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# Health Care Seeking Behavior and Provider Responses for HCV-Positive African Americans

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*Walden University*

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# Walden University

College of Health Sciences

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Kathleen Bailey

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Walden University  
2015

Abstract

Health Care Seeking Behavior and Provider Responses for  
HCV-Positive African Americans

by

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MS, University of California, Los Angeles, 1994

BS, California State University, Long Beach, 1991

Doctoral Study Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Philosophy

Public Health

Walden University

November 2015

## Abstract

Of the 3.5 million persons infected with chronic HCV in the United States, the African American population is the largest racial group with chronic HCV. Disparities in access to care and treatment involve a complex set of individual, interpersonal, socioeconomic, and environmental factors that influence the course of HCV infection in the African American population, resulting in poorer outcomes and survival. Drawing upon both the theory of reasoned action and the theory of planned behavior, this study was conducted to determine whether the seeking of health care by HCV-positive African Americans and the responses of health care providers to HCV-positive African Americans had improved since 2008 following the introduction of new treatment options, as compared to other HCV-positive racial/ethnic groups, using secondary data analyses with survey datasets from the National Health and Nutrition Examination Survey, 2005-2012. Using chi-square test of difference and logistic regression analyses, the study did not identify a statistically significant relationship between health care seeking behavior and responses from health care providers for HCV-positive African Americans before (2005-2008) and after (2009-2012) the introduction of new treatment options as compared to other HCV-positive racial/ethnic groups. Given the ongoing development of new and improved drugs to treat HCV infection, further research might focus on the HCV-infected population as a whole to ascertain whether differences exist as compared to earlier therapies before 2013. This study may drive social change within the health care community by raising awareness of the risks of HCV infection resulting in less provider bias and the introduction of resources into the African American and underserved communities that will improve outcomes and reduce barriers to care.

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## Chapter 1: Introduction to the Study

### **Introduction**

There are approximately 3.5 million people with chronic hepatitis C virus (HCV) infection in the United States (Centers for Disease Control and Prevention, 2012a). African Americans have a two-fold higher prevalence (3.0%) compared to Caucasians (1.3%) and Hispanics (1.5%; Kemmer & Neff, 2010). In addition, HCV-infected African Americans are disproportionately affected when it comes to HCV-related morbidity, mortality, access to care, quality of care, and treatment response. African Americans have poorer health outcomes, including a two-fold higher rate of liver cancer, a 2- to 3-times higher rate of liver cancer-related mortality, and lower rates of survival from liver transplantation (Layden et al., 2012; Pearlman, 2006). Since 2008, newer treatment options have been available for HCV infection; prior to 2008, the treatment for HCV infection had remained the same for 13 years. Although previous researchers have examined health disparities in HCV-infected African Americans, very little research has been published concerning this cohort since newer treatment options were made available. Understanding the association between health disparities in HCV-infected African Americans since the introduction of newer treatment options could help public health professionals and healthcare providers develop strategies for eliminating health disparities affecting HCV-infected African Americans, including earlier prevention measures employing community-based clinics, providers, and resources for low socioeconomic communities to promote antistigmatization and better access and treatment. The most recent data on HCV infection in the U.S. population were collected by the 2011-2012 National Health and Nutrition Examination Survey (NHANES). The

research used the NHANES datasets for an 8-year period (2005-2012) to examine the health care seeking behavior and provider responses of HCV-positive African Americans.

In this chapter, I discuss the current status of HCV infection in the United States and provide a brief summary of the relation between HCV infection and African Americans. I also describe the specific goals of the research, the hypotheses tested, and operational definitions. In addition, I discuss the scope, assumptions, delimitations, and limitations of the study. Finally, I provide a brief summary of the expected significance of the results as they relate to advancing knowledge, practice, and social change.

### **Background**

In the United States, HCV is a major cause of chronic liver disease, end-stage liver disease, and liver cancer (Centers for Disease Control and Prevention, 2012a). Among persons who acquire HCV, 20% to 25% will naturally clear the virus; the remaining will not clear the virus and will become chronically infected with HCV (Centers for Disease Control and Prevention, 2012a). Over the period of the first 20 years, 20% of persons with chronic HCV will develop cirrhosis (permanent scarring of the liver); one to seven persons with chronic HCV will develop liver cancer yearly (Centers for Disease Control and Prevention, 2012a; Kanda, Yokosuka, & Omata, 2013). Major causes of death in the HCV-infected population are end-stage liver disease and liver cancer; the only therapeutic option is a liver transplant (Layden et al., 2012). Most persons infected with HCV do not experience symptoms and will only seek medical attention in the late stages of liver disease when symptoms finally appear.

HCV infection is more prevalent in the African American population than in any other racial group. Although African Americans represent only 13% of the U.S.

population, they make up almost one quarter (22%) of all HCV cases (Centers for Disease Control and Prevention, 2012a). End-stage liver disease from HCV is one of the leading causes of death for African Americans between the ages of 45 and 64 (Pearlman, 2006). Overall, there is a two-fold higher incidence of HCV-related mortality for African Americans as compared to non-Hispanic Whites (Saab, Jackson, Nieto, & Francois, 2014). African Americans infected with HCV have poorer health outcomes and lower rates of survival from liver transplantation (Layden et al., 2012; Pearlman, 2006). When African Americans infected with HCV are given the current treatment, their rates of sustained viral response (SVR) and viral clearance are lower compared to Caucasians (Burton, Passarella, & McGuire, 2012).

The major risk factor for HCV infection is injection drug use. The overall rate of HCV infection is estimated at between 60% and 90% among injection drug users (IDUs); in addition, 60% of new HCV cases occur in this cohort (Nelson et al., 2011). African Americans have a higher prevalence of injection drug use, which contributes to their higher rate of HCV infection (Amon et al., 2008). Results from the 2011 National Survey on Drug Use and Health found that reported illicit drug use within the past month was highest for the following groups: (a) African Americans (10%), (b) males (9%), (c) ages 18-25 (23.8%), (d) those who did not graduate from high school (11.1%), and (e) unemployed (17.2%; U.S. Department of Health and Human Services, 2012). Studies have found that African American injection drug users have a greater burden of injection-related health issues, including higher HCV rates, as compared to non-Hispanic White injection drug users (Jordan et al., 2013; Korthuis et al., 2012). Although HCV treatment can be effective among injection drug users, assessment and uptake remain low (Grebely

et al., 2009). Injection drug users may be wrought with actual or perceived stigmatization that keeps them from seeking care, including HCV testing (Jordan et al., 2013). In addition to the issue of injection drug use, African Americans are disproportionately affected by socioeconomic factors, lack of adequate health insurance, and high treatment costs, which affect their health and contribute to disparities in health care access and treatment, as demonstrated in their poorer outcomes and survival of HCV infection (Melia et al., 2011).

By 2019, the direct medical costs of treating persons with chronic HCV infection are projected to exceed \$10.7 billion; the societal cost from premature death is estimated at \$54.2 billion (Wong, McQuillan, McHutchison, & Poynard, 2000). From the years 2008 to 2011, pivotal clinical trials introducing novel direct-acting antivirals (DAAs) for the treatment of HCV infection were made available in the United States, followed by the Food and Drug Administration's approval of two new DAAs, telaprevir and boceprevir, in May 2011. Prior to 2008, the treatment for HCV infection had remained unchanged for 13 years. Newer treatment options have demonstrated improved response rates for African Americans (Burton et al., 2012). As a result, it is even more imperative that the health disparities impeding the care and treatment of HCV-infected African Americans are overcome with earlier intervention to reduce costs and improve outcomes. Because HCV is a major health problem in the United States and significant health disparities affect HCV-infected African Americans, it is important to determine whether the introduction of newer treatment options with better response rates has improved both health care seeking behavior and provider responses for this population.

### **Problem Statement**

There are disparities in access to care and treatment affecting the African American population that are demonstrated in this population's outcomes and survival of hepatitis C virus (HCV) infection (Artinyan et al., 2010; Davila & El-Serag, 2006; Jan et al., 2012). Rates of HCV infection and HCV-related mortality are twice as high for African Americans as compared to non-Hispanic Whites (Saab et al., 2014). Disparities also exist for HCV-infected African Americans due to disproportionately low socioeconomic status indicators (e.g., income and education); greater risk for and burden of disease; and insufficient access to, delivery of, and quality of health care (Artinyan et al., 2010; Davila & El-Serag, 2006; Sloane, Chen, & Howell, 2006; Tohme, Xing, Liao, & Holmberg, 2013). Beginning in 2008, pivotal clinical trials introducing novel direct-acting antivirals (DAAs) for the treatment of HCV infection were made available in the United States; in May 2011, the Food and Drug Administration approved two new DAAs, telaprevir and boceprevir. Prior to 2008, the standard of care for HCV infection had remained the same for 13 years. As a result, no previous studies have examined the health care seeking behavior and provider responses associated with HCV-positive African Americans since the introduction of newer treatment options.

### **Purpose of the Study**

In this quantitative study, I used data from the 2005-2012 NHANES datasets to determine whether the seeking of health care by African Americans who are HCV-positive, and the offering of treatment by providers to African Americans who are HCV-positive, had improved since 2008 following the introduction of new treatment options. The independent variable was HCV-positive persons who completed the 2005-2012

NHANES Hepatitis C Follow-Up Questionnaire (HCQ). The dependent variables were the health care seeking behavior of HCV-positive persons and provider responses to HCV-positive persons and were represented by 10 questions from the NHANES Hepatitis C Follow-Up Questionnaire (HCQ).

### **Research Questions and Hypotheses**

Two research questions guided this research. The questions, including null and alternative hypotheses, were as follows:

#### **Research Question 1**

Has the seeking of health care, as defined by self-report HCQ responses, by HCV-positive African Americans improved since 2008 following the introduction of new treatment options as compared to other HCV-positive racial/ethnic groups?

Null hypothesis ( $H_0$ 1): Seeking of health care, as defined by self-report HCQ responses, by HCV-positive African Americans has not improved since 2008 following the introduction of new treatment options as compared to other HCV-positive racial/ethnic groups.

Alternative hypothesis ( $H_a$ 1): Seeking of health care, as defined by self-report HCQ responses, by HCV-positive African Americans has improved since 2008 following the introduction of new treatment options as compared to other HCV-positive racial/ethnic groups.

#### **Research Question 2**

Has the response from health care providers, as defined by self-report HCQ responses, to HCV-positive African Americans improved since 2008 following the



introduction of new treatment options as compared to other HCV-positive racial/ethnic groups?

Null hypothesis ( $H_0$ 2): The response from health care providers, as defined by self-report HCQ responses, to HCV-positive African Americans has not improved since 2008 following the introduction of new treatment options as compared to other HCV-positive racial/ethnic groups.

Alternative hypothesis ( $H_a$ 2): The response from health care providers, as defined by self-report HCQ responses, to HCV-positive African Americans has improved since 2008 following the introduction of new treatment options as compared to other HCV-positive racial/ethnic groups.

### **Theoretical Framework for the Study**

The theory of reasoned action (TRA) was developed by Ajzen and Fishbein in 1980, and evolved out of the expectancy value models in an attempt to understand the incongruity between attitude and behavior (Ajzen, 1991). The TRA indicates that the intention to perform a behavior is a function of attitudes toward engaging in the behavior and perceived normative pressure to perform the behavior (Glanz, Rimer, & Viswanath, 2008). Therefore, performing a behavior is a function of a person's intentions, which represents a combination of the person's own attitudes toward the behavior and his or her subjective norms (Linke, Robinson, & Pekmezi, 2013). By understanding a person's attitude toward a health behavior (including the consequences of the health behavior), and what the person believes other people, especially influential people, would expect him or her to do, one can have an impact on whether the individual will seek medical care.

It has been demonstrated that TRA is most useful in predicting behaviors under

volitional or perceived control; however, as discovered later on by Ajzen and Fishbein, some behaviors are not entirely within an individual's control (Ajzen, 1991; Linke et al., 2013). In an attempt to better predict health behaviors, the theory of planned behavior (TPB) was also incorporated into the theoretical framework (Ajzen, 1991). The TPB adds a construct called *perceived behavioral control*, which is defined as individuals' perceptions of their ability to perform a given behavior (Ajzen, 1991). This theory introduces an individual's *control beliefs*, which are defined as (a) the presence or absence of perceived facilitators and barriers associated with a given behavior and (b) the impact of these facilitators and barriers (Linke et al., 2013).

TRA and TPB were applied in the effort to determine health-seeking behaviors and influence behavioral change in the African American population infected with hepatitis C with regard to medical care access, follow-up, and treatment. In this research, I attempted to determine whether the influence of newer drug treatments had improved health-seeking behavior and provider responses for African Americans infected with hepatitis C. In its focus on real-world application, this study may serve to promote action on attitudes about HCV risk reduction, response to social norms (in the African American community), and intentions to change risky behaviors (e.g., intravenous drug use, risky sex practices) (Kiragu & Pulerwitz, 1999).

### **Nature of the Study**

This study was a quantitative assessment that used secondary data from the National Health and Nutrition Examination Survey (NHANES) and Hepatitis C Follow-Up Questionnaire (HCQ) for the following time periods: (a) 2005-2008 (before the introduction of new treatment options) and (b) 2009-2012 (during and after the

introduction of new treatment options). Both surveys used a Likert-type format and collected relevant information from respondents that included sociodemographic information, health insurance status, drug use, health care seeking behavior, and provider responses. Using the NHANES datasets, I conducted analyses of categorical variables that included age, gender, race, education, poverty index, health insurance status, and history of illegal injection drug use to provide descriptive statistics. The independent variable consisted of all participants who tested positive for hepatitis C and completed the HCQ. The dependent variables, health care seeking behavior and provider responses, were assessed through a total of 10 HCQ questions. Using the 2005-2012 HCQ datasets, I conducted statistical analyses of 10 survey questions using chi-square for frequencies and Fisher's exact where applicable (e.g., small cell sizes) to examine all participants by racial/ethnic group in two time periods: 2005-2008 and 2009-2012 (Field, 2013).

The study population was composed of 2005-2012 NHANES survey participants 6 years of age or older who tested positive for hepatitis C (anti-HCV) and who also completed a Hepatitis C Follow-Up Questionnaire (HCQ) over the telephone. All four NHANES 2-year datasets from 2005 to 2012 provided all the relevant questionnaires and variables necessary to conduct the research. The NHANES collates nationally representative data on the health and nutritional status of the noninstitutionalized civilian population of the United States (Centers for Disease Control and Prevention, 2013a). NHANES uses a stratified and multistage probability sampling design and collects information from persons using standardized household interviews, physical examinations, and testing of biologic samples; the data are published in 2-year cycles (Ditah et al., 2014). Data were collected according to NHANES procedures (Protocol

#2005-06, Protocol #2011-17), which were approved by the Ethics Review Board of the National Center for Health Statistics Research (Centers for Disease Control and Prevention, 2012b). I describe the survey population and data collection methods in detail in Chapter 3.

### **Operational Definitions**

The following terms and phrases are defined as used in the present study.

*Hepatitis C antibody positive confirmed*: hepatitis C antibody (anti-HCV) positive is a value that is calculated on all examinees 6 years or older by a serum specimen with laboratory testing as follows: Samples testing positive for anti-HCV by the screening test are tested in the confirmatory RIBA assay for antibody to Hepatitis C virus; samples with a positive RIBA result are reported as confirmed positive for antibody to HCV (Centers for Disease Control and Prevention, 2012c). Samples with a negative RIBA result are reported as negative for antibody to HCV. Samples with indeterminate RIBA results are tested for HCV-RNA (Centers for Disease Control and Prevention, 2012d).

*HCV-positive*: This term is defined as applying to those NHANES participants who tested positive for antibody to HCV (anti-HCV), as well as to participants with indeterminate anti-HCV results who tested positive for HCV-RNA for survey years 2005-2012 (Denniston, Kleven, McQuillan, & Jiles, 2012).

### **Assumptions**

Assumptions are factors that can potentially influence a study, but for which no hard data exist (Simon, 2011). The assumptions, although not controlled for, are considered probably true and necessary; if they were absent, the study would become irrelevant (Simon, 2011).

This study was based on the following assumptions:

- All study participants met NHANES eligibility.
- All NHANES surveys and questionnaires were administered according to the survey protocol.
- All study participants answered the NHANES survey truthfully.
- All laboratory samples were collected, handled, and analyzed according to laboratory protocols.
- All data downloaded from the CDC website were current and correct and have been handled and stored according to accepted data-management practices.

### **Scope and Delimitations**

The scope of this study was the 2005-2012 NHANES study populations; the sample population used for the study was defined as consisting of individuals 6 years of age or older who were anti-HCV positive and completed the Hepatitis C Follow-Up Questionnaire (HCQ). The NHANES total population for the time period 2005-2012 equaled 40,790 persons. For this same time period, a total of 394 (1.3%) out of 29,752 serum samples tested positive for anti-HCV antibody (Centers for Disease Control and Prevention, 2013a). One hundred thirty-two (33%) of the 394 anti-HCV positive individuals completed the HCQ. Data for the 2005-2012 NHANES surveys were collected from January 2005 through December 2012. Although NHANES provides a representative sample of the U.S. population, the National Center for Health Statistics analytic guidelines recommend combining HCQ data with other cycles when doing analysis and indicate that data from HCQs should not be used with sample weights to make national estimates due to small sample size and a response rate below 50% (Centers

for Disease Control and Prevention, 2012c). The study was bound by the characteristics of the 2005-2012 NHANES study populations. The study did not analyze respondents who refused to complete the HCQ phone interview after being notified of an HCV positive test result, or respondents for whom data were missing.

