failure : Y__ N__
Hypertension : Y__ N__
Hyperlipidemia : Y__ N__
Hx LE amputation : Y__ N__

Hospital Admissions

Admissions to the hospital during the past year ___

Social norms and attitudes Discrimination, racism

Do you think that Doctors treat African American and other people of different race the same? Y__ N__
Do you think that most people think that Doctors treat African American and other people of different race the same? Y__ N__
Do you think that Racial discrimination is common while getting treatment for ESKD in the dialysis center? Y__ N__
Do you in most Dialysis Center, African American and other people receive the same kind of care? Y__ N__
Do you think being African American affects the type of care you receive in the Dialysis Center?
Y__ N__

Food insecurity FI Score(Q1, Q2, Q3)

How Often did the following happen?

1. Food didn't last
Often true or sometimes true__ Never true or Don't know__

2. Couldn't afford balanced meals
Often true or sometimes true__ Never true or Don't know__

3. Cut size or skip meals
Almost every month or Some months but not every month
1 or 2 months__ No__

4. Eat less because not enough money
Yes__ No or Don't know__

5. Hungry but didn't eat
Yes__ No or Don't know__

Substance abuse

In the past year, how often have you used Tobacco:
Daily__ More than once a day__ several times a week__ Once a month__ Once in a while__ Not at all__
Money spent on Tobacco in the past month:
0-20__ 20-40__ 40-60__ 60-80__ 80-100__ 100+__
In the past year, how often have you used Alcohol:
Daily__ More than once a day__ several times a week__ Once a month__ Once in a while__ Not at all__
Money spent on Alcohol in the past month:
0-20__ 20-40__ 40-60__ 60-80__ 80-100__ 100+__
In the past year, how often have you used prescription drugs for non-medical reasons?
Daily__ More than once a day__ several times a week__ Once a month__ Once in a while__ Not at all__
Money spent on prescription drugs for non-medical reasons:
0-20__ 20-40__ 40-60__ 60-80__ 80-100__ 100+__
Other Drug Use: Yes__ No__
Money spent on drugs?

Depression

Depression Severity Score indicator:
0-4 none,
5-9 mild,
10-14 moderate,
15-19 moderately severe,
20-27 severe
(Not all_0_ Several days_1_ More than half the days _2_ Nearly Every day_3_)

Little interest or pleasure in doing things? Not all__ Several days__ More than half the days __ Nearly Every day__ Feeling down, depressed, or hopeless? Not all__ Several days__ More than half the days __ Nearly Every day__ Trouble falling or staying asleep, or sleeping too much? Not all__ Several days__ More than half the days __ Nearly Every day__ Feeling tired or having little energy? Not all__ Several days__ More than half the days __ Nearly Every day__ Poor appetite or overeating? Not all__ Several days__ More than half the days __ Nearly Every day__ Feeling bad about yourself - or that you are a failure or have let yourself or your family down? Not all__ Several days__ More than half the days __ Nearly Every day__ Trouble concentrating on things, such as reading the newspaper or watching television? Not all__ Several days__ More than half the days __ Nearly Every day__ Moving or speaking so slowly that other people could have noticed? Or the opposite - being so fidgety or restless that you have been moving around a lot more than usual? Not all__ Several days__ More than half the days __ Nearly Every day__ Thoughts that you would be better off dead, or of hurting yourself in some way? Not all__ Several days__ More than half the days __ Nearly Every day__

Visual Acuity

Normal Visual acuity Moderate Visual Impairment Severe Visual Impairment Profound Visual Impairment Blindness means central visual acuity

Diabetic Retinopathy (DR)

No DR : ___ Mild non-proliferative diabetic retinopathy (NPDR) : ___ Moderate NPDR : ___ Severe NPDR : ___ Proliferative diabetic retinopathy (PDR) : ___ Diabetic macular edema (DME) : ___ Mild diabetic macular edema : ___ Moderate diabetic macular edema : ___ Severe diabetic macular edema : ___

Comments:

Data reviewed by: Date:

Dr. Principal Investigator
Dr. Co-Investigator

Phase 2

Kidney Disease and Quality of Life (KDQOL-36)

The Kidney Disease Quality of Life (KDQOL) (About KDQOL, n.d.) survey is a kidney disease-specific measure of Health-related quality of life HRQOL. The first version contained the Medical Outcomes Study 36 (MOS SF-36) as a generic chronic disease core, and added items relevant to

patients with kidney disease, such as symptoms, burden of illness, social interaction, staff encouragement, and patient satisfaction.