### **Limitations**

The NHANES variables were derived from self-report of the respondent; as a result, the potential exists for the variables to be affected by recall bias or misunderstanding of the question (Centers for Disease Control and Prevention, 2012e). The HCQ has a nonresponse bias that needs to be assessed and reported, and any information on reasons for missing data should be presented (Perlin, 2003). The sample of HCV-positive participants was small and cannot be generalized to the U.S. population. The independent variable, serum anti-HCV antibody level, was subject to measurement variation, as well as to examiner effects (Centers for Disease Control and Prevention, 2012e). To address these limitations, public health and scientific communities reviewed the NHANES protocols (Centers for Disease Control and Prevention, 2013b). Field staff interviewers are involved in comprehensive training and retraining on an annual basis; quality control measures are also implemented with interviewer monitoring, as well as data collection processes and systems (Centers for Disease Control and Prevention, 2013b). Another analytic limitation of the NHANES sample is that it was selected from a relatively small number of sampling units (PSUs) or counties, which may introduce a higher level of uncertainty in the annual estimates (Perlin, 2003). The computation of 2-year datasets is preferred to decrease variability in annual estimates.

### **Significance of the Study**

The aim of this research was to determine whether health care seeking behavior and provider responses for HCV-positive African Americans have improved since 2008 with the introduction of newer treatment options as compared to other HCV-positive racial/ethnic groups. Given that the African American population has the highest prevalence of HCV infection in the United States, it is important to understand the health disparities that make it difficult to identify and prevent transmission of this deadly virus within African American communities. There are gaps that need further investigation in order to enable understanding of the “access to care” element for the African American population; in other words, more information is needed to answer the following questions: “What percentage of the population that has been diagnosed with HCV has medical insurance and is seeking health care for HCV?” “Where is the misstep when it comes to the care of this population?” “Is it with the providers’ responses and treatment decisions, or is it with the population who, although they have medical insurance, are not seeking medical attention; or, on the other hand, do not have medical insurance and are not seeking medical attention?”

HCV infection remains a critical public health challenge in the African American population. African Americans are most at risk of infection and transmission due to illegal injection drug use behavior, in addition to worse health outcomes including increased morbidity and mortality. In order to reduce overall HCV prevalence at the population level, promotion, education, and intervention strategies need to be based in African American communities. The findings add to the body of research on health inequities with minority and underserved populations, including populations with lower

socioeconomic status in general. Positive social change may occur in the way of reinforcing awareness of the risks of HCV infection, reducing provider bias, and introducing resources into the African American communities to allow better access to care for this population, improving outcomes and removing barriers to care. The findings may introduce implications for future research to assess why African Americans do not access health care and potential solutions to those barriers, perhaps with a community-based participatory approach formed by an integrated group of health care providers, community members, patients, families, and other key stakeholders.

### **Summary**

HCV infection is a serious health problem within the African American community. There are disparities with access to care and treatment for the HCV-positive African American population that result in poorer morbidity and mortality (Artinyan et al., 2010; Davila & El-Serag, 2006; Jan et al., 2012). Disparities also exist for HCV-infected African Americans due to disproportionately lower socioeconomic status, greater risk for and burden of disease, and insufficient access to, delivery of, and quality of health care (Artinyan et al., 2010; Davila & El-Serag, 2006; Sloane, Chen, & Howell, 2006; Tohme, Xing, Liao, & Holmberg, 2013). Newer treatment options have improved cure rates for all HCV-infected populations. This study addressed the following question: Has the health care seeking behavior and provider responses for HCV-positive African Americans improved since 2008 with the introduction of newer treatment options as compared to other HCV-positive racial/ethnic groups? The study's findings may guide public health policies and health care providers in targeting groups that are most at risk.



In Chapter 2, I provide background information on the results of previous research related to HCV infection, based on an extensive literature search. I examine the role of HCV infection in the United States, and its epidemiology, risk factors, morbidity, mortality, sociodemographic factors, economic burden, and treatment. I also specifically examine HCV infection in the African American population, including epidemiology, risk factors, clinical features, and access to care and treatment.

## Chapter 2: Literature Review

### **Introduction**

There are disparities in access to medical care and treatment for the African American population that are demonstrated in their outcomes and survival of hepatitis C virus (HCV) infection (Artinyan et al., 2010; Davila & El-Serag, 2006; Jan et al., 2012). The rates of HCV infection and HCV-related mortality are twice as high for African Americans as compared to non-Hispanic Whites (Saab et al., 2014). Disparities also exist for HCV-infected African Americans due to disproportionately lower socioeconomic status indicators (e.g., income and education); greater risk for and burden of disease; and insufficient access to, delivery of, and quality of health care (Artinyan et al., 2010; Davila & El-Serag, 2006; Sloane et al., 2006; Tohme, Xing, Liao, & Holmberg, 2013).

In 2008, pivotal clinical trials introducing novel direct-acting antivirals (DAAs) for the treatment of HCV infection were made available in the United States, followed by the Food and Drug Administration's approval in 2011 of two new DAAs, telaprevir and boceprevir. Prior to 2008, the treatment for HCV infection had remained the same for 13 years. The new treatment regimens using DAAs with pegylated interferon and ribavirin have improved sustained viral response (SVR) rates for the HCV-infected African American population as compared to the previous non-DAA therapies (50-62% versus 19-21%, respectively; Burton et al., 2012). The purpose of this research was to determine whether the seeking of health care by HCV-positive African Americans, and the responses from health care providers to HCV-positive African Americans, had improved since 2008 following the introduction of new treatment options, as compared to other

HCV-positive racial/ethnic groups, using survey datasets from the National Health and Nutrition Examination Survey (NHANES).

This literature review addresses HCV infection in the United States, and its epidemiology, risk factors, morbidity, mortality, sociodemographic factors, economic burden, and treatment. This review also specifically addresses HCV infection in the African American population, including epidemiology, risk factors, clinical features, and access to care and treatment.

### **Literature Search Strategy**

Within the Walden University Library, I used the following research databases to conduct this literature review: MEDLINE, PubMed, ScienceDirect, Cochrane Reviews, and Academic Search Complete. Within the UCLA Library, I used the ProQuest research database to conduct this literature review. Search terms included *African American, hepatitis C, United States, access to care, disparities, epidemiology, race, risk factors, treatment, socioeconomic status, injection drug use, and health seeking behavior*. I did not limit the search by year of publication and searched all databases up to the present date. In addition, I located additional governmental and medical information resources by using Google.

I identified a total of 175 publications from the years 1990 to 2015 for review, and I included all publications based on their relevance to the present study. The articles selected were grouped into the following categories as they related to hepatitis C in the United States: epidemiology, liver cancer/transplant, burden and/or cost, treatment response and/or uptake, injection drug use, African American and/or race, and health seeking behavior. The majority of the cited references were published in peer-reviewed,

scientific journals. Almost all of the selected studies took place in the United States, with the exception of a few international review articles that included the United States.

### **Theoretical Framework**

The theory of reasoned action (TRA) and theory of planned behavior (TPB) were developed in an effort to explain why people behave in the way they do and to understand the decisions and actions that make a person change an unhealthy behavior to a healthier behavior (Lezin, 2015). Both are useful to those wishing to assess and better understand health care seeking behaviors, as well as to influence behavioral change in the African American population infected with HCV with regard to medical care access, follow-up, and treatment. Through this research, I attempted to assess and understand whether the influence of newer drug treatments had improved access to care for African Americans infected with HCV. Further, I hoped to form a bridge from this research to real-world application by promoting action concerning attitudes about HCV risk reduction, response to social norms (in the African American community), and intentions to change risky behaviors (e.g., intravenous drug use, risky sex practices; Kiragu & Pulerwitz, 1999).

#### **Theory of Reasoned Action**

TRA centers on a person's intention to behave in a certain way. An *intention* is a "plan or a likelihood that someone will behave in a particular way in specific situations," whether this happens or not (Glanz et al., 2008, p. xx). For example, a person infected with HCV may be thinking about seeking follow-up care and/or treatment, but may or may not actually follow through on that intent. To understand behavioral intent, TRA may be used to examine the person's (or population's) attitudes toward the behavior, as well as subjective norms (Linke et al., 2013). Subjective norms are influenced by how a

person believes those around him or her will think about the behavior in question; these people are generally influential in some way and may include parents, friends, partners, or a pastor. Jordan and colleagues (2013) explored the perceptions of drug users and found that leveraging support from peers may be a valuable way to engage injection drug users in HCV care.

As discussed previously, people's attitudes and norms decide their intentions, which, in turn, are the main drivers of behavior (Lezin, 2015). People's attitudes toward a particular behavior are influenced by their beliefs about the outcome of the behavior and their evaluation of the potential outcome. Mehta and colleagues (2008) found that the majority of HCV-infected injection drug users reported that a belief that treatment would not cure them. African American injection drug users from another study perceived treatment as unimportant because they lacked symptoms, providers minimized the severity of the disease, or providers did not recommend treatment (Jordan et al., 2013). The more there is an understanding of a person's or population's attitudes and norms, the greater the ability to introduce more precise and successful interventions.

### **Theory of Planned Behavior**

To enhance the prediction process concerning a person's health behaviors, TPB can also be incorporated into research. TPB brings with it a paradigm called *perceived behavioral control*, which is defined as the extent to which people believe that they do or do not possess the necessary skills and resources to overcome any difficulties in engaging in a behavior (Ajzen, 1991). TPB involves consideration of volitional control as a variable. *Volitional control*, by definition, requires having the resources, opportunity, and support available to perform a specific behavior (Ajzen, 1991). In the published

literature, several studies have demonstrated that health disparities prevent these elements from being available for African Americans infected with HCV and that therefore, this population lacks the ability or behavior to seek and receive adequate and proper care (Artinyan et al., 2010; Backus et al., 2014; Ditah et al., 2014; Jan et al., 2012; Jordan et al., 2013; Mathur et al., 2010).

### **Hepatitis C Virus Infection in the United States**

The hepatitis C virus (HCV) was discovered by researchers in 1989; prior to that time, it was known as *non-A, non-B hepatitis* (Lindenbach & Rice, 2005). HCV consists of a 9,600 nucleotide genome-single polyprotein; there are seven genotypes that predict treatment response, with genotype 1 (harder to treat) accounting for approximately 70% of infections in the United States (Ward, 2014). HCV is the most common blood-borne infection in the United States (Ditah et al., 2014). Diagnosis of HCV is confirmed by two tests: (a) anti-HCV antibody test and (b) HCV RNA test. If both tests are positive, a person is HCV infected and requires a medical evaluation for active infection and liver disease (Centers for Disease Control and Prevention, 2015a; Gretch, 1997).

Prevalence of HCV infection in the United States has been estimated from 2.7 to 3.5 million persons, which equals 1.0-1.4% of the population (Denniston et al., 2014; Ditah et al., 2014). Since the introduction of effective screening of blood product donors in the 1990s, the incidence of new infections has declined dramatically; in 2012, only 21,870 persons were estimated to have acquired new HCV infections (Centers for Disease Control and Prevention, 2015b). Among all persons who initially acquire HCV, 20-25% will clear the virus naturally and 75-80% will develop chronic HCV (Centers for Disease Control and Prevention, 2012a). Within the first 20 years, 20% of persons with

chronic HCV will develop cirrhosis (permanent scarring of the liver); one to seven will develop liver cancer yearly (Centers for Disease Control and Prevention, 2012a; Kanda et al., 2013).

### **Risk Factors**

The risk factors for acquiring HCV in the United States include injection drug use, sexual transmission, perinatal transmission, occupational exposures among health workers, incarceration, intranasal drug use, tattooing, receipt of solid organ transplantation, and other percutaneous exposures, including a history of receiving a blood product transfusion prior to 1992, hemophilia with receipt of factor concentrates made before 1987, and hemodialysis (U.S. Preventive Services Task Force, 2014). In addition, adults born between 1945 and 1965 have been identified as a high-risk group because they are more likely to have received blood transfusions before 1992 or to have a history of other risk factors for exposure decades earlier (U.S. Preventive Services Task Force, 2014). In at least 21% of HCV-positive individuals, no risk factors for infection are identified (U.S. Preventive Services Task Force, 2014).

**Injection drug use.** Injection drug use is the most prevalent risk behavior and primary driver for HCV virus transmission (Centers for Disease Control and Prevention, 2015b). The mortality rate for injection drug users (IDUs) who are infected with HCV is 1 to 2 per 100 person years (Degenhardt, Hall, & Warner-Smith, 2006). Researchers have found that IDUs account for 60% of newly diagnosed HCV cases (Jordan et al., 2013; Nelson et al., 2011). Prevalence of HCV among IDUs is 65% and greater than 80% among long-term IDUs (Hagan et al., 2008). A global systematic review of over 1,100 data sources found that approximately 73% of all IDUs in the United States carry

chronic HCV infection (Nelson et al., 2011). In a meta-analysis of HCV-infected IDUs, researchers found that the 20-year cirrhosis prevalence was 15% (John-Baptiste et al., 2010). Researchers have identified the following sociodemographic characteristics to be associated with IDUs: a lack of health insurance, transportation problems, insufficient disposable income to cover health care costs, residing in low medical coverage areas, an education level of high school or less, low income level, homelessness, and unemployment (Oche, 2014). In addition, researchers have found that IDUs who engage in syringe/needle sharing behavior have lower educational attainment (Korthuis et al., 2012). Although HCV treatment can be effective among IDUs, assessment and uptake remain low (Grebely et al., 2009). Injection drug users may be wrought with experiences of actual or perceived stigmatization that keep them from seeking care, including HCV testing (Jordan et al., 2013). Researchers have found that once diagnosed, many IDUs do not receive clear messages about their HCV infection and the follow-up needed, which has also resulted in mistrust of health care providers (Jordan et al., 2013).

**Sexual transmission.** Although sexual transmission of HCV in the general population remains controversial, there is evidence that HCV transmission occurs through sexual contact, especially among HIV-positive men who have sex with men (MSM; Bradshaw, Matthews, & Danta, 2013; Tohme & Holmberg, 2010). Heterosexual transmission of HCV is estimated to occur at a rate of 0-0.6% per year (Bradshaw et al., 2013). Researchers have found evidence suggesting that there is no increased risk of sexual transmission of HCV among heterosexual couples in regular relationships (Tohme & Holmberg, 2010). On the contrary, a heterosexual person who has multiple sexual partners has a 2- to 3-fold risk of acquiring HCV infection through sexual transmission



(Tohme & Holmberg, 2010). Women who are HIV positive or have other sexually transmitted diseases (STDs) have up to a 4-fold risk of acquiring HCV infection (Tohme & Holmberg, 2010). The risk is greatest for sexual contact between HIV-positive MSM (aOR 4.1-5.7), and this risk increases with high-risk sexual behavior and the presence of genital ulcerative disease (Tohme & Holmberg, 2010).

**Perinatal transmission.** Chronic HCV infection is the most common form in pregnant women; acute hepatitis C is very rare during pregnancy (Floreani, 2013). Chronic HCV infection does not have an adverse effect on either the course of the pregnancy or the newborn infant's birth weight; conversely, pregnancy does not induce a negative impact on a woman's HCV infection as well (Floreani, 2013). The overall rate of mother-to-child transmission is 3 to 5%, with the most important risk factors for vertical transmission including high viral load, HIV coinfection, and invasive procedures (Floreani, 2013). Viral clearance prior to pregnancy is the goal to reduce vertical transmission of HCV (Floreani, 2013).

**Occupational exposures among health workers.** For workers who are exposed, there is currently no recommended prophylaxis for HCV (Zingman, 2013). The risk of transmission of HCV from an occupational exposure of needlestick is 1.8% (Zingman, 2013). The risk of transmission from HCV from a single mucous membrane exposure is negligible (Zingman, 2013).

**Incarceration.** Approximately 2.2 million people in the United States are incarcerated, and up to 1 in 3 carries HCV infection (Centers for Disease Control and Prevention, 2014a). The prevalence of chronic HCV infection among prison inmates ranges as high as 12% to 35% (Centers for Disease Control and Prevention, 2014a).

HCV infection in this setting is primarily associated with a history of injection drug use. Transmission in this setting may result from sharing equipment used for injecting drugs, tattooing, and piercing with other people who are already infected; sexual transmission is a component as well (Centers for Disease Control and Prevention, 2014a).

**Intranasal drug use.** Researchers have demonstrated that blood and HCV RNA are present in nasal secretions and drug-sniffing devices of HCV-infected intranasal drug users (Aaron et al., 2008). In addition, researchers have suggested that with episodes of active drug sniffing, HCV will be present with greater frequency and quantity, which may exacerbate discharge of nasal fluids and blood (Aaron et al., 2008). Little is known about the quantity of virus required for transmission, but researchers have demonstrated that HCV can remain viable on environmental surfaces for up to 16 hours (Krawczynski et al., 2003).

**Tattooing.** Researchers who conducted a systematic review of the literature over an 18-year period (1994-2011) found no definitive evidence of transmission of HCV infection when sterile equipment or professional tattoo parlors were used (Tohme & Holmberg, 2012). They did find that the risk of HCV transmission was 2- to 3.5-fold higher when tattoos were applied in nonprofessional settings including prisons or by friends (Tohme & Holmberg, 2012).

**Solid organ transplant recipient.** HCV infection is the leading indication for liver transplantation worldwide (Levitsky et al., 2013). Among kidney transplant recipients, 10-year survival is approximately 15% lower in HCV-positive compared to HCV-negative individuals (Levitsky et al., 2013). Other organ transplants that were examined either have no long-term data (heart, small bowel, and pancreas) or have shown

no difference in survival between HCV-positive versus HCV-negative recipients (lung; Levitsky et al., 2013).

**Percutaneous exposures.** Due to the implementation of blood product screening in the early 1990s, the prevalence of percutaneous exposures has greatly diminished. Although HCV infection is an independent risk factor for mortality in hemodialysis patients, researchers found the prevalence in hemodialysis units to be 14% and a seroconversion rate of 2.5% per 100 patient-years (Fissell et al., 2004).

Due to donor selection and testing improvements, the blood supply in the United States has become immensely safer (Zou, Stramer, & Dodd, 2012). Researchers who examined donor risk found the HCV incidence rate among repeat donors to be in the range of 2.16 and 2.98 per 100,000 person-years; the residual risk of HCV virus among all allogeneic donations was found to be below 1 per 1 million donations (Zou et al., 2012).

A majority of the cases of HCV infection in persons with hemophilia are presumed to result from blood transfusions before sensitive screening tests were introduced in 1992 (Orman & Fried, 2012). Persons with hemophilia acquire HCV infection at a lower mean age of 9-10 years relative to other groups at risk (Orman & Fried, 2012). Researchers have reported the prevalence of HCV infection among persons with sickle-cell disease ranging from 10-20% and among persons with thalassemia at 35% (Orman & Fried, 2012).

**Born during 1945-1965.** Seventy-five percent of all persons living with HCV infection and 75% of HCV-associated deaths are attributed to those who were born during the years 1945 to 1965 (Centers for Disease Control and Prevention, 2015a). The

prevalence of HCV antibodies in this cohort is approximately 3%, which is 5 times higher than in other age cohorts (Centers for Disease Control and Prevention, 2015a). As a result, the Centers for Disease Control and Prevention (2015a) have added the birth cohort of 1945-1965 to the HCV one-time screening recommendations.

### **Morbidity and Mortality**

HCV is the cause of death or contributing cause of death in approximately 15,000 people per year with more than 70% of deaths in people ages 45 to 64 years old (Centers for Disease Control and Prevention, 2015a). Since 2007, mortality among HCV-infected persons continues to exceed deaths from HIV/AIDS in the United States (Centers for Disease Control and Prevention, 2015a). HCV-infected individuals have mortality rates up to 3 times higher than those in the general population; in addition, they carry an 8- to 12-year reduction in overall life expectancy (Jacobson, Cacoub, Dal Maso, Harrison, & Younossi, 2010). Major factors associated with an increased risk of death include chronic liver disease, co-infection with hepatitis B or HIV, alcohol-related conditions, and minority status (Centers for Disease Control and Prevention, 2015a). End-stage liver disease and hepatocellular carcinoma are significant causes of death in this population, with liver transplantation as the only therapeutic option for many of these patients (Klevens, Hu, Jiles, & Holmberg, 2012; Layden et al., 2012). In 2011, chronic liver disease, including cirrhosis, was the 12<sup>th</sup> leading cause of death in the United States, and viral hepatitis-associated death rates were highest among persons infected with HCV (Centers for Disease Control and Prevention, 2015a). For those who do not succumb to cirrhosis, this disease is still wrought with other physical and psychological manifestations which can include fatigue, vasculitis, arthralgias, neuropathy,

lymphoproliferative malignancies, insulin resistance, type 2 diabetes, depression, and cognitive impairment (Jacobson et al., 2010). These extrahepatic manifestations have contributed to approximately 15% of all HCV-related hospitalizations (Moorman, 2013).

**Liver transplantation.** HCV infection is the leading indication for liver transplantation. Post-transplantation HCV recurrence is universal and the rate is accelerated in the new graft compared to pre-transplantation (Levitsky et al., 2013). Post-transplantation recipients demonstrate a recurrence of HCV infection within the first 5 years (Levitsky et al., 2009). Overall 5-year patient survival is 65%, and 5-year graft survival is 60% in HCV-infected recipients (Levitsky et al., 2009). With the onset of recurrent HCV cirrhosis comes a 50% incidence of liver decompensation within one year, which results in a 1- and 4-year patient survival of only 66% and 33%, respectively (Brown, 2005).

### **Sociodemographic Characteristics**

There are sociodemographic disparities that exist with the HCV infected population. Researchers examined the National Health and Nutrition Examination Survey (NHANES) data over an 8-year period (2003-2010) and found that almost one-half of chronic HCV infected persons were between the ages of 40-59 years, and 64% were male (Denniston et al., 2014). In addition, if a person had less than a high school education/GED (< 12<sup>th</sup> grade), they were twice as likely to have chronic HCV infection (OR 2.0, 1.2-3.3); if a person had a family income less than two times the poverty level (equals @ \$22,000-52,000 based on household size), they were almost four times as likely to have chronic HCV infection (OR 3.7, 2.6-5.3; Denniston et al., 2014). On the contrary, using the same data, researchers found the percentage of current, unresolved

HCV infection was lowest among those with a college education (57.3%; Liu, Holmberg, Kamili, & Xu, 2014).

Researchers who examined survival of patients with hepatocellular carcinoma found that lower income patients continue to have the worst survival as compared to middle- and high-income patients (Artinyan et al., 2010). Inconsistencies in access to appropriate care as well as differences in underlying disease are thought to be contributors (Artinyan et al., 2010). Researchers who examined liver cirrhosis using the NHANES data over a 12-year period (1999-2010) found the prevalence to be higher in those living below the poverty level, and those with less than a high school education (Scaglione et al., 2014). The goals of HCV infection as a major public health challenge include increasing both the proportion of persons who get tested, and the proportion of persons who test positive receiving the appropriate referral to care and treatment (Centers for Disease Control and Prevention, 2015a).

### **Economic Burden**

The excessive burden of high treatment costs for managing HCV and its sequelae not only impacts the patient, but also impacts private and government health care agencies (Jacobson et al, 2010). Progressive liver disease and its associated health care costs can be avoided with early diagnosis and treatment of HCV infection. Researchers have found that direct healthcare costs associated with chronic HCV infection increase in association with the progression of liver disease, and are highest in persons with end-stage liver disease (Gordon et al., 2012). By 2019, the direct medical costs of chronic HCV infection are projected to exceed \$10.7 billion along with a societal impact from premature mortality estimated at \$54.2 billion (Wong et al., 2000). Researchers showed

that birth cohort screening of all patients born between 1945 and 1965 is cost-effective at a rate of \$2,874 per case identified and can add between \$15,700 and \$35,700 per quality-adjusted life year (QALY) based on the type of HCV treatment provided (Rein et al., 2012).

### **Treatment of HCV Infection**

In 2011, the Food and Drug Administration approved two new direct-acting antivirals (DAAs) against HCV, telaprevir (TVR) and boceprevir (BOC), in combination with pegylated interferon and ribavirin (U.S. Food and Drug Administration, 2011). In studies, the triple combination of TVR or BOC plus pegylated interferon and ribavirin have demonstrated sustained viral response (SVR) rates in treatment-naïve, genotype 1 patients as high as 66% to 69% (Kanda et al., 2013). Overall, SVR rates are lower in previous relapse, partial response, non-response, and relapse populations (Kanda et al., 2013). As of 2013, there is now a total of six second generation DAAs being used (alone or in combination) for the treatment of HCV infection (U.S. Food and Drug Administration, 2014). In studies, high rates of SVR (89%-90%) have been demonstrated in treatment-naïve patients with second generation DAAs (Kohli, Shaffer, Sherman, & Kottlilil, 2014).

### **HCV Infection in African Americans**

African Americans account for 22% of persons infected with HCV in the United States (Fleckenstein, 2004). The prevalence of chronic HCV infection in the African American population is 2-fold higher than the Hispanic and Caucasian populations (3% versus 1.3% and 1.5%, respectively; Kemmer & Neff, 2010). Over a 10-year period, researchers found that African Americans carried the greatest burden of HCV infection;

during this same time period, there was also a 27.3% increase in the rate of HCV infection for this population (Centers for Disease Control and Prevention, 2015a; Ditah et al., 2014). Researchers who examined the epidemiology of HCV infection using the NHANES datasets between the years 2001 and 2010 found that African Americans had a 1.5- to 2-fold greater risk of having HCV infection versus all other ethnic groups (Ditah et al., 2014; Denniston et al., 2014). In addition, HCV-infected African Americans are disproportionately affected when it comes to morbidity, mortality, access to care, quality of care, and treatment response.

Hepatitis-C related chronic liver disease is a leading cause of death among African American persons 45 to 64 years of age (Centers for Disease Control and Prevention, 2012a). Researchers have demonstrated that African Americans have poorer health outcomes including a two-fold higher rate of liver cancer, a two to three times higher rate of liver cancer-related mortality, and lower rates of survival from liver transplantation (Layden et al., 2012; Pearlman, 2006). In addition, this population suffers from health disparities that lead to inadequate and inappropriate treatment and care. Researchers have found that risk factors associated with HCV-related liver disease morbidity and mortality include ethnicity, access to HCV therapy, and a favorable treatment response (Grebely & Dore, 2011).

### **Injection Drug Use**

African Americans are substantially and persistently overrepresented among people diagnosed with injection-related health problems, including higher HCV rates as compared to non-Hispanic White injection drug users (IDUs; Amon et al., 2008).

Between May 2005 and February 2006, the CDC's National HIV Behavior Surveillance



System (NHBS) interviewed more than 10,000 IDUs; African Americans made up almost one-half (47.1%) of those who participated (Centers for Disease Control and Prevention, 2009a). In addition, results showed that during the preceding 12 months, one-third of African American participants reported sharing syringes or injection equipment (29.1% and 33.1%, respectively; Centers for Disease Control and Prevention, 2009a). In addition, 31.4% of African American IDUs reported never getting tested for HCV infection in their lifetime (Centers for Disease Control and Prevention, 2009a). Data on the socioeconomic status of IDUs in the United States is difficult to find in the current literature.

Researchers surveyed 600 IDUs in New York City and found that African Americans were less likely to attend a private medical office in the past year; whereas, those with higher income and health insurance coverage were more likely to attend a private medical office (Turner, Harripersaud, Crawford, Rivera, & Fuller, 2013). The relationship between injection drug use and HCV transmission among the African American population is well established. In four U.S. cities over a 10-year period (1994-2004), researchers found that although overall trend declined, the prevalence of HCV infection in the African American IDUs remained unchanged (Amon et al., 2008). These same researchers also found that HCV antibody positive prevalence increases with age, number of years injecting, and intensity of injection drug use (Amon et al., 2008).

### **Socioeconomic Status**

Low socioeconomic status and less education are often associated with high risk behaviors, including injection drug use, and thus, a higher risk of HCV infection (Ditah et al., 2014). African Americans are at greater risk for HCV infection due to a poorer socioeconomic status including poverty, lower employment rates and lack of education

(Estrada, 2005; Fuller et al., 2005; Galea & Vlahov, 2002). In the United States, African Americans have one of the highest national poverty rates (25.8%); poverty rates of 20% or higher exist in 43 states for the African American population (Macartney, Bishaw, & Fontenot, 2013). Even higher poverty rates exist for African Americans in both single male-headed households (27%), and single female-headed households (40%); this results in African American children being three times more likely to live in poverty than Caucasian children (Macartney et al., 2013). Poverty can lead to early school dropout, loss of self-worth, and the uptake of illegal or socially unacceptable activities, such as injection drug use, which puts African Americans at risk for HCV infection (Estrada, 2005).

For the age group 16 to 24 years old, as compared to all students combined, African Americans have higher rates of not being enrolled in school, and not earning a high school diploma (National Center for Education Statistics, 2011). A researcher that examined the adverse effects from a poor socioeconomic status among the IDU population found that 64% of African American males had completed less than 12 years of school (Galea & Vlahov, 2002). Other researchers found that the initiation of injection drug use was associated with neighborhood level factors including African American race, lower employment rates, and lower education levels (Fuller et al., 2005).

### **Clinical Features**

Of the 20-25% who spontaneously clear hepatitis C virus from their body, the rate is lowest among African Americans versus Caucasians and Hispanics (9% versus 27% and 31%, respectively) (Mir, Stepanova, Afendy, Kugelmas, & Younossi, 2012).

Researchers have discovered that variation in genes involved in the immune response

may contribute to the ability of an individual to clear the hepatitis C virus (Thomas et al., 2009). Researchers conducted a genome-wide association study which identified a single nucleotide polymorphism of the IL28b gene; from this gene, there are three genotypes: C/C, C/T, and T/T (Ge et al., 2009). Researchers examined these three genotypes and their influence on natural HCV clearance and found that African Americans carry a higher frequency of the IL28b T/T genotype, which is more strongly associated with lower rates of natural clearance of HCV versus the other two genotypes (Thomas et al., 2009). These findings help to explain some of the variability in spontaneous HCV clearance with African Americans leaving still yet more to be discovered with epidemiological, viral, and host factor associations.

**Liver cancer.** HCV-infected persons are at risk for developing liver cancer after two or more decades of infection; those at greatest risk have cirrhosis or advanced fibrosis (de Oliveria Andrade et al., 2009). Persons with HCV-related cirrhosis have a 2-6% risk of developing liver cancer after two or more decades (de Oliveria Andrade et al., 2009). There is a 17-fold increased risk of developing liver cancer for HCV-infected persons compared to HCV-negative persons (de Oliveria Andrade et al., 2009). The 5-year overall survival of persons with liver cancer ranges from 6% to 7% (Artinyan et al., 2010).

Racial inequities in liver cancer outcomes have been observed (Davila & El-Serag, 2006; Sloane et al., 2006). African Americans have higher rates of liver cancer from HCV infection (Burton et al., 2012). Researchers examined risk factors for liver cancer in persons with HCV-related cirrhosis and found that “African American race” was independently associated with the development of liver cancer in this cohort (Sarbah et

al., 2004). Researchers examined trends in survival of liver cancer over forty years and discovered that African Americans have the worst survival, compared with all other ethnic subgroups (HR 1.66, 95% CI, 1.29-2.12,  $p < .001$ ; Artinyan et al., 2010). Researchers who examined 3 national registries over a 21-year period found that, compared to Caucasians, African Americans had an 11% higher mortality risk, and the lowest 3-year survival from liver cancer (Davila & El-Serag, 2006).

**Liver transplant.** Researchers examined racial/ethnic disparities in liver transplant patients and found that the transplant rate for African Americans was significantly lower versus Caucasians (Mathur, Schaubel, Gong, Guidinger, & Merion, 2010). Other researchers examined the race related differences during the first 2 years post liver transplantation and found a greater severity of HCV recurrence and fibrosis progression among African American recipients; in addition, a higher percentage of severe fibrosis and poorer patient survival was present in the African American recipient/White donor group (Layden et al., 2012).

### **Access to Care and Treatment**

Disparities with access to care and treatment for the African American population are demonstrated in their outcomes and survival of HCV infection. Using the NHANES data from 2003 to 2010, researchers found that African Americans carried the highest percentage (91.1%) of current, unresolved HCV infections (Liu et al., 2014). In a broad population-based study using two national databases, researchers examined 40 years of liver cancer survival trends and found that both lower income patients and African Americans continued to have the worst survival rates (Artinyan et al., 2010). Other researchers have shown similar findings in which health outcomes have not been

identical when it comes to race, with significantly poorer survival in African Americans; researchers have addressed these disparities by suggesting racial and health biases in the delivery of appropriate treatment (Davila & El-Serag, 2006; Sloane et al., 2006).

Researchers that examined liver cancer outcomes over a nine-year period in African Americans versus Caucasians in an inner-city urban setting found that African Americans were more likely to present with late stage liver disease (cirrhosis), and with a larger tumor size at time of cancer diagnosis (Jan et al., 2012). This same African American cohort was also less likely to have private insurance, and a greater prevalence of IDUs (Jan et al., 2012).