The KDQOL-36, available since 2002, is a 36-item HRQOL survey with five subscales:

- ***The SF-12 measure of physical (PCS) and mental (MCS) functining (1-12)***, set of questions with items about general health, activity limits, ability to accomplish desired tasks, depression and anxiety, energy level, and social activities.
- ***Burden of Kidney Disease subscale (13-16)***, set of questions with items about how much kidney disease interferes with daily life, takes up time, causes frustration, or makes the respondent feel like a burden.
- ***Symptoms and Problems subscale (17-28b)***, set of questions with items about how bothered a respondent feels by sore muscles, chest pain, cramps, itchy or dry skin, shortness of breath, faintness/dizziness, lack of appetite, feeling washed out or drained, numbness in the hands or feet, nausea, or problems with dialysis access.
- ***Effects of Kidney Disease on Daily Life subscale (29-36)***, set of questions with items about how bothered the respondent feels by fluid limits, diet restrictions, ability to work around the house or travel, feeling dependent on doctors and other medical staff, stress or worries, sex life, and personal appearance.

Impact of Vision Impairment

Participants answer how bother they were by a daily activity whether leisure or activity was impacted due to vision.

Phase 3

Visual Acuity test:

Normal Visual acuity

- **Snellen visual acuity = 20/20 or better**

Moderate Visual Impairment:

- Snellen visual acuity = 20/70 to 20/160

Severe Visual Impairment:

- Snellen visual acuity = 20/200 to 20/400
- **OR** visual field of 20 degrees or less

Profound Visual Impairment:

- Snellen visual acuity = 20/500 to 20/1000
- **OR** visual field of 10 degrees or less

Blindness means central visual acuity

- Snellen visual acuity = 20/200 to 20/400 or less in the better eye with the use of a correcting lens.
- Total blindness is the complete lack of light perception and form perception, and is recorded as "NLP," an abbreviation for "no light perception."

Rosembaum Eye Chart


ROSENBAUM POCKET VISION SCREENER
95
874
2843
distance equivalent
Point
Jaeger
26 16
14 10
10 7
8 5
6 3
5 2
4 1
3 1+
Card is held in good light 14 inches from eye. Record vision for each eye separately with and without glasses. Presbyopic patients should read thru bifocal segment. Check myopes with glasses only.
PUPIL GAUGE (mm.)
2 3 4 5 6 7 8 9

Informed Consent Form

You Are Being Asked to Be in a Research Study

Concise presentation of key concepts

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study, you will be one of 100 people who are being studied, at Emory affiliated dialysis centers.

Why is this study being done?
This study is being done to answer the question: To finding the number of and the severity of eye disease such as diabetic retinopathy (DR) among Black patients with End-Stage Kidney Disease. You are being asked to be in this research study because you match the population needed for this study. Population is older than 18 years, diagnosed with Type 1 or type 2 diabetes, has End-stage kidney disease, and used dialysis for more than 6 months.

Do you have to be in the study?
It is your decision to be part of this research study. You do not have to be in it. Before you make your decision, you should take time to learn about the study.

What do I have to do if I choose to participate in this study?
If you are eligible and want to be part of the study, you will participate for a 1-time visit. In that visit, the researchers will ask you to do the following: check how well you see using an eye chart, assess for eye disease with special camera and fill out a survey. All these tests will be paid for by the study.

How is this study going to help you?
If you are in the study, you will be helping the researchers answer the study question. The picture of your eye will assess for diabetic retinopathy (DR). If the patient is discovered to have DR, they will be referred to their ophthalmology or to the Emory Retinal Program.

What are the risks or discomforts I should know about before making a decision?
The study will only take one visit and the main risks are relatively small, like being bored or losing time. For a full list of expected risks, got to the "What are the possible risks and discomforts?" section of this document.

Alternatives to Joining This Study
Since this is not a treatment study, the alternative is not to participate.

Costs

You WILL NOT have to pay for any of the study tests. In fact, you will be compensated for your time with one-time $20 gift card.

What Should I Do Next?
Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions (e.g., about exact time commitment, about unfamiliar words, more details on specific procedures, etc.). Take time to consider this and talk about it with your family and friends.

Page Break

Emory University and Grady Health System
Consent to be a Research Subject / HIPAA Authorization

Title: **Prevalence and Severity of Diabetic Retinopathy in African Americans with End-Stage Kidney Disease**

IRB #: 02826

Principal Investigador: Guillermo E Umpierrez, MD

Study-Supporter:

Introduction
You are being asked to be in a medical research study. This form is designed to tell you everything you need to think about before you decide if you want to be a part of the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.** The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.