**Health-seeking behavior.** With the African American population, themes that have emerged regarding barriers to health seeking behavior include socioeconomic status, lack of health insurance, language barriers, lack of awareness of the need for care, racism, discrimination, distrust of the medical establishment, and religion or spirituality (Cheatham, Barksdale, & Rodgers, 2008; Hewins-Maroney, Schumaker, & Williams, 2005; Rooks, Wiltshire, Elder, Belue, & Gary, 2012). Researchers who examined the source of information on health care used by African Americans in low-income households found that informal channels were preferred with over half (53.9%) using their family physician, and one-third (30.4%) using their family members (Spink & Cole, 2001). Lower socioeconomic status and minority groups are more likely to rely on interpersonal and non-medical sources for health information, health maintenance and treatment of illnesses (Rooks et al., 2012; Kontos, Emmons, Puleo, & Viswanath, 2011). Relying solely on health care provider interactions can be problematic as well since African Americans often report fewer participatory medical visits due to real or perceived

barriers of unfair treatment or mistrust (Blanchard, Nayar, & Lurie, 2007; Johnson, Roter, Powe, & Cooper, 2004). Researchers found that as education level increases, the odds of seeking health information increases for all racial and ethnic groups including African Americans (Rooks et al., 2012). Ethnic/racial minority groups with lower education levels may have disparities from low health literacy. Low health literacy can result in communication challenges, limited understanding and input on a person's care, and a withdrawal from accessing care due to embarrassment and/or masculinity issues (Rooks et al., 2012).

An examination of the racial differences in HCV treatment eligibility found that African Americans are 36% less likely than Caucasians to receive treatment for HCV infection (Melia et al., 2011). In addition, African Americans have co-morbidities that can impede their eligibility to receive treatment; they suffer from higher rates of neutropenia, anemia, diabetes, and renal dysfunction (Melia et al., 2011). Overall, this introduces the paradox of African Americans carrying the greatest burden of HCV, and yet having lower treatment efficacy due to poorer response rates or ineligibility. Along with the individual co-morbidities that impact low treatment rates, African Americans are also disproportionately affected by the lack of adequate health insurance, and high treatment costs which present barriers to care for this population (Melia et al., 2011).

African Americans infected with HCV have significantly lower rates of SVR from treatment (Melia et al., 2011; Muir et al., 2004). Part of this is attributed to evidence linking African Americans to carrying a high rate of IL28B T/T genotype, which is associated with lower interferon responsiveness resulting in treatment-induced HCV clearance, versus other genotypes (Thomas et al., 2009). Persons who achieve SVR

have a clear advantage at histological and clinical levels versus those who do not achieve SVR (Muir et al., 2011). Prior to the approval and use of DAAs, the treatment of HCV had not changed for 13 years, so the existing body of knowledge examining HCV-infected African Americans with these new treatment options remains scarce. In all phase III clinical trials of the first generation DAAs (TVR and BOC) plus peglyated interferon and ribavirin, African Americans only comprised 10.6% of combined enrollment (Burton et al., 2012). When this African American cohort was analyzed, researchers found that SVR rates had vastly improved with the use of DAA therapy (TVR or BOC plus peglyated interferon and ribavirin) versus the previous non-DAA therapy (50-62% versus 19-21%, respectively; Burton et al, 2012).

Clinical studies using second generation DAAs are eliminating the use of an interferon-based regimen, and therefore, removing the reduced treatment effect of the more prominent IL28B T/T genotype with the African American cohort. Proof of concept studies have demonstrated that interferon-free, second generation DAA regimens (with or without ribavirin) are resulting in efficacious outcomes for this difficult to treat population (Highleyman, 2013; Osinusi, Bon, & Herrmann, 2013).

### **Summary**

In the United States, African Americans are at particularly high risk of HCV infection. Several researchers have demonstrated that HCV-infected African Americans suffer from poorer responses to treatment, lower rates of cure, higher incidences of liver cancer, higher death rates from liver cancer, and poorer survival rates with liver transplantation. In addition, researchers have demonstrated that there are health disparities with HCV-infected African Americans as a result of injection drug use, lower

socioeconomic status, perceived or actual bias with health care, poorer access to care, and inappropriate treatment. The NHANES datasets have been used extensively to study hepatitis C infection status in the U.S. population. The addition of the Hepatitis C Follow-Up Questionnaire (HCQ) in 2001 along with years of testing participants for anti-HCV antibody status have made the NHANES datasets very informative and useful. For this study, I used the NHANES datasets over an 8-year period, 2005-2012, which included identification of those who are infected with HCV, race, and HCQ self-report responses, in order that I was able to examine the health care seeking behavior and provider responses in this cohort during both pre- (2005-2008) and post- (2009-2012) DAA periods. In Chapter 3, I present the research design and approach used to address the research questions and hypotheses. Additionally, I discuss the setting and sample of the study, and describe procedures for sampling, subject recruitment, and data collection. I also discuss the instrumentation validity and reliability, and operationalization of the variables. The threats to validity and ethical considerations are also discussed in this chapter.



## Chapter 3: Research Method

### Introduction

In the United States, approximately 3.5 million persons carry chronic HCV infection, with African Americans carrying a disproportionately large burden of this disease (Centers for Disease Control and Prevention, 2012a). African Americans (3%) carry a 2-fold higher prevalence when compared with Caucasians (1.5%) and Hispanics (1.3%; Kemmer & Neff, 2010). A leading cause of death for African Americans ages 45-64 is HCV-related chronic liver disease (Pearlman, 2006). In addition, HCV-infected African Americans are afflicted with poorer survival rates from liver transplant and higher incidences of liver cancer and liver cancer-related mortality as compared to Caucasians (Layden et al., 2012). When given treatment for HCV infection, African Americans have lower rates of response and viral clearance compared to Caucasians (Burton et al., 2012). A high prevalence of injection drug use combined with lower socioeconomic status introduces limited access to health care, bias, stigmatization, and inferior quality of care (Davila & El-Serag, 2006; Sloane et al., 2006). African Americans experience disparities in access to care that are reflected in the outcome and survival of HCV infection; along with the individual comorbidities that impact low treatment rates, African Americans are disproportionately affected by lack of adequate health insurance and high treatment costs (Melia et al., 2011). As of 2008, there have been newer treatment options available that have substantially increased the rates of sustained virologic response (SVR) for all genotype 1 infected persons, including African Americans (Burton et al., 2012). The most recent data on HCV infection in the U.S. population were collected by the 2011-2012 National Health and Nutrition Examination

Survey (NHANES). In this quantitative study, I used secondary datasets from the NHANES and the Hepatitis C Follow-Up Questionnaire (HCQ) for the years 2005-2012 to determine whether the seeking of health care by HCV-positive African Americans and health care provider responses to HCV-positive African Americans had improved since 2008 following the introduction of new treatment options as compared to other HCV-positive racial/ethnic groups.

In this chapter, I describe the research methodology, including the study design and rationale. I also describe the study population, sampling strategy, and procedures for sampling, recruitment, data collection, and quality assurance. The independent and dependent variables and covariates are also defined and described. Lastly, I discuss threats to validity, bias, methodological limitations, and ethical considerations.

### **Research Design and Rationale**

This study used a quantitative, nonexperimental research design with cross-sectional survey data from four 2-year NHANES datasets and HCQs (2005-2012) to examine the health care seeking behavior and provider responses associated with HCV-positive African Americans, as compared to other HCV-positive racial/ethnic groups, since 2008, when newer treatment options for HCV were made available in the United States. The study compared the influence of race/ethnicity on health care seeking behavior and provider responses of HCV-positive HCQ respondents within two time periods, 2005-2008 and 2009-2012. The dependent variables were health care seeking behavior and provider responses, and the independent variable was HCV-positive HCQ respondents. The covariates included age, gender, race, education, poverty index, health

insurance status, and history of illegal injection drug use. The research questions and null and alternate hypotheses leading this study were as follows:

### **Research Question 1**

Has the seeking of health care, as defined by self-report HCQ responses, by HCV-positive African Americans improved since 2008 following the introduction of new treatment options as compared to other HCV-positive racial/ethnic groups?

Null hypothesis ( $H_01$ ): Seeking of health care, as defined by self-report HCQ responses, by HCV-positive African Americans has not improved since 2008 following the introduction of new treatment options as compared to other HCV-positive racial/ethnic groups.

Alternative hypothesis ( $H_a1$ ): Seeking of health care, as defined by self-report HCQ responses, by HCV-positive African Americans has improved since 2008 following the introduction of new treatment options as compared to other HCV-positive racial/ethnic groups.

### **Research Question 2**

Has the response from health care providers, as defined by self-report HCQ responses, to HCV-positive African Americans improved since 2008 following the introduction of new treatment options as compared to other HCV-positive racial/ethnic groups?

Null hypothesis ( $H_02$ ): The response from health care providers, as defined by self-report HCQ responses, to HCV-positive African Americans has not improved since 2008 following the introduction of new treatment options as compared to other HCV-positive racial/ethnic groups.

Alternative hypothesis ( $H_{a2}$ ): The response from health care providers, as defined by self-report HCQ responses, to HCV-positive African Americans has improved since 2008 following the introduction of new treatment options as compared to other HCV-positive racial/ethnic groups.

Quantitative methodology was selected for this study because this method can be used to analyze numerical data statistically to assess multiple variables, test hypotheses, and explain a particular phenomenon (Muijs, 2010). The study hypotheses were tested using numerical variables, which were quantified by statistical analysis. Correlational research is conducted in order to determine the extent of a relationship between two or more variables using statistical data and can be interpreted to recognize trends, but it does not go so far in its analysis as to establish cause and effect (Muijs, 2010). Specific to this study was the relationship that existed between the identified variables of health care seeking behavior and provider responses with HCV-positive African Americans compared to other racial/ethnic groups and two 4-year time periods, 2005-2008 and 2009-2012, which occurred before and after the introduction of newer treatment options, respectively. By using quantitative statistical analysis, I was able to code data for analysis of relationships between the key variables (Field, 2013). A qualitative research design would not have been appropriate for this study because it would have involved investigative methodologies such as ethnographic, naturalistic, anthropological, or participant observer approaches (Key, 1997). Further, the qualitative method emphasizes the importance of looking at variables in a natural setting in which they are found (Key, 1997).

I conducted an inferential study to test the research hypotheses using secondary data from a cross-sectional survey study. The use of cross-sectional survey data allows the researcher to look at the relationship between variables, and if the survey is repeated, the researcher can look at aggregate change over time in a population (King-Hele, 2005). Benefits of using successive cross-sectional survey data over time include the following: (a) a reasonable amount of comparability, (b) the data are representative at each specified time point (e.g., years), and (c) it is possible to examine impact on groups (King-Hele, 2005). Limitations of using successive cross-sectional survey data over time include: (a) reliance on the continuity of the data, (b) not being able to establish individual change, and (c) inability to determine a causal relationship (King-Hele, 2005). Despite these limitations, the use of secondary data from a cross-sectional survey study was appropriate because this study investigated an association that had yet to be examined in the body of scientific knowledge.

Other quantitative methods such as *ex post facto*, quasi-experimental, and true experimental were not used because the purpose of those research methods did not fit the research objective. Researchers conducting *ex post facto* studies investigate possible cause-and-effect relationships by observing an existing condition or state of affairs and searching back in time for plausible causal factors; those conducting true experimental studies deliberately control and manipulate the independent variable to observe the effect of that change on another dependent variable; and those conducting quasi-experimental studies make comparisons between groups that are not equal, or comparisons within a group over time (time-series; Creswell, 2009; Milstein & Wetterhall, 2013). In this study, I evaluated whether health care seeking behavior and provider responses for HCV-

positive African Americans, compared to other HCV-positive racial/ethnic groups, had changed since the introduction of newer treatment options, and as such, quantitative methodology using secondary data from a cross-sectional survey study was the appropriate means by which to evaluate these outcomes among the study population represented by NHANES 2005-2012. There were no time or resource constraints anticipated for this study.

## **Methodology**

### **Setting and Sample**

This study used secondary data from four 2-year NHANES datasets (2005-2012). All of these datasets provided the independent and dependent variables and covariates in the public domain setting. The target population for NHANES is the noninstitutionalized civilian population of the United States (Centers for Disease Control and Prevention, 2013a). The 2005-2012 NHANES datasets contained data for a total of 40,790 study participants who were interviewed; of these, 39,303 (96.3%) participants underwent the medical exam portion of the study (Centers for Disease Control and Prevention, 2014b). Of the study participants who underwent the medical exam portion of the study, there were 32,650 (83.0% of persons 6 years and older) who had serum samples drawn for the screening hepatitis C antibody test (Centers for Disease Control and Prevention, 2014b). The study population was defined as all NHANES participants 6 years of age and older who tested positive for the anti-HCV antibody and were contacted during the follow-up survey and interviewed. For the NHANES 2005-2012 datasets, the total number of study participants who tested positive for the anti-HCV antibody was 394 (1.2% of all those

screened), of those, 132 (33.0%) completed the Hepatitis C Follow-Up Questionnaire (HCQ).

**Sampling procedures.** The NHANES used a stratified and multistage probability sampling design and collected information from persons using standardized household interviews, physical examinations, and testing of biologic samples; the data were published in 2-year cycles (Ditah et al., 2014). The NHANES sampling procedure consisted of four stages (Centers for Disease Control and Prevention, 2013a). Stage 1 was the primary sampling units (PSUs); these were selected from strata defined by geography and proportions of minority populations, and were drawn mostly from single counties in the United States (Centers for Disease Control and Prevention, 2013a). Additional stages of sampling were performed to select for three secondary sampling units: (a) segments (city blocks) that were selected by probability proportional to a measure size, (b) households that were randomly drawn, and (c) individuals who were randomly drawn with designated age-sex-race/ethnicity screening subdomains (Centers for Disease Control and Prevention, 2013a). In order to obtain correct national estimates from the NHANES data, each sampled person was assigned a numerical sample weight (Centers for Disease Control and Prevention, 2013a). In addition, because the sample was defined by strata and by the primary and secondary sampling units, the sampling error was calculated on the counts of the groups, not the individuals; this also demonstrated a more efficient data collection process (Centers for Disease Control and Prevention, 2013a).

**Power analysis.** The sample size was chosen in relation to population size as a result of a predefined subunit of the NHANES population: all HCV-positive participants

who completed the HCQ in the time period of 2005-2012. The National Center for Health Statistics analytic guidelines state that data from the Hepatitis C Follow-Up Questionnaire (HCQ) should not be used with sample weights to make national estimates because of the small sample size and a response rate below 50% (Denniston et al., 2012).

The statistical power of a study represents the probability that the researcher will avoid making a Type I error of rejecting a null hypothesis that is true (Tomczak, Tomczak, Kleka, & Lew, 2014). The higher or bigger the alpha level is (e.g.,  $\alpha = 0.05$ ), the more likely the researcher will be to reject a true null hypothesis (a Type I error); the lower or smaller the alpha level is (e.g.,  $\alpha = .001$ ), the more likely it is that the researcher will accept a false null hypothesis (a Type II error; Tomczak et al., 2014).

I used G\*Power v.3.1.9.2, an open domain statistical power analysis program, to calculate the sample size based upon an analysis of variance (ANOVA) statistical test (Buchner, Erdfelder, Faul, & Lang, 2013). The calculation with G\*Power included the following: (a) test family = F tests; (b) statistical test = ANOVA: fixed effects, special, main effects, and interactions; (c) type of power analysis = a priori: compute required sample size – given  $\alpha$ , power, and effect size; (d) effect size  $f = .25$  (as per Cohen's conventions for medium effect size); (e) alpha level = 0.05; (f) power = 0.80; (g) numerator  $df = 1$ ; and (h) number of groups = 2. The G\*Power analysis calculated the total sample size as 128 subjects.

### **Procedures for Recruitment, Participation, and Data Collection**

The Division of Health and Examination Statistics releases NHANES public-use data files on a biannual basis, which, according to the data user agreement, must be used solely for the purpose of health statistical reporting and analysis as specified by the



Public Health Service Act [Section 308 (d)] (Centers for Disease Control and Prevention, 2009b). The households that were randomly selected and identified for inclusion in the NHANES sample were mailed an advance introductory letter informing them that an NHANES interviewer would be visiting their home (Centers for Disease Control and Prevention, 2010). Upon arriving at the home, the NHANES interviewer provided an official identification badge; if the occupant had not seen the advance letter, a copy was given to the occupant for review (Centers for Disease Control and Prevention, 2010). The NHANES interviewer asked residents a few short questions (“Household Screener Questionnaire Module”) to determine if their household was eligible for the study; if one or more persons were selected to participate, consent forms were signed for both the household interview and medical examination components of the survey (Centers for Disease Control and Prevention, 2010).

**Household interview component.** The household interview component (HIC) included demographic, socioeconomic, dietary, and health-related questions (Centers for Disease Control and Prevention, 2013a). The NHANES computer-assisted personal interview (CAPI) software program that was used to collect the interview data had built-in data edit and consistency checks (Centers for Disease Control and Prevention, 2013a). The data edit checks alerted the interviewer when unusual or potentially erroneous data values were recorded; the consistency checks were used to alert the interviewer when information was recorded that was inconsistent with previous data entries or respondent characteristics such as the respondent’s age (Centers for Disease Control and Prevention, 2013a). Additional assistance in the interview process included preprogrammed questionnaire “skip” patterns to reduce respondent burden, as well as standardized

descriptions of the terminology and concepts that were used in the questionnaires (Centers for Disease and Prevention, 2013a).

**Medical examination component.** If a participant had agreed to complete the medical examination component (MEC), he or she was provided medical, dental, and physiological measurements, as well as laboratory tests administered by a MEC survey team (coordinator, manager, one physician, two dietary interviewers, three certified medical technologists, four health technicians, one phlebotomist, two interviewers, and one computer data manager; Centers for Disease Control and Prevention, 2010). Some of the medical findings from the examination were given to the examinees before they exited the MEC; the other reportable survey findings were mailed to participants after the laboratory assays and special tests were completed (Centers for Disease Control and Prevention, 2010).

**Screening for Hepatitis C.** Participants 6 years of age or older who tested positive for anti-HCV antibody were sent a report of findings (ROF) letter that informed them (or parents of participants < 18 years of age) of the following: (a) HCV test result, (b) HCV transmission information, (c) effect on the liver, (d) effect on general health, and (e) encouragement to follow up with a healthcare provider (Denniston et al., 2012). Approximately 6 months following the ROF letter, a Hepatitis C Follow-Up Questionnaire (HCQ) was administered over the telephone (Denniston et al., 2012).

### **Instrumentation and Materials**

The NHANES is designed to assess the health and nutritional status of adults and children in the United States; findings are used to determine the prevalence of major diseases and risk factors for disease, as well as to expand health knowledge for the nation

to inform health programs and services (Centers for Disease Control and Prevention, 2013a). Based upon this scope, the NHANES survey represented the most applicable source of data for this study.

Age, gender, race, education, poverty index, health insurance status, and history of illegal injection drug use were collected via household interview component. Anti-HCV antibody level was determined via blood sample collected via venipuncture during the medical examination component of the survey. Health care seeking behavior and provider response questions were collected using the 2005-2012 HCQs. The 2005-2012 Demographics modules collected the age, gender, race, education, and poverty index variables. The 2005-2012 Questionnaire modules collected the variables of health insurance status, and history of illegal injection drug use.

**Study variables and covariates.** A list of the independent variable, dependent study variables derived from the HCQ, and the covariates are provided in Table 1.

Table 1

*Independent and Dependent Variables and Covariates Used in This Study*

Variable type	Variable name	Variable source and label	Value	Level of measurement
Independent	Anti-HCV antibody	MEC, LBDHCV	1,2,5	Categorical
	Hepatitis C RNA	MEC, LBXHCR	1,2	Categorical
HCQ—Health Care Seeking				
Dependent	Seen a doctor about test result?	HCQ, HCQ070	1,2	Categorical
Dependent	Have a doctor's appointment?	HCQ, HCQ080	1,2	Categorical
Dependent	Why not treated? (patient decision)	HCQ, HCQ140A-E	1,2	Categorical
HCQ - Provider Response				
Dependent	Did doctor do additional tests?	HCQ, HCQ090	1,2	Categorical
Dependent	What doctor told about test result?	HCQ, HCQ100	1,2,3,4	Categorical
Dependent	Ever had a liver biopsy?	HCQ, HCQ110	1,2	Categorical
Dependent	Doctor advised about medications?	HCQ, HCQ121	1,2	Categorical
Dependent	Doctor advised you should be treated?	HCQ, HCQ124	1,2	Categorical
Dependent	Doctor advised you should not be treated?	HCQ, HCQ126A-E	1,2	Categorical
Dependent	Treated with these medicines?	HCQ, HCQ130	1,2	Categorical
Covariate	Gender	Demographics module, RIAGENDR	1,2	Categorical

*(table continues)*

Variable type	Variable name	Variable source and label	Value	Level of measurement
Covariate	Age	Demographics module, RIDAGEYR	0 to 85	Continuous
Covariate	Race/Ethnicity	Demographics module, RIDRETH1	1,2,3,4,5	Categorical
Covariate	Education (respondent 6-19 years old)	Demographics module, DMDEDUC3	0 to 15	Categorical
Covariate	Education (respondent 20+ years old)	Demographics module, DMDEDUC2	1,2,3,4,5	Categorical
Covariate	Poverty Index	Demographics module, INDFMPIR	0 to 5.0	Continuous
Covariate	Health insurance status	Health insurance module, HIQ011	1,2	Categorical
Covariate	History of illegal injection drug use	Drug use module, DUQ370	1,2	Categorical

Table 2

*Variable Source and Labels—Descriptions*

Variable label	Description
MEC	Medical examination component
LBDHCV	Hepatitis C antibody (confirmed)
LBXHCR	Hepatitis C RNA (HCV-RNA)
HCQ	Hepatitis C Follow-Up Questionnaire
RIAGENDR	Gender
RIDAGEYR	Age at screening
RIDRETH1	Race/Ethnicity
DMDEDUC3	Education Level—Children/Youth 6-19
DMDEDUC2	Education Level—Adults 20+
INDFMPIR	Poverty income ratio (PIR)
HIQ	Health insurance
DUQ	Drug use

**Independent variable.** The independent variable, anti-HCV antibody, is a value that was calculated on all examinees 6 years or older by a serum specimen with laboratory testing as follows: samples testing positive for anti-HCV by the screening test were tested in the confirmatory RIBA assay for antibody to hepatitis C virus; samples with a positive RIBA result were reported as confirmed positive for antibody to HCV (Centers for Disease Control and Prevention, 2012c). Samples with a negative RIBA result were reported as such (Centers for Disease Control and Prevention, 2012c). Samples with an indeterminate RIBA result were tested for hepatitis C RNA (HCV-RNA). For inferential statistics, anti-HCV antibody was a categorical variable and reported as positive (1), negative (2), or indeterminate (3); HCV-RNA was a categorical variable and reported as positive (1), or negative (2). Subjects who had positive anti-HCV or positive HCV-RNA were included in the analysis. Subjects who had negative or missing values were excluded from analysis.

***Dependent variables.*** The dependent variables were a specific series of questions from the HCQ that examined health care seeking behavior and provider responses. Each variable had self-reported responses, and each variable was individually evaluated during the study analyses.

***Health care seeking behavior variables.*** Health care seeking behavior variables from the HCQ for this study included the following:

- Seen a doctor about test result? The test result was defined as either the participant's first positive hepatitis C test, or the NHANES positive hepatitis C test. This was a categorical variable and was reported as (1) yes, and (2) no.
- Have an appointment to see a doctor about test result? This was a categorical variable and was reported as (1) yes, and (2) no.
- Why did you decide not to be treated? This was a categorical variable that was reported as (1) yes, and (2) no for each of the 5 options provided by the interviewer: (a) side effects are unpleasant, (b) need to self-inject the medicine, (c) too expensive, (d) hope of better future treatments, and (e) some other reason given.

***Provider response variables.*** Provider response variables from the HCQ for this study included the following:

- Did doctor do additional tests? This was a categorical variable and was reported as (1) yes, and (2) no.
- What doctor told you about test result? This was a categorical variable and was reported as (1) hepatitis C and needs a regular medical follow-up, (2) tested positive for hepatitis C, but do not need to do anything or worry about it,

(3) really don't have hepatitis C because a follow-up test showed that the positive test result was in error, and (4) Other.

- Ever had a liver biopsy? This was a categorical variable and was reported as (1) yes, and (2) no.
- Doctor advised about medications used to treat hepatitis C? This was a categorical variable and was reported as (1) yes, and (2) no.
- Doctor advised you should be treated with medication such as interferon and ribavirin? This was a categorical variable and was reported as (1) yes, and (2) no.
- Doctor advised you should not be treated? This was a categorical variable that was reported as (1) yes, and (2) no for each of the 5 options provided by the interviewer: (a) liver enzymes were normal, (b) did not have liver disease, (c) do not need to do anything, (d) can wait to be treated at a later time, and (e) no reason given.
- Treated with these medicines? This was a categorical variable and was reported as (1) yes, and (2) no.

***Covariates.*** Confounding variables for this study included gender, age, race, education, poverty index, health insurance status, and history of illegal injection drug use.

- Gender. Gender was a categorical variable and was reported as either male (1) or female (2). All subjects had a reported gender. There were no missing, refused, or unknown values for the sample population.



- **Age.** Age was calculated based on participants' date of birth. If the actual date of birth was missing, then the reported age was used. For NHANES 2005-2006, age in years was reported as a continuous variable with ages between 1 and 84 years of age, and all adults who were 85 years and older were categorically assigned a value of '85'. For NHANES 2007-2012, age in years was reported as a continuous variables with ages between 1 and 80 years of age, and all adults who were 80 years and older were categorically assigned a value of '80'. All subjects had a reported age. There were no missing, refused, or unknown values for the sample population. For the inferential analysis, the age variable was recoded into age groups reported as (1) <30 years, (2) 30-49 years (3) 50-69 years, and (4) 70+ years. These age groups were chosen to capture the young persons (<30 years) and baby boomer (50-69 years) cohorts at risk for HCV infection. Seventy-five percent of all persons living with HCV infection and 75% of HCV-associated deaths are attributed to those who were born during the years of 1945 to 1965 (a.k.a., baby boomers; Centers for Disease Control and Prevention, 2015a). In 2011, the Centers for Disease Control and Prevention Hepatitis C Surveillance found the largest increases in rate of acute hepatitis C among persons aged 0-29 years when compared to all age groups; in addition, researchers found a trend of increasing HCV infections among adolescents and young adults in the United States (Centers for Disease Control and Prevention, 2014c).
- **Race/Ethnicity.** This was a categorical variable and was reported as Mexican American (1), Other Hispanic (2), Non-Hispanic White (3), Non-Hispanic

Black (4), and Other Race – Including Multi-Racial (5). If respondents self-identified as “Mexican American” they were coded as such; if respondents self-identified as “Hispanic” they were coded as “Other Hispanic” (Centers for Disease Control and Prevention, 2012c). All other respondents were categorized based on their self-reported races as coded above. There were no missing, refused, or unknown values for the sample population. For the inferential analysis, the race variable was recoded into three categorical groups reported as (1) Caucasian, (2) African American, and (3) Hispanic/other.

- Education. There were two scales used for this categorical variable: ages 6-19 years and 20+ years. For those ages 6-19 years, the codes were the highest grade or level of education and reported as (0) never attended/kindergarten only, (1-12) single grades 1 thru 12, (13) high school graduate, (14) GED or equivalent, and (15) more than high school. For those ages 20 and over, the codes were reported as (1) less than 9<sup>th</sup> grade, (2) 9-11<sup>th</sup> grade (includes 12<sup>th</sup> grade with no diploma), (3) high school graduate/GED or equivalent, (4) some college or AA degree, and (5) college graduate or above. There were no missing, refused, or unknown values for the sample population. For the inferential analysis, the education variable for ages 6-19 years was recoded into the same education groups as the ages 20 years and older scale. This allowed the merging of all persons ages 6 and older into the following education groups reported as (1) less than high school (includes 12<sup>th</sup> grade

with no diploma), (2) high school graduate/GED or equivalent, (3) more than high school, and (4) Don't know.

- **Poverty Index.** This number was calculated by dividing family income by the poverty guidelines, specific to family size, as well as the appropriate year and state. This continuous variable was reported as a range value from 0 to 5.00 with values at or above 5.00 coded as 5.00 or more. For the inferential analysis, the poverty index variable was recoded into three categorical groups reported as (1) < 1.0 (below poverty level), (2) 1.0-1.9 (near poverty level), and (3) 2.0 or greater (above poverty level). There were 15 missing values for the sample population.
- **Health Insurance Status.** This was a categorical variable and was reported as (1) yes or (2) no. There were no missing, refused, or unknown values for the sample population.
- **History of Illegal Injection Drug Use.** This was a categorical variable and was reported as (1) yes or (2) no. The age groups for each of the NHANES datasets that was released for this variable included: 2005-2006 ages 20-59, 2007-2008 ages 20-69, 2009-2010 ages 18 and older, 2011-2012 ages 18-69. There were 19 missing values for the sample population.

### **Data Analysis Plan**

NHANES 2005-2012 data were released to the public in SAS transport files (Centers for Disease Control and Prevention, 2013c). All relevant data files required for the study were opened by the software application Statistical Package for the Social Sciences (SPSS) version 21.0, and then converted and used in SAV format for all data

analyses that was performed. SPSS was suitable for this study because it was able to do merging, coding, and recoding of data, in addition to generating tabulated reports, charts, plots of distributions and trends, descriptive statistics, and complex data manipulation and analysis (Field, 2013).

The 2005-2012 NHANES data sets that were downloaded from the Centers for Disease Control and Prevention website included: (a) demographics, (b) health insurance, (c) drug use, (d) laboratory – hepatitis C, and (e) HCQ. Frequency counts were performed and matched against reported frequencies for each variable in the Data Documentation, Code Book and Frequencies reports for the years 2005-2012 issued by the Centers for Disease Control and Prevention (2013a). All survey data had built in edit and consistency checks and quality control measures after collection including staff review and external verification with respondents (Centers for Disease Control and Prevention, 2013b). The NHANES Medical Examination Component laboratory is a Clinical Laboratory Improvement Act (CLIA)-certified lab and used both internal and external surveillance measures to monitor quality assurance and quality control (Centers for Disease Control and Prevention, 2014d). Missing values counts from downloaded data variables were verified against the CDC reported missing value counts in the public files. All missing values were deleted and excluded for analysis thus eliminating any potential for missing value bias. I used both descriptive and inferential statistics in this study. Descriptive statistics simply describes what is or what the data shows with simple summaries about the sample and the measures; inferential statistics allows the researcher to try and reach conclusions that extend beyond the immediate data alone (Field, 2013).

**Descriptive statistics.** The characteristics of participants for the NHANES data set were summarized into two time periods, 2005-2008 and 2009-2012, using a frequency table that reports the number and percentage of occurrence. This included: (a) total number of participants who completed the HIC and MEC, (b) total number of participants who had a serum sample tested for anti-HCV antibody, (c) total number of participants who were anti-HCV positive, and (d) total number of participants who completed the HCQ. The characteristics of the participants who completed the HCQ were reported in two time periods, 2005-2008 and 2009-2012, using a frequency table and included the number and percentage for the covariates of age, gender, race, education, poverty index, health insurance status, and history of illegal injection drug use. The characteristics of the participants who completed the HCQ were reported by three racial/ethnic groups (Caucasian, African American, Hispanic/Other) in two time periods, 2005-2008 and 2009-2012, and used a frequency table that included the number and percentage for the covariates of age, gender, education, poverty index, health insurance status, and history of illegal injection drug use.

**Inferential statistics.** Inferential statistical methods were used to answer the research questions. The chi-square test for independence was used to examine if there was a relationship between two or more categorical variables (Laerd Statistics, 2013). In order to conduct this test, two assumptions needed to be met: (a) the two variables should be measured at an ordinal or nominal level, and (b) the two variables should consist of two or more categorical, independent groups (Laerd Statistics, 2013). This method was appropriate to test the hypotheses of the study as it did not require normal distribution or variance assumptions about the populations from which the samples were drawn and was

designed for ordinal or nominal data (Laerd Statistics, 2013). For each of the 10 dependent variables (HCQ responses), a chi-square test for independence was conducted with three racial/ethnic groups (Caucasian, African American, Hispanic/Other) to compare the differences with their health care seeking behavior and provider responses before the introduction of new treatment options (time period 2005-2008) and after the introduction of new treatment options (time period 2009-2012). If the sample size was smaller than 5, a Fisher's exact test was conducted. In order to account for confounders, I used multiple logistic regression and explored the associations between the HCQ responses of each racial/ethnic group in two time periods as described above. The multiple logistic regression model included the covariates of age, gender, education, poverty index, health insurance status, and history of illegal injection drug use. Specific statistical methods used to test the hypotheses are described below.

***Research Question 1.*** Has the seeking of health care, as defined by self-report HCQ responses, by HCV-positive African Americans improved since 2008 following the introduction of new treatment options as compared to other HCV-positive racial/ethnic groups?

Null hypothesis ( $H_0$ 1): Seeking of health care, as defined by self-report HCQ responses, by HCV-positive African Americans has not improved since 2008 following the introduction of new treatment options as compared to other HCV-positive racial/ethnic groups.

Alternative hypothesis ( $H_a$ 1): Seeking of health care, as defined by self-report HCQ responses, by HCV-positive African Americans has improved since 2008 following

the introduction of new treatment options as compared to other HCV-positive racial/ethnic groups.

To test Research Question 1, a chi-square test for independence was conducted with three categorical independent HCV-positive racial/ethnic groups who were HCQ respondents (Caucasian, African American, Hispanic/Other). Each racial/ethnic group's HCQ answers were compared for two time periods (2005-2008 and 2009-2012). Health care seeking behavior was defined as the following three HCQ answers: (a) I saw a doctor about the hepatitis C test result, (b) I have an appointment to see a doctor about the hepatitis C test result, and (c) I decided not to get treated because (5 choices): side effects are unpleasant, need to self-inject medicine, too expensive, hope of future better treatments and, some other reason given. An improvement is defined as an increase in the number of individuals who saw a doctor or have an appointment to see a doctor, and a decrease in the number of individuals who decided not to get treated. Any probability value of significance ( $p$ -value) which is less than or equal to the level of significance (0.05) was considered statistically significant. Given that multiple factors can influence health care seeking behavior, a multivariable logistic regression analysis was conducted in order to determine the independent relation between the three HCQ answers of HCV-positive participants in two time periods (2005-2008 and 2009-2012) after controlling for the covariates of age, gender, race/ethnicity, education, poverty index, health insurance status, and history of illegal injection drug use.