Before making your decision:

- Please carefully read this form or have it read to you
- Please listen to the study doctor or study staff explain the study to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form, you will not give up any legal rights.

What is the purpose of this study?
The purpose of this study is to find the number and the severity of eye disease such as diabetic retinopathy (DR) among Black patients with End-Stage Kidney Disease.

What will I be asked to do?
The test will take place in the dialysis center. You will be guided through an exam to see how well your eyes can see. The exam will have you identify numbers, letters, or symbols on a paper chart. Next, a picture of both eyes will be taken with a special camera, while you sit in chair. An eye drop (Phenylephrine 2.5%) will be place to dilate your pupils and allow to take a good photograph. The last step will have you answer two surveys and a list of questions focused on social determinants of healthcare such as education level, number of clinic-visits this year, etc. This visit will take place for one time only during your scheduled dialysis session

Who owns my study information and samples?
If you join this study, you will be donating your study information. You will not receive any compensation if your information is used in other studies. If you withdraw from the study, data that were already collected may be still be used for this study.

What are the possible risks and discomforts?
There are no other risks or discomfort.
An eye drops to dilate your pupil may be used to facilitate the retinal photograph. It takes about 15 to 30 minutes for the pupils to dilate, with a duration up to 4 to 6 hours. Because dilated pupils can't control the amount of light, the glare outside may bother you. You will avoid driving for 6 hours after the procedure.
Burning or stinging, headache, sensitivity to light, or blurred vision may occur. These side effects may go away during treatment as your body adjusts to the medicine. You may also experience eye irritation but is less common side effect.

Will I benefit directly from the study?
This study is not designed to benefit you directly. This study is designed to learn more about number of eye disease such as diabetic retinopathy (DR) among Black patients with End-Stage Kidney Disease. The picture of your eyes will measure the presence and severity of DR. If you have newly diagnosed DR, we will refer you to an ophthalmologist or to the Emory Retinal Program. The study results may also be used to help others in the future.

Will I be compensated for my time and effort?
You will get one-time $20 for the completed study visit, to compensate you for your time and effort. Compensation only occurs after the completion of the study visit. If you do not finish the study, we will not compensate you for the parts of the visit you have completed. The payment type will be a gift card given at the end of visit.

What are my other options?
This study does not provide a treatment option. So, if you decide not to enter this study, your care will not change in any way.

How will you protect my private information that you collect in this study?

Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Study records can be opened by court order. They also may be provided in response to a subpoena or a request for the production of documents.

Storing and Sharing your Information

De-identified data from this study (data that has been stripped of all information that can identify you), may be placed into public databases where, in addition to having no direct identifiers, researchers will need to sign data use agreements before accessing the data. We will remove or code any personal information that could identify you before your information is shared. This will ensure that, by current scientific standards and known methods, it is extremely unlikely that anyone would be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Your data from this study may be useful for other research being done by investigators at Emory or elsewhere. To help further science, we may provide your deidentified data and/or specimens to other researchers. If we do, we will not include any information that could identify you. If your data or specimens are labeled with your study ID, we will not allow the other investigators to link that ID to your identifiable information.
As they become available, do you want us to contact you and ask whether you want to receive your results? If so, let the study team know, and they will contact you as the results become available.

Medical Record

If you have been an Emory and Grady Health System patient before, then you already have an Emory and Grady Health System medical record. If you have never been an Emory and Grady Health System patient, you do not have one. An Emory and Grady Health System medical record will be made for you if an Emory and Grady Health System provider or facility gives you any services or procedures for this study.

Copies of the consent form/HIPAA authorization that you sign will be put in any Emory and Grady Health System medical record you have now or any time during the study.

Emory and Grady Health System may create study information about you that can help with your care. The results of study tests. These study results will be put in your Emory and Grady Health System medical record. Anyone who has access to your medical records will be able to have access to all the study information placed there. The confidentiality of the study information in your medical record will be protected by laws like the HIPAA privacy rule. State and federal laws may not protect the research information from disclosure.

The results of some study tests will be used only for research purposes and will *not* be placed in your medical record. For this study, those items include: pictures of your eye exam.

Tests done at non-Emory and Grady Health System places may not become part of your Emory and Grady Health System medical record. Also, if you decide to be in this study, it is up to you to let your other health providers know.