**Research Question 2.** Has the response from health care providers, as defined by self-report HCQ responses, to HCV-positive African Americans improved since 2008

following the introduction of new treatment options as compared to other HCV-positive racial/ethnic groups?

Null hypothesis ( $H_0$ 2): The response from health care providers, as defined by self-report HCQ responses, to HCV-positive African Americans has not improved since 2008 following the introduction of new treatment options as compared to other HCV-positive racial/ethnic groups.

Alternative hypothesis ( $H_a$ 2): The response from health care providers, as defined by self-report HCQ responses, to HCV-positive African Americans has improved since 2008 following the introduction of new treatment options as compared to other HCV-positive racial/ethnic groups.

To test Research Question 2, a chi-square test for independence was conducted with three categorical independent HCV-positive racial/ethnic groups who were HCQ respondents (Caucasian, African American, Hispanic/Other). Each racial/ethnic group's HCQ answers were compared for two time periods (2005-2008 and 2009-2012). The response from health care providers was defined as the following seven HCQ answers: (a) the doctor did other blood tests to check the liver, (b) the doctor told me I need regular medical follow-up, (c) the doctor told me I do not need to do anything or worry about my hepatitis C, (d) I had a liver biopsy, (e) the doctor told me there are medicines that can be used to treat hepatitis C, (f) I was treated with the medication, (g) the doctor told me I should not be treated because (5 choices): liver enzymes are normal, do not have liver disease, don't need to do anything, wait to be treated at a later time and, no reason specified. For response from health care providers, an improvement was defined as an increase in the number of individuals who: (a) had additional tests done, (b) need regular



medical follow-up, (c) had a liver biopsy, (d) informed there are medicines that can be used to treat hepatitis C, and (e) who were given medication for their HCV infection. Any probability value of significance ( $p$ -value) which is less than or equal to the level of significance (0.05) was considered statistically significant. Given that multiple factors can influence responses from a health care provider, a multivariable logistic regression analysis was conducted in order to determine the independent relation between the seven HCQ answers of HCV-positive participants in two time periods (2005-2008 and 2009-2012) after controlling for the covariates of age, gender, race/ethnicity, education, poverty index, health insurance status, and history of illegal injection drug use.

### **Threats to Internal and External Validity**

There are threats that exist with both internal and external validity and can occur at any time during the research process (Creswell, 2009). The NHANES has been utilized as a nationwide surveillance system for over 40 years; in addition, the analyses of responses from the U.S. noninstitutionalized adult population indicated that the NHANES measures had good construct validity (Centers for Disease Control and Prevention, 2013a). In using secondary data analysis, assessing the validity of the measures includes examining the questions that were asked for face validity; there is a threat if the questions are found to be meaningless, problematic or open to a range of interpretation (Creswell, 2009). Internal validity is focused on the study design and the degree of control applied over potential extraneous variables that can threaten the internal validity (Slack & Draugalis, 2001). This control can lessen the potential for alternative explanations for treatment effects while consequently providing more confidence that the effects are due to the independent variable (Slack & Draugalis, 2001). When a researcher

draws incorrect inferences from the study data to other past or future settings it introduces threats to external validity (Creswell, 2009).

With regard to the validity of the NHANES survey instrument, a thorough examination of the instrument will include information on all three types of validity: content, construct, and empirical (Frankfort-Nachmias & Nachmias, 2008). To ensure content validity of this instrument, face validity can be utilized to compare the questions to other questionnaires on the same subject (e.g. hepatitis c status, health status; Frankfort-Nachmias & Nachmias, 2008). For the launch of the continuous survey, and biannually after the survey began, new content proposals were solicited and ascertained if they were safe, feasible, and of sufficient public health significance, as well as appropriateness and feasibility, to include in NHANES (Centers for Disease Control and Prevention, 2013d). This demonstrated an establishment of construct validity by determining whether the instrument is logically and empirically tied to the concepts and theoretical assumptions that are being employed in the research studies (Frankfort-Nachmias & Nachmias, 2008). If the proposal was accepted, the protocol was fully developed and prepared for field-testing prior to use in NHANES (Centers for Disease Control and Prevention, 2013d). This addressed the empirical validity of the instrument by examining the relationship between the measuring instrument and the measured outcomes, as they relate to the real world and the variables being measured (Frankfort-Nachmias & Nachmias, 2008). With regard to laboratory methods, they were tested and deemed reliable and valid prior to their inclusion in NHANES (Centers for Disease Control and Prevention, 2013d).

### **Bias and Methodological Limitations**

Bias is the result of systematic errors in the research study that result in an incorrect estimate of the association between exposures and outcomes. The types of biases addressed here include sampling bias, selection bias, nonresponse bias, and recall bias. Methodological limitations are also addressed which may impact or limit further studies.

Bias in sampling is a systematic error in sampling procedures that leads to a distortion in the results of the study and eliminates the representativeness of the sample (Frankfort-Nachmias & Nachmias, 2008). The NHANES sampling procedure consisted of four stages (Centers for Disease Control and Prevention, 2013a). Stage 1 was the primary sampling units (PSUs); these were selected from strata defined by geography and proportions of minority populations, and were mostly single counties in the United States (Centers for Disease Control and Prevention, 2013a). Additional stages of sampling were performed to select for three secondary sampling units: (a) segments (city blocks) that were selected by probability proportional to a measure size, (b) households that were randomly drawn, and (c) individuals that were randomly drawn with designated age-sex-race/ethnicity screening sub-domains (Centers for Disease Control and Prevention, 2013a). In order to obtain correct national estimates from the NHANES data, each sampled person was assigned a numerical sample weight (Centers for Disease Control and Prevention, 2013a). In addition, because the sample is defined by strata and by the primary and secondary sampling units, the sampling error was calculated on the counts of the groups, not the individuals; this also demonstrated a more efficient data collection process (Centers for Disease Control and Prevention, 2013a). Overall, the NHANES

dataset assisted with controlling for sampling bias because it did not favor one group over another, but used a cross-section of all persons who reply to be surveyed in the United States (Frankfort-Nachmias & Nachmias, 2008). In this same vein, selection bias was also reduced using this complex sampling method of patient selection.

Nonresponse bias occurs when some respondents included in the sample do not respond (Creswell, 2009). Because NHANES used a complex sample design, sample weights were used to account for stratification, clustering, and the unequal probability of subject selection into the survey (Perlin, 2003). Each NHANES oversampled certain population subgroups, and this was taken into account through appropriate weighting. The issue of using weights was critical to the correct analysis of NHANES data; inappropriate use of weights may have resulted in a flawed analysis and questionable study results (Perlin, 2003). Sample weights were also used to adjust for possible bias resulting from subject nonresponse (Perlin, 2003). Nonresponse is a key issue with any survey, and nonresponse bias needs to be assessed, reported, and include any information on reasons for missing data (Perlin, 2003).

In addressing methodological limitations, when analyzing the NHANES data, sample weights were used to produce correct population estimates because each sample weight does not have equal probability of selection into the survey (Perlin, 2003). Although the current NHANES was conducted using annual samples that are nationally representative, the sample size in any one year was relatively small, resulting in large variability for estimates, especially with detailed analyses such as the study's primary cohort of only HCV-positive participants (Perlin, 2003). Another analytic limitation is that the NHANES sample was selected from a relatively small number of sampling units

(PSUs) or counties which can introduce a higher level of uncertainty in the annual estimates (Perlin, 2003). The computation of 2-year datasets was preferred to decrease variability in annual estimates.

### **Ethical Procedures and Considerations**

Institutional Review Board (IRB) approval is required for all research involving human subjects. Human subjects are defined as one or more living individuals about whom an investigator (whether professional or student) conducting research obtains (a) data through intervention or interaction with the individual or, (b) identifiable private information (U.S. Department of Health and Human Services, 2014). This study used archived, deidentified secondary data that had been released by the Centers for Disease Control and Prevention (2012b) to the public domain and may be reproduced without permission; therefore, I did not need to obtain informed consent. This study received Walden University Institutional Review Board approval prior to any data analysis (IRB Approval Number: 08-06-15-0171822). In doing so, I was protecting the University, the study participants, and myself by ensuring that my dissertation research was in compliance with the University's ethical standards as well as U.S. federal regulations (Walden University, 2014). Regarding the IRB's process for NHANES, the National Center for Health Statistics had a Research Ethics Review Board that approved each NHANES survey; the protocol number and approval information can be obtained and referenced from the Centers for Disease Control and Prevention (2012b) website:  
<http://www.cdc.gov/nchs/nhanes/irba98.htm>

The main ethical consideration with this research study was the protection of the survey participants' identity. In order to protect subject confidentiality, the NHANES did

not include certain information (e.g., subject address or location, date of birth) with the publically available data; in addition, many data elements were never be made available to the public (Perlin, 2003). Laboratory samples, medical examinations, and survey responses were all deidentified and identifier code numbers were used in place of names or other identifying information (Centers for Disease Control and Prevention, 2012b). With HCV testing, the only demographic information attached to the HCV serum samples was age in 20-year groups, sex, race or ethnic group, and sampling location (Perlin, 2003).

Prior to the Centers for Disease Control and Prevention (2012b) collecting the health information for the NHANES, they obtained informed consent from all survey participants assuring them that data collected was only to be used for stated purposes and would not be disclosed or released to others without consent of the individual or the establishment “in accordance with section 308(d) of the Public Health Service Act”. An informed consent was provided to disclose that blood samples were to be tested, and maximum safeguards would be utilized to protect each sample person’s confidentiality (Perlin, 2003). The NHANES consent also informed participants that the Centers for Disease Control and Prevention (2011) allowed other collaborators and researchers to use survey data, but their privacy was protected by the assignment of code numbers in place of names, and abstaining from revealing any other facts that could directly identify the person. Storage of all data will be maintained in two locations, a laptop computer and an external hard drive, for no less than five years upon completion of the dissertation, and with sole accessibility of myself only. This study was performed to fulfill the requirements for the Doctorate of Philosophy in Public Health and Epidemiology at

Walden University. I have no financial interest in Walden University and claim no financial or other conflicts of interest with any other party.

### **Summary**

In Chapter 3, I presented the detailed methodology of this research study, which included the research design and approach used to address the research questions and hypotheses. Additionally, I discussed the setting and sample of the study and described procedures for sampling, subject recruitment, and data collection. I also discussed the instrumentation validity and reliability and operationalization of the variables. Threats to validity and ethical considerations were also discussed in this chapter. In Chapter 4, I discuss the results of the statistical analyses, as well as the results of each of the research questions.

## Chapter 4: Results

### Introduction

The purpose of this study was to examine health care seeking behavior and provider responses for HCV-positive African Americans in the noninstitutionalized U.S. population. The research questions and associated null hypotheses for this study were:

Research Question 1: Has the seeking of health care, as defined by self-report HCQ responses, by HCV-positive African Americans improved since 2008 following the introduction of new treatment options as compared to other HCV-positive racial/ethnic groups?

Null hypothesis ( $H_01$ ): Seeking of health care, as defined by self-report HCQ responses, by HCV-positive African Americans has not improved since 2008 following the introduction of new treatment options as compared to other HCV-positive racial/ethnic groups.

Alternative hypothesis ( $H_a1$ ): Seeking of health care, as defined by self-report HCQ responses, by HCV-positive African Americans has improved since 2008 following the introduction of new treatment options as compared to other HCV-positive racial/ethnic groups.

Research Question 2: Has the response from health care providers, as defined by self-report HCQ responses, to HCV-positive African Americans improved since 2008 following the introduction of new treatment options as compared to other HCV-positive racial/ethnic groups?

Null hypothesis ( $H_02$ ): The response from health care providers, as defined by self-report HCQ responses, to HCV-positive African Americans has not improved since



2008 following the introduction of new treatment options as compared to other HCV-positive racial/ethnic groups.

Alternative hypothesis ( $H_{a2}$ ): The response from health care providers, as defined by self-report HCQ responses, to HCV-positive African Americans has improved since 2008 following the introduction of new treatment options as compared to other HCV-positive racial/ethnic groups.

These hypotheses were tested using secondary data from the National Health and Examination Survey (NHANES) 2005-2012, which was a stratified, multistage probability sample of the civilian, noninstitutionalized U.S. population. The study analyzed data from participants who tested positive for past or current HCV infection and were interviewed as part of the Hepatitis C Follow-Up Questionnaire (HCQ) during the NHANES conducted from 2005 through 2012. The associations between dichotomous HCQ responses from three racial/ethnic groups (Caucasian, African American, Hispanic/Other) were compared to evaluate the differences in health care seeking behavior and provider responses before the introduction of new treatment options (time period 2005-2008) and after the introduction of new treatment options (time period 2009-2012) using chi-square test of independence. If the sample size was smaller than 5, a Fisher's exact test was conducted. The associations between the HCQ responses of each of the three racial/ethnic groups from two time periods, 2005-2008 and 2009-2012, with the covariates of age, gender, education, poverty index, health insurance status, and history of illegal injection drug use, were analyzed using binomial logistic regression.

In this chapter, I present the descriptive statistics of the dichotomized dependent and independent variables as well as the study covariates. I also present the results for

the inferential statistics analysis and hypothesis testing for the two research questions, as well as summarize the significant findings as they relate to the research questions.

### **Data Collection**

The secondary source of the data, the NHANES survey, used a stratified and multistage probability sampling design and collected information from persons using standardized household interviews, physical examinations, and testing of biologic samples; the data were published in 2-year cycles (Centers for Disease Control and Prevention, 2013a). The NHANES sampling procedure consisted of four stages (Centers for Disease Control and Prevention, 2013a). Stage 1 was the primary sampling units (PSUs); these were selected from strata defined by geography and proportions of minority populations and were mostly single counties in the United States (Centers for Disease Control and Prevention, 2013a). Additional stages of sampling were performed to select for three secondary sampling units: (a) segments (city blocks) that were selected by probability proportional to a measure size, (b) households that were randomly drawn, and (c) individuals who were randomly drawn with designated age-sex-race/ethnicity screening subdomains (Centers for Disease Control and Prevention, 2013a). In order to obtain correct national estimates from the NHANES data, each sampled person was assigned a numerical sample weight (Centers for Disease Control and Prevention, 2013a). In addition, because the sample was defined by strata and by the primary and secondary sampling units, the sampling error was calculated on the counts of the groups, not the individuals; this also demonstrated a more efficient data collection process (Centers for Disease Control and Prevention, 2013a). Data for the 2005 through 2012 surveys were

collected between January 2005 and December 2012 (Centers for Disease Control and Prevention, 2013a).

For the NHANES 2005 through 2012, a total of 40,790 participants completed the household interview component (HIC); of these, a total of 39,303 (96.3%) participants underwent the medical examination component (MEC; Centers for Disease Control and Prevention, 2014b). Participants 6 years of age or older who had a positive test result for anti-HCV or, beginning in 2007, had an indeterminate test result for anti-HCV and a positive HCV-RNA, were sent a report of findings (ROF) letter informing them, or the parents of individuals < 18 years of age, of their HCV test result and encouraging them to follow up with a health care provider. Approximately 4 to 5 months after the ROF was mailed, a Hepatitis C Follow-Up Questionnaire (HCQ) was administered by telephone. Persons  $\geq$  18 years of age were interviewed directly; an adult proxy provided information for individuals < 18 years of age and for individuals unable to answer themselves. The HCQ was mentioned in the informed consent and also in the ROF letter. The sample for analysis was all individuals who completed the HCQ 2005 through 2012.

## **Results**

### **Univariate Analysis**

NCHS analytic guidelines state that data from the Hepatitis C Follow-Up Questionnaire (HCQ) should not be used with sample weights to make national estimates because of small sample size and a response rate below 50% (Centers for Disease Control and Prevention, 2012c). Therefore, analyses were conducted in SPSS 21.0 using chi-square and, where appropriate (i.e., small cell sizes), Fisher's exact tests. Percentages

reported are percentages of respondents, not population estimates. Results were considered statistically significant at the 0.05 level.

Data from four 2-year cycles (2005-2012) of the Hepatitis C Follow-Up Questionnaire were combined with the NHANES demographic information, health insurance, and injection drug use data. As shown in Table 3, a total of 32,630 (83.0%) participants had serum samples drawn for the screening hepatitis C antibody test; the total number of individuals who had a positive HCV result was 394 (1.2% of all those screened), of which 132 (33.5%) completed the Hepatitis C Follow-Up Questionnaire (HCQ).

Table 3

*Characteristics of Participants, NHANES, Time Periods 2005-2008 and 2009-2012*

	NHANES 2005-2012		NHANES 2005-2008		NHANES 2009-2012	
Number of participants	40,790		20,497		20,293	
	<i>N</i>	%	<i>N</i>	%	<i>N</i>	%
Completed HIC and MEC*	39,303	96.3	19,712	96.2	19,591	96.5
Tested for anti-HCV	32,630	83.0	16,218	82.3	16,412	83.8
Positive for anti-HCV**	394	1.2	194	1.2	200	1.2
Completed HCQ***	132	33.5	66	34.0	66	33.0

\* = Household interview component and medical examination component.

\*\* = All positive anti-HCV results and indeterminate anti-HCV results that tested positive for HCV-RNA.

\*\*\* = Hepatitis C Follow-Up Questionnaire.

All results pertain to the “study sample” of 132 individuals who tested positive for current or past infection and responded to the HCQ, and are compared in two 4-year time periods, 2005-2008 and 2009-2012; therefore, these results are not generalizable. Table 4

reports the frequencies and percentages for the categorical variables of characteristics for the study sample ( $n = 132$ ), the 2005-2008 sample ( $n = 66$ ), and the 2009-2012 sample ( $n = 66$ ). Using chi-square test of difference between the two time periods, participants in the 2005-2008 time period were more likely to be younger than age 50 ( $p < 0.05$ ) and Caucasian ( $p < 0.05$ ) as compared to participants in the 2009-2012 time period (Table 4). The results demonstrated no statistically significant difference of participants between the two time periods when comparing the characteristics of gender, education, poverty index level, health insurance status, and history of illegal injection drug use.

Table 4

*Characteristics of Participants, NHANES Hepatitis C Follow-Up Questionnaire, Time Periods 2005-2008 and 2009-2012*

	Study sample		2005–2008 sample		2009–2012 sample		<i>P</i> value*
	<i>N</i>	%	<i>N</i>	%	<i>N</i>	%	
Sample size	132		66		66		
Age group (years)							
< 30	3	2.3	3	4.5	0		
30-49	46	34.8	30	45.5	16	24.2	<0.05
50-69	77	58.3	33	50.0	44	66.7	
70 +	6	4.6	0		6	9.1	
Gender							
Male	83	62.9	39	59.1	44	66.7	
Female	49	37.1	27	40.9	22	33.3	
Race/ethnicity							
Caucasian	51	38.6	33	50.0	18	27.3	< 0.05
African American	47	35.6	20	30.3	27	40.9	
Hispanic/other	34	25.8	13	19.7	21	31.8	
Education							
Less than high school <sup>a</sup>	45	34.1	18	27.2	27	40.9	
HS graduate/GED	40	30.3	28	42.5	12	18.2	
More than high school	46	35.1	20	31.3	26	39.3	
Don't know	1	1.0			1	1.5	
Income							
Below poverty level	33	28.2	14	23.3	19	33.3	
Near poverty level	44	37.6	26	43.3	18	31.6	
Above poverty level	40	34.2	20	33.3	20	35.1	
Missing			6		9		
Health insurance							
Yes	95	71.2	50	75.8	45	68.2	
No	37	28.0	16	24.2	21	31.8	
History of illegal injection drug use							
Yes	57	50.4	29	49.2	28	51.9	
No	56	49.6	30	50.8	26	48.1	
Missing			7		12		

\* = *P* value for chi-square test of difference between time periods 2005-2008 and 2009-2012. (Fisher's exact test used for small cell sizes).

a = includes 12<sup>th</sup> grade with no diploma.

The characteristics of the study sample were also analyzed by three racial/ethnic groups (Caucasian, African American, and Hispanic/Other) between the two time periods, 2005-2008 and 2009-2012, and reported as frequencies and percentages as shown in Table 5. Using chi-square test of difference to compare each racial/ethnic group (e.g. Caucasian v. Caucasian) between the two time periods, the Hispanic/Other group in the 2005-2008 time period were more likely to be younger than 50 years of age ( $p < 0.05$ ) as compared to the Hispanic/Other group in the 2009-2012 time period. The results demonstrated no additional statistically significant difference with each racial/ethnic group between the two time periods when comparing the characteristics of gender, education, poverty index level, health insurance status, and history of illegal injection drug use.

Table 5

*Characteristics of Participants by Race/Ethnicity, NHANES Hepatitis C Follow-Up Questionnaire, Time Periods 2005-2008 and 2009-2012*

Race/Ethnicity	2005–2008 sample (N = 66)						2009–2012 sample (N = 66)					
	Caucasian		African American		Hispanic/ Other		Caucasian		African American		Hispanic/ Other	
	N	%	N	%	N	%	N	%	N	%	N	%
Age group (years)												
< 30	2	66.7	0		1	33.3*	0	0.0	0	0.0	0	0.0
30-49	19	63.3	5	16.7	6	20.0*	6	37.5	3	18.8	7	43.8
50-69	12	36.4	15	45.5	6	18.2	12	27.3	18	40.9	14	31.8
70 +	0	0.0	0	0.0	0	0.0	0	0.0	6	100.0	0	0.0
Gender												
Male	20	51.3	12	30.8	7	17.9	12	27.3	18	40.9	14	31.8
Female	13	48.1	8	29.6	6	22.2	6	27.3	9	40.9	7	31.8
Education												
Less than high school**	7	38.8	8	44.4	3	16.7	5	18.5	8	29.6	14	51.9
H.S. graduate/GED	16	57.1	7	25.0	5	17.9	4	33.3	6	50.0	2	16.7
More than H.S.	10	50.0	5	25.0	5	25.0	9	34.6	12	46.2	5	19.2
Don't know									1	3.7		
Poverty index <sup>a</sup>												
< 1.0 (below poverty)	8	57.1	5	35.7	1	7.1	4	21.1	8	42.1	7	36.8
1.0-1.9 (near poverty)	15	57.7	4	15.4	7	26.9	8	44.4	4	22.2	6	33.3
2.0+ (above poverty)	9	45.0	9	45.0	2	10.0	3	15.0	12	60.0	5	25.0
Have health insurance												
Yes	20	40.0	17	34.0	13	26.0	11	24.4	21	46.7	13	28.9
No	13	81.3	3	18.8	0	0.0	7	33.3	6	28.6	8	38.1
History of illegal injection drug use <sup>b</sup>												
Yes	16	55.2	7	24.1	6	20.7	9	32.1	9	32.1	10	35.7
No	15	50.0	11	36.7	4	13.3	7	26.9	11	42.3	8	30.8

\* = *P* value < 0.05 for chi-square test of difference for comparison of each racial/ethnic group between time periods 2005-2008 and 2009-2012 (Fisher's exact test used for small cell sizes).

\*\* = Includes 12<sup>th</sup> grade with no diploma

a = 2005-2008: n = 60 (6 missing data); 2009-2012: n = 57 (9 missing data).

b = 2005-2008: n = 59 (7 missing data); 2009-2012: n = 54 (12 missing data).



## **Inferential Statistics**

NCHS analytic guidelines state that data from the Hepatitis C Follow-Up Questionnaire (HCQ) should not be used with sample weights to make national estimates because of small sample size and a response rate below 50% (Centers for Disease Control and Prevention, 2012d). Therefore, analyses were conducted in SPSS 21.0 using chi-square and, where appropriate (i.e. small cell sizes), Fisher's exact tests. Percentages reported are percent of respondents, not population estimates. Results were considered statistically significant at the 0.05 level.

For Research Question 1, the variables of interest were three of the HCV-positive participants' responses from the Hepatitis C Follow-Up Questionnaire (HCQ). For Research Question 2, the variables of interest were seven of the HCV-positive participants' responses from the HCQ. For both Research Questions 1 and 2, HCV-positive participants were defined as those who took the screening hepatitis C anti-HCV test from the NHANES medical examination component, had a positive result, were mailed a Review of Findings letter, and completed the HCQ. For both Research Questions 1 and 2, the participants were categorized into three racial/ethnic groups (Caucasian, African American, Hispanic/Other) and compared between two time periods, 2005-2008 and 2009-2012. In order to determine the independent relationship between the 10 HCQ responses of all participants and each racial/ethnic group in two time periods, the study analysis included logistic regression after controlling for the covariates of age, gender, race/ethnicity, education, poverty index, health insurance status, and history of illegal injection drug use.

**Results for Research Question 1**

Research Question 1 was: Has the seeking of health care by HCV-positive African Americans improved since 2008 following the introduction of new treatment options as compared to other HCV-positive racial/ethnic groups? For Research Question 1, a chi-square test of difference, or Fisher's exact test for small cell sizes, was conducted for each racial/ethnic group's health care seeking responses between two time periods, 2005-2008 and 2009-2012 (Table 6). The results demonstrated no statistically significant difference of each racial/ethnic group's health care seeking responses between the two time periods.

**Results for Research Question 2**

Research Question 2 was: Has the response from health care providers to HCV-positive African Americans improved since 2008 following the introduction of new treatment options as compared to other HCV-positive racial/ethnic groups? For Research Question 2, a chi-square test of difference, or Fisher's exact test for small cell sizes, was conducted for each racial/ethnic group's health care provider responses between two time periods, 2005-2008 and 2009-2012 (Table 6). The results demonstrated no statistically significant difference of each racial/ethnic group's health care provider responses between the two time periods.

Table 6

*Influence of Race/Ethnicity on Participants' Responses, NHANES Hepatitis C Follow-Up Questionnaire, Time Periods 2005-2008 and 2009-2012\**

Racial/Ethnic group	2005-2008 sample						2009-2012 sample					
	Cauc		AA		H/O		Cauc		AA		H/O	
	N	%	N	%	N	%	N	%	N	%	N	%
<u>Health care seeking responses</u>												
I saw a doctor about the hepatitis C test result <sup>a</sup>	27	81.8	15	75.0	11	84.6	15	83.3	22	81.5	17	81.0
I have an appointment to see a doctor about the hepatitis C test result	1	16.7	1	20.0	1	50.0	0	0.0	0	0.0	0	0.0
I decided not to get treated because:												
Side effects are unpleasant	4	50.0	1	50.0	1	50.0	3	50.0	1	33.3	1	20.0
Need to self-inject medicine	2	28.6	0	0.0	0	0.0	3	60.0	1	33.3	3	60.0
Too expensive	5	71.4	0	0.0	1	50.0	4	66.7	1	33.3	0	0.0
Hope of better future treatments	3	2.9	0	0.0	0	0.0	1	20.0	1	33.3	1	20.0
Some other reason given	5	62.5	3	100.0	1	50.0	4	66.7	2	50.0	2	40.0
<u>Health care provider responses</u>												
Doctor did other blood tests to check the liver	24	88.9	15	100.0	10	90.9	15	100.0	18	85.7	14	82.4
Don't know	2	7.4	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Doctor told me I have hepatitis C and:												
I need regular medical follow-up	16	59.3	8	53.3	4	40.0	9	60.0	8	38.1	10	58.8
I do not need to worry about it	7	25.9	6	40.0	5	50.0	0	0.0	8	38.1	4	23.5
Other	3	11.1	0	0.0	1	10.0	5	33.3	5	23.8	3	17.6
Don't know	1	3.7	1	6.7	0	0.0	1	6.7	0	0.0	0	0.0
I had a liver biopsy	10	50.0	6	66.7	4	66.7	8	53.3	9	69.2	7	53.8
Doctor advised me about meds used to treat hepatitis C (such as Interferon and Ribavirin)	17	85.0	8	88.9	5	83.3	13	86.7	13	100.0	11	91.7
Doctor advised me I should be treated	13	76.5	5	62.5	4	80.0	10	76.9	9	69.2	8	66.7
I was treated with the medications	9	52.9	4	57.1	3	60.0	6	46.2	8	66.7	7	58.3
Doctor told me I should not be treated because:												
Liver enzymes are normal	2	50.0	0	0.0	1	100.0	1	33.3	1	50.0	1	25.0
Do not have liver disease	0	0.0	0	0.0	0	0.0	1	33.3	1	50.0	1	25.0
Don't need to do anything	0	0.0	0	0.0	0	0.0	1	33.3	0	0.0	0	0.0
Wait to be treated at a later time	0	0.0	2	100.0	0	0.0	1	33.3	2	100.0	1	25.0
No reason specified	1	25.0	0	0.0	0	0.0	1	33.3	0	0.0	1	25.0

\* = Total and percentage are "within race" categories; missing data values were not included in the calculations – only valid responses.

a = test result is defined as either the participant's first positive hepatitis C test result or the NHANES positive hepatitis C result.

Table 7 reports the frequencies and percentages for both health care seeking and health care provider HCQ responses of all participants in two time periods, 2005-2008 and 2009-2012. Missing data values were not included in the calculations, only valid responses defined as “yes” or “no” to the HCQ questions. Using chi-square test of difference, or Fisher’s exact test for small cell sizes, between the two time periods, the results demonstrated no statistically significant difference of participants’ responses between the two time periods. Within each time period (2005-2008 and 2009-2012) most participants had reported that they had seen a doctor about their hepatitis C result (80.3% and 81.8%, respectively) (Table 7). Of the participants within each time period (2005-2008 and 2009-2012) who had already seen a doctor, just over half (53.8% and 50.9%, respectively) reported they were told that they had hepatitis C and needed a regular medical follow-up. Approximately 60% of participants within each time period (2005-2008 and 2009-2012) reported having had a liver biopsy. Approximately 70% of participants within each time period (2005-2008 and 2009-2012) reported being advised by the doctor that they should be treated with medications. Just over one-half of the participants within both time periods (2005-2008 and 2009-2012) reported that they decided not to get treated because the treatment was too expensive (54.5% and 57.1%, respectively).

Table 7

*Participants' Responses, NHANES Hepatitis C Follow-Up Questionnaire, Time Periods 2005-2008 and 2009-2012\**

		2005 – 2008		2009 – 2012		P Value**
		Sample		Sample		
		N	%	N	%	
<b>Health Care Seeking Responses</b>						
	I saw a doctor about the hepatitis C test result <sup>a</sup>	53	80.3	54	81.8	NS
	I have an appointment to see a doctor about the hepatitis C test result	3	23.1	0	0.0	NS
	I decided not to get treated because:					
	Side effects are unpleasant	6	50.0	5	35.7	
	Need to self-inject medicine	2	18.2	4	30.8	
	Too expensive	6	54.5	8	57.1	
	Hope of better future treatments	3	27.3	3	23.1	
	Some other reason given	9	69.2	8	53.3	NS
<b>Health Care Provider Responses</b>						
	Doctor did other blood tests to check the liver	49	92.5	47	88.7	
	Don't know	2	3.8	1	1.9	NS
	Doctor told me I have hepatitis C and:					
	I need regular medical follow-up	28	53.8	27	50.9	
	I do not need to worry about it	18	34.6	12	22.6	
	Other	4	7.7	13	24.5	
	Don't know	2	3.8	1	1.9	NS
	I had a liver biopsy	20	57.1	24	58.5	NS
	Doctor advised me about medications used to treat hepatitis C (such as Interferon and Ribavirin)	30	85.7	37	92.5	NS
	Doctor advised me I should be treated	22	73.3	27	71.1	NS
	I was treated with the medications	16	55.2	21	56.8	NS
	Doctor told me I should not be treated because:					
	Liver enzymes are normal	3	42.9	3	33.3	
	Do not have liver disease	0	0.0	3	33.3	
	Don't need to do anything	0	0.0	1	11.1	
	Wait to be treated at a later time	2	33.3	4	44.4	
	No reason specified	1	14.3	2	22.2	NS

\* = missing data values were not included in the calculation - only valid responses.

\*\* = P value for chi-square test of difference between time periods 2005-2008 and 2009-2012. (Fisher's exact test used for small cell sizes).

NS = not significant.

a = test result is defined as either the participant's first positive hepatitis C test result or the NHANES positive hepatitis C result.

## Logistic Regression Results

Logistic regression was conducted to examine HCQ responses of all participants and each racial/ethnic group (Caucasian, African American, Hispanic/Other) within two 4-year time periods (2005-2008 and 2009-2012), and as a pooled analysis for the total 8-year time period of 2005 to 2012 while controlling for the covariates of age, gender, race/ethnicity, education, poverty index, health insurance status, and history of illegal injection drug use.

**2005 to 2008 time period.** Table 8 contains the results from the logistic regression analysis for the 2005 to 2008 4-year time period for HCQ participants who saw a doctor about their test result. The model wald chi-square was significant,  $\chi^2(1) = 4.018, p < 0.05$ . This result indicated a statistically significant association between having health insurance and seeing a doctor about the test result. The odds ratio of 537.33 (95% CI: 1.150 to 251113.35) showed that participants who had health insurance were 537.33 times more likely than those who did not have health insurance to see a doctor about their HCV-positive test result.

Table 8

*Logistic Regression: Having Health Insurance Predicting Seeing a Doctor About the Test Result—2005-2008*

Predictor	n	Wald $\chi^2$	Df	p	OR	95% CI	
						Lower	Upper
I have health insurance	54	4.018	1	<0.05	537.33	1.150	251113.35

Table 9 contains the results from the logistic regression analysis for the 2005 to 2008 4-year time period for HCQ participants who had a liver biopsy. The model wald

chi-square was significant,  $X^2(1) = 5.009, p < 0.05$ . This result indicated a statistically significant association between having health insurance and having had a liver biopsy. The odds ratio of 76.67 (95% CI: 1.715 to 3427.80) showed that participants who had health insurance were 76.67 times more likely than those who did not have health insurance to have had a liver biopsy.