Costs

There will be no costs to you for participating in this study. You will not be charged for any of the research activities

Withdrawal from the Study

You have the right to leave a study at any time without penalty.
The researchers also have the right to stop your participation in this study without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. As part of this study, we will be requesting health care entities who are covered by the Health Insurance Portability and Accountability Act and regulations (HIPAA) to provide us with health information that identifies you ("individually identifiable health information" or "IIHI"). Because the health care entities are covered by HIPAA, we must have your authorization to obtain your IIHI from them. However, the researchers who get your IIHI from the health care entities are not covered by HIPAA. Once they receive your IIHI from the health care entities, they will put it in a separate research record that is not a part of your medical record. IIHI placed in the separate research record is not be covered by HIPAA.

Purpose of this Authorization:

By signing this form, you give us permission to get your IIHI from health care entities and to use and share your IIHI as described in this document. You do not have to sign this form. If you do not sign this form, then you may not participate in the research study.

No Provision of Treatment

There is no research-related treatment involved in this study. You may receive any non-research related treatment whether or not you sign this form.

IHI that Will be Used/Disclosed:

The IHI that we will use or share for the main research study includes:

- Medical information about you including your medical history and present/past medications.
- Results of exams, procedures and tests you have before and during the study.
- Laboratory test results.

Purposes for Which Your IIHI Will be Used/Disclosed:

We will use and share your IIHI for the conduct and oversight of the research study. Once we have your IIHI we will keep it in a separate research record that will be used for the conduct of

the study. If you leave the study, we may use your IIHI to determine your vital status or contact information.

Use and Disclosure of Your Information That is Required by Law:
We will use and disclose your IIHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults. We will also comply with legal requests or orders that require us to disclose your IIHI. These include subpoenas or court orders.

Authorization to Use IIHI is Required to Participate:
By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form.

People Who will Use/Disclose Your IIHI:
The following people and groups will use and disclose your IIHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your IIHI to conduct the study.
- Emory and Grady Health System may use and disclose your IIHI to run normal business operations.
- The Principal Investigator and research staff will share your IIHI with other people and groups to help conduct the study or to provide oversight for the study.
- The following people and groups will use your IIHI to make sure the research is done correctly and safely:
    - Emory and Grady Health System offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory IRB, the Grady Research Oversight Committee, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
    - Government agencies that regulate the research including:
    - Public health agencies.
    - Research monitors and reviewer.
    - Accreditation agencies.
- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your IIHI may be shared with that new institution and their oversight offices.

Expiration of Your Authorization
Your IIHI will be used until this research study ends.

Revoking Your Authorization

If you sign this form, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must contact the study team at: Dr. Guillermo E. Umpierrez, 69 Jesse Hill Jr Dr. SE, Atlanta, GA, 30303

At that point, the researchers would not collect any more of your IIHI. But they may use or disclose the information you already gave them so they can follow the law, protect your safety, or make sure that the study was done properly and the data is correct.

Other Items You Should Know about Your Privacy
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them. The study supporter, and people and companies working with the Study supporter on this study are not covered by the Privacy Rules. They will only use and disclose your information as described in this Consent and Authorization.

To maintain the integrity of this research study, you generally will not have access to your PHI related to this research until the study is complete. When the study ends, and at your request, you generally will have access to your PHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without identifiers may be used or disclosed with other people or organizations for purposes besides this study.

Contact Information
Contact [study contact Dr. Guillermo Umpierrez at 404-778-1665:

- if you have any questions about this study or your part in it,
- if you have questions, or concerns about the research

Contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu:

- if you have questions about your rights as a research participant.
- if you have complaints about the research or an issue you rather discuss with someone outside the research team.

You may also let the IRB know about your experience as a research participant through our Research Participant Survey at **https://tinyurl.com/ycewgkke.**

If you are a patient receiving care from the Grady Health System and have a question about your rights, you may contact the Office of Research Administration at research@gmh.edu.

TO BE FILLED OUT BY SUBJECT ONLY

Please **print** your name, **sign**, and **date** below if you agree to be in this research study. By signing this consent and authorization form, you will not give up any of your legal rights. We will give you a copy of the signed form to keep.

Name of Subject

Signature of Subject (18 or older and able to consent) Date Time

Signature of Legally Authorized Representative Date Time

Authority of Legally Authorized Representative or Relationship to Subject

TO BE FILLED OUT BY STUDY TEAM ONLY

Name of Person Conducting Informed Consent Discussion

Signature of Person Conducting Informed Consent Discussion Date Time