Table 9

*Logistic Regression: Having Health Insurance Predicting Having Had a Liver Biopsy—2005-2008*

Predictor	n	Wald $X^2$	df	p	OR	95% CI	
						Lower	Upper
I have had a liver biopsy	27	5.009	1	<0.05	76.67	1.715	3427.80

**2009 to 2012 time period.** Table 10 contains the results from the logistic regression analysis for the 2009 to 2012 4-year time period for HCQ participants who saw a doctor about their test result. The model wald chi-square was significant,  $X^2(1) = 5.065, p < 0.05$ . This result indicated a statistically significant association between having health insurance and seeing a doctor about the test result. The odds ratio of 12.50 (95% CI: 1.39 to 112.69) showed that participants who had health insurance were 12.5 times more likely than those who did not have health insurance to see a doctor about their HCV-positive test result.

Table 10

*Logistic Regression: Having Health Insurance Predicting Seeing a Doctor About the Test Result—2009-2012*

Predictor	n	Wald X <sup>2</sup>	df	p	OR	95% CI	
						Lower	Upper
I have health insurance	48	5.065	1	<0.05	12.50	1.39	112.69

**2005 to 2012 time period.** Table 11 contains the results from the logistic regression analysis for the 2005 to 2012 8-year time period for HCQ participants who saw a doctor about their test result. The model wald chi-square was significant,  $X^2(1) = 1.332, p < 0.05$ . This result indicated a statistically significant association between having health insurance and seeing a doctor about the test result. The odds ratio of 12.32 (95% CI: 2.99 to 50.80) showed that participants who had health insurance were 12.32 times more likely than those who did not have health insurance to see a doctor about their HCV-positive test result.

Table 11

*Logistic Regression: Having Health Insurance Predicting Seeing a Doctor About the Test Result—2005-2012*

Predictor	n	Wald X <sup>2</sup>	df	p	OR	95% CI	
						Lower	Upper
I have health insurance	102	1.332	1	<0.05	12.32	2.99	50.80

Table 12 contains the results from the logistic regression analysis for the 2005 to 2012 8-year time period for HCQ participants who have had a liver biopsy. The model wald chi-square was significant,  $X^2(1) = 6.942, p < 0.05$ . This result indicated a



statistically significant association between having health insurance and having had a liver biopsy. The odds ratio of 12.69 (95% CI: 1.92 to 84.02) showed that participants who had health insurance were 12.69 times more likely than those who did not have health insurance to have had a liver biopsy.

Table 12

*Logistic Regression: Having Health Insurance Predicting Having Had a Liver Biopsy—2005-2012*

Predictor	n	Wald $X^2$	df	p	OR	95% CI	
						Lower	Upper
I have health insurance	56	6.942	1	<0.05	12.69	1.92	84.02

Table 13 contains the results from the logistic regression analysis for the 2005 to 2012 8-year time period for Caucasian HCQ participants who saw a doctor about their test result. The model wald chi-square was significant,  $X^2(1) = 3.84, p = 0.05$ . This result indicated a statistically significant association between having health insurance and seeing a doctor about the test result. The odds ratio of 21.53 (95% CI: 1.00 to 463.81) showed that Caucasian participants who had health insurance were 12.32 times more likely than those who did not have health insurance to see a doctor about their HCV-positive test result.

Table 13

*Logistic Regression: Having Health Insurance Predicting Seeing a Doctor About the Test Result for Caucasian Ethnicity—2005-2012*

Predictor	N	Wald X <sup>2</sup>	df	p	OR	95% CI	
						Lower	Upper
I have health insurance	43	3.84	1	0.05	21.53	1.00	463.81

Table 14 contains the results from the logistic regression analysis for the 2005 to 2012 8-year time period for African American HCQ participants who saw a doctor about their test result. The model wald chi-square was significant,  $X^2(1) = 3.83$ ,  $p = 0.05$ . This result indicated a statistically significant association between having health insurance and seeing a doctor about the test result. The odds ratio of 59.96 (95% CI: .99 to 3263.77) showed that African American participants who had health insurance were 59.96 times more likely than those who did not have health insurance to see a doctor about their HCV-positive test result.

Table 14

*Logistic Regression: Having Health Insurance Predicting Seeing a Doctor About the Test Result for African American Ethnicity—2005-2012*

Predictor	n	Wald X <sup>2</sup>	df	p	OR	95% CI	
						Lower	Upper
I have health insurance	35	3.83	1	0.05	56.96	.99	3263.77

Based on the result of the data analyses used in this study, both stated null hypotheses were not rejected and it was concluded that there were no statistically significant associations between the health care seeking behavior and responses from health care providers for HCV-positive African Americans before (2005-2008) and after

(2009-2012) the introduction of new treatment options as compared to other HCV-positive racial/ethnic groups. When controlling for the covariates of age, gender, race/ethnicity, education, poverty index, health insurance status, and history of illegal injection drug use, logistic regression did reveal that having health insurance was a significant determinant of being likely to see a doctor for the HCV-positive test result for all participants in both the 4-year time periods (2005-2008 and 2009-2012), as well as all participants, Caucasians, and African Americans as an 8-year pooled analysis (2005 to 2012). Additionally, the results revealed that having health insurance was a significant determinant of having had a liver biopsy for all participants in the 4-year time period of 2005 to 2008, and all participants in the 8-year pooled analysis (2005 to 2012). The logistic regression did not identify any other results of statistical significance with all participants or each racial/ethnic group in both time periods (2005-2008 and 2009-2012) and as a pooled analysis (2005-2012).

### **Summary**

In conclusion, the findings of this study do not support the hypotheses that there is a statistically significant relationship between the health care seeking behavior and provider responses of HCV-positive African Americans before (2005-2008) and after (2009-2012) the introduction of new treatment options as compared to other HCV-positive racial/ethnic groups within the framework of the theory of planned behavior and theory of reasoned action model. In Chapter 5, I will interpret these results in the context of the current theories and understanding of HCV-positive African Americans and potential risk factors. Further, I will present limitations of the study and a summary of

findings. Recommendations for further research as well as the potential impact these findings may have on social change will be also be discussed in Chapter 5.

## Chapter 5: Discussion

### **Introduction**

The hepatitis C virus (HCV) is a major cause of liver disease, hepatocellular carcinoma, and end stage liver disease in the United States (Centers for Disease Control and Prevention, 2012a). As previously discussed, African Americans represent only 13% of the U.S. population, but make up the largest racial group (22%) out of the 3.5 million persons infected with chronic HCV. Disparities in access to care and treatment include a complex set of individual, interpersonal, socioeconomic, and environmental factors that influence the course of HCV infection in the African American population, resulting in poorer outcomes and survival.

This research study used quantitative data from the 2005-2012 NHANES datasets. The purpose of this study was to determine whether the seeking of health care by HCV-positive African Americans and the responses from health care providers to HCV-positive African Americans have improved since 2008 following the introduction of new treatment options, as compared to other HCV-positive racial/ethnic groups. To date, no published studies were found concerning the relationship between the seeking of health care and provider responses for HCV-positive African Americans before and after the introduction of new treatment options.

Based on the results from the chi-square test of difference and logistic regression analyses conducted for hypothesis testing, I failed to reject the null hypotheses for my two research questions. It was determined that the health care seeking behavior and health care provider responses for HCV-positive African Americans had not improved as of 2008 with the introduction of new treatment options, as compared to other HCV-

positive racial/ethnic groups. The results from the logistic regression revealed that all participants in both of the 4-year time periods studied (2005-2008 and 2009-2012) who had health insurance were more likely to see a doctor for their HCV-positive test result. These same results were also found in the 8-year pooled analysis (2005-2012) with all participants, Caucasians, and African Americans. Additionally, the results revealed that all participants in the 4-year time period of 2005 to 2008, and all participants in the 8-year pooled analysis (2005-2012) who had health insurance were more likely to have had a liver biopsy.

### **Interpretation of the Findings**

Overall, the findings of this study indicated that there had not been any improvement in the health care seeking behavior and provider responses for HCV-positive African Americans or other HCV-positive racial/ethnic groups since 2008 with the introduction of newer treatment options. Participants in the 2005-2008 time period were more likely to be younger than age 50 ( $p < 0.05$ ) and Caucasian ( $p < 0.05$ ) as compared to participants in the 2009-2012 time period. In comparing each of the racial/ethnic groups between the two time periods, the Hispanic/Other group in the 2005-2008 time period was more likely to be younger than 50 years of age ( $p < 0.05$ ) as compared to the Hispanic/Other group in the 2009-2012 time period. A statistically significant relationship did not exist with each of the racial/ethnic group's (Caucasian, African American, Hispanic/Other) responses to the Hepatitis C Follow-Up Questionnaire (HCQ) between two time periods (2005-2008 and 2009-2012). Eighty-one percent of the study sample reported that they had seen a doctor about their past or current HCV infection, with 51% having reported being told that they had hepatitis C and

needed a regular medical checkup. Although approximately 70% of all participants were told that they should be treated with medications, of those who had decided not to get treated, 58% had reported that this was because the treatment was too expensive.

With the inclusion of sociodemographic covariates in the regression models, results indicated significant associations with participants who had health insurance. Having health insurance, while controlling for other variables, was significantly associated with the HCQ response of *“I have seen a doctor about my test result”*. This was evident in all participants in both time periods (2005-2008 and 2009-2012), and as a pooled analysis (2005-2012) with all participants, and both Caucasian and African American racial/ethnic groups. In addition, having health insurance, while controlling for other variables, was significantly associated with the HCQ response of *“I had a liver biopsy”*. This was evident in all participants in both the 2005 to 2008 4-year time period, and as an 8-year pooled analysis (2005-2012). A total of 72% of the study sample had health insurance, with 58% reporting having had a liver biopsy; and, as previously discussed, 81% of the study sample reported having seen a doctor about their past or current HCV infection.

These findings are consistent with those of researchers who examined the impact of having health insurance coverage. Turner et al. (2013) surveyed 600 injection drug users in New York City and found that African Americans were less likely to have visited a private medical office in the past year, whereas those with higher income and health insurance coverage were more likely to visit a private medical office. Melia et al. (2011) found that HCV-positive African Americans are disproportionately affected by lack of adequate health insurance and high treatment costs. Gordon et al. (2015) found that

having private health insurance coverage was associated with lower odds of cirrhosis in hepatitis C patients.

### **Limitations of the Study**

There were several limitations to this study. The NHANES survey is cross-sectional by design. Limitations of using successive cross-sectional survey data over time include: (a) reliance on the continuity of the data, (b) inability to establish individual change, and c) inability to determine a causal relationship (King-Hele, 2005). As NHANES data were collected at one point in time, longitudinal trends in health behavior cannot be examined. Selection bias and sampling bias may be limitations of the study; however, the NHANES survey uses a complex, stratified, multistage probability sampling procedure to minimize this potential risk (Centers for Disease Control and Prevention, 2013a). Although the Hepatitis C Follow-Up Questionnaire (HCQ) is nested within the NHANES, the data from the HCQ cannot be used to generate population estimates because of the small number of respondents and low response rate. Frequencies for some questions may be affected by differences in characteristics of HCQ participants versus nonparticipants. In addition, the small sample size limited the power to detect statistically significant differences between subgroups. Lastly, as the data are self-reported, another limitation is the usual biases associated with such data (e.g., recall bias and/or information bias), including the possibility of participants not understanding questions regarding medical information, such as whether they had a particular medical procedure or blood test performed or what they had been told by a health care provider.



## Recommendations

This study reported results for a sample of NHANES participants who responded to a follow-up questionnaire after having tested positive for past or current HCV infection from 2005 through 2012, which, to my knowledge, is the only questionnaire of such individuals to be conducted as part of a national population-based study. Overall, the study did not find any significant improvements in the health care seeking behavior or provider responses for HCV-positive African Americans since 2008 after the introduction of new treatment options as compared to other HCV-positive racial/ethnic groups. The landscape and discovery of new and improved direct-acting antivirals (DAAs) to treat HCV infection are continuing to evolve into regimens with shorter durations, better tolerability, and higher cure rates. During the time period in which the first-generation DAAs were available and being used to treat HCV-infected individuals, there already existed ongoing studies of second-generation DAAs that demonstrated even better tolerability and efficacy. In these studies, even higher rates of sustained viral response or cure (89%-90%) have been demonstrated in treatment-naïve patients as compared to first-generation agents (Kohli, Shaffer, Sherman, & Kottlil, 2014). In addition, one study conducted in 2013 found that 90% of physicians in the United States reported that they were “warehousing” patients (holding off treatment) in expectation of more efficacious and tolerable new therapies (Taylor, 2013). As of 2015, there is currently a total of six second-generation DAAs that have been approved and are being used (alone or in combination) for the treatment of HCV infection (U.S. Food and Drug Administration, 2014). With second-generation DAAs providing improvements in efficacy and tolerability across all racial/ethnic groups, further research might focus on the HCV-

infected population as a whole to determine whether differences exist in health care seeking behavior and provider responses as compared to the first-generation DAAs. Additional research may also be needed to evaluate strategies to enhance assessment, adherence, and treatment responses among those at risk, including special populations, particularly as new treatments for HCV infection continue to become available.

Due to the close association between a person having health insurance coverage and seeing a doctor and/or having a liver biopsy, future research efforts might focus on a closer examination of health insurance status as a predictor for seeking medical care and/or getting medical procedures in different clinical settings. In addition, over one-half of the study participants who decided not to get treated with medications reported that it was because the HCV treatment was too expensive. Obamacare's individual mandate required most Americans to obtain health insurance by January 1, 2014 (obamacareusa.org, 2015). Future research might also examine the potential association that health insurance coverage has on the screening and preventive care efforts for hepatitis C, as well as treatment and outcomes.

### **Implications for Social Change**

These research findings suggest that more intensive efforts are needed to identify and test those at risk for HCV infection and the need to educate patients and providers about appropriate interaction on prevention decisions and actions. Prior to this study, no previously published study had compared the health care seeking behavior and provider responses of HCV-positive African Americans before the introduction of new treatment options (2005-2008) and after the introduction of new treatment options (2009-2012) as compared to other HCV-positive racial/ethnic groups. HCV infection remains a critical

public health challenge in the African American population. African Americans are most at risk for infection and transmission due to illegal injection drug use behavior, in addition to worse health outcomes to include increased morbidity and mortality. Positive social change may happen by emphasizing the awareness of the risks of HCV infection, reducing provider bias, removing barriers to care, and introducing resources into the African American and underserved communities; as a result, there may be improvements in screening, treatment, and outcomes. The findings of this study may aid public health professionals in the design of public health policies, educational programs, and screening and treatment recommendations that could lead to positive social change among the groups most at risk for hepatitis C infection.

Prevention is the key to reducing the risk of HCV transmission. The findings of this study may impact change socially by increasing public communication within the African American communities which would raise awareness of the risks of HCV infection; as well as the potential implementation of local neighborhood-level clinics, syringe exchange programs, and additional resources in the lower and poor communities to improve access to health care and outcomes for this afflicted population.

### **Conclusion**

To my knowledge, this study was the first study to explore the association between the health care seeking behavior and provider responses for HCV-positive African Americans before and after the introduction of new treatment options as compared to other HCV-positive racial/ethnic groups. Results from the study did not identify a statistically significant relationship of health care seeking behavior and provider responses between the two time periods. With regard to analyzing the

covariates, the study did identify a significant association between having health insurance coverage and seeing a doctor about the HCV test result and/or having a liver biopsy. The findings from this study add to the body of knowledge by quantifying the association between the health care seeking behavior and provider responses over an 8-year period collectively and within each racial/ethnic group (Caucasian, African American, Hispanic/Other).

There have been numerous approaches to prevention and intervention of HCV infection. The identification, counseling, and testing of persons at risk should be a top priority. The National Prevention Information Network provides persons and health care professionals with the most current information, resources, and tools to support your organization's efforts to prevent viral hepatitis; as well as links to find hepatitis C providers/clinics in a specific area for networking, and access to federal and private funding opportunities (Centers for Disease Control and Prevention, 2012). All of these resources can be beneficial to educate the healthcare professional on persons at risk for HCV, and who should be screened, plus access to patient-centric educational resources.

For the African American population, increasing awareness and knowledge among health care providers and communities about hepatitis C infection, and improving access to quality prevention, research trials, care, and treatment services, while eliminating disparities is essential. With the landscape and discovery of new and improved drugs to treat HCV infection continuing to evolve into regimens with shorter durations, better tolerability, and higher cure rates, the findings of this study lay the groundwork for researchers to comparatively assess any improvement or changes in health care seeking behavior and provider responses by HCV-infected populations

moving forward. The results of this study do not support the hypotheses that the health care seeking behavior and health care provider responses for HCV-positive African Americans has improved as of 2008 with the introduction of new treatment options, as compared to other HCV-positive racial/ethnic groups.

